Annals of Health Law

Volume 26
Issue 2 *Summer 2017*

Article 3

2017

Mobile Health Innovation and Interagency Coordination

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An app that can tell when a phone's owner is having a seizure.[1] A device that transforms a phone into a mobile EKG machine.[2] An app that helps patients track their moles over time—and maybe alerts them when they should see a doctor.[3] Just a few years ago, these descriptions would have sounded like science fiction. But each of these products is now available to patients, and the mobile health industry is growing rapidly.[4] Even as of 2015, there were well over 100,000 mobile health apps available for download, with the market continuing to grow.[5]

The rapid expansion of the mobile health industry has opened up tremendous possibilities for gathering and using personal health data to discover new correlations and solve vexing problems of human illness.[6] It has also begun to give patients unprecedented control over their own health information.[7] But unlike most other healthcare technologies, mobile health apps like those described above often operate in a comparatively lawless

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1. Kendall Morgan, *There's An App for That*, ELSEVIER (June 25, 2015), https://www.elsevier.com/atlas/story/people/theresanappforthat.

2. Jonah Comstock, *AliveCor ECG gets FDA Clearance for Two More Algorithms*, MOBIHEALTHNEWS (Jan. 29, 2015), http://www.mobihealthnews.com/40089/alivecor-ecg-gets-fda-clearance-for-two-more-algorithms.

3. OHSU Dermatology, *What is MoleMapper?*, OHSU HEALTHCARE (2017), https://www.ohsu.edu/xd/health/services/dermatology/war-on-melanoma/mole-mapper.cfm.

4. Joshua A. Krisch, *Questioning the Value of Health Apps*, N.Y. TIMES (Mar. 16, 2015), http://well.blogs.nytimes.com/2015/03/16/health-apps-provide-pictures-if-not-proof-of-health/?_r=0.

5. *Id.*

6. Doug Vogel et al., *Mobile Health*, 23 ELECTRONIC MARKETS 3, 3 (Feb. 6, 2013), https://link.springer.com/article/10.1007/s12525-013-0121-y.

7. Eric Topol, *Coming Soon to a Health System Near You: Digitized, Democratized Medicine*, HEALTHCARE FINANCIAL MEMBERSHIP ASS'N (Apr. 27, 2016), http://www.hfma.org/Leadership/Archives/2016/Spring/Coming_Soon_to_a_Health_System_Near_You__Digitized,_Democratized_Medicine/.

world, free from both innovation-promoting tools and regulatory enforcement strategies used by most of the administrative agencies traditionally operating in the healthcare space.[8]

Many scholars have considered the regulatory landscape around mobile health technologies and argued for a different regulatory system, or used the landscape to analyze the safety of mobile health applications or the privacy of the data they gather.[9] This essay expands this scholarly focus in two ways. First, it focuses on the innovation incentives created by this legal framework, a topic considered by few scholars. Second, and perhaps more importantly, it focuses on the ways in which different administrative agencies with different statutory responsibilities both do and should coordinate to promote incentives for innovation in mobile health technologies.

Part I considers the ways in which traditional innovation incentives like patents and FDA regulation fail to cover mobile health technologies in the way that they cover traditional health care technologies. Part II goes on to consider two key ways in which mobile health companies have adapted to this novel regulatory environment—either by attempting to avoid regulation or, alternatively, by embracing it. Part III shifts focus from the companies responding to the innovation landscape to the administrative agencies setting it. Specifically, Part III considers the ways in which agencies have begun to coordinate their efforts in the mobile health space. How do—and how can—these agencies, which lack formally shared regulatory authority over the innovation space, nonetheless cooperate to promote incentives for innovation? Administrative law and health innovation scholars have begun to consider this question more generally, and this essay extends the argument to the mobile health space.

I. THE LEGAL LANDSCAPE SURROUNDING MOBILE HEALTH INNOVATION

Although mobile health technologies have great potential to change the

8. Jordan Cohen & Joanne Hawana, *Mobile Health Apps Continue to Make Headlines*, MINTZ LEVIN (Jan. 25, 2017, 3:25 PM), https://www.healthlawpolicymatters.com /2016/03/16/mobile-health-apps-continues-to-face-privacy-security-and-consumer-protection-issues/.

9. *See, e.g.*, Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173 (2014); Nathan G. Cortez, I. Glenn Cohen, & Aaron S. Kesselheim, *FDA Regulation of Mobile Health Technologies*, 371 N. ENG. J. MED. 372 (2014); Fazal Khan, *The "Uberization" of Healthcare: The Forthcoming Legal Storm over Mobile Health Technology's Impact on the Medical Profession*, 26 HEALTH MATRIX 123 (2016); Anna B. Laakmann, *A Property Theory of Medical Innovation*, 56 JURIMETRICS J. 117 (2016); Nicolas Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS OF HEALTH LAW 62 (2016); Nicolas Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. ENT. & TECH. L. 327 (2017).

way in which health care is delivered, analyzed, and evaluated, the legal landscape surrounding mobile health technologies differs significantly from that surrounding other, more typical health care technologies.[10] This Part considers the ways in which areas of law that traditionally operate to regulate innovation in the medical technology space—patent law, FDA regulation, and insurance coverage—fail to read on mobile health technologies.

For most health care technologies, innovation is channeled through a series of different legal structures. Some of these legal structures are designed explicitly to promote innovation, like intellectual property law,[11] while others are designed primarily to ensure the quality and accuracy of marketed technologies, like FDA regulation and insurance coverage.[12] Companies producing drugs and traditional medical devices must contemplate each of these legal regimes during the innovation process.[13] However, for many mobile health technologies, the situation has been reversed.[14] These three areas of law are largely inapplicable to mobile health in ways that affect the pattern of innovation we see.

Patent Law. — Current case law significantly limits the kinds of protection that mobile apps could enjoy, particularly in contrast to those granted to pharmaceuticals. Patent law is typically thought to play a key role in the development of new pharmaceutical technologies.[15] Due to the high costs of discovering new drugs and lengthy period required to bring them through the FDA approval process,[16] pharmaceutical companies cite patent law as an

10. Khan, *supra* note 9, at 141–43.

11. *See* Heidi Williams, *Intellectual Property Rights and Innovation: Evidence from Health Care Markets*, 16 INNOVATION POL'Y AND THE ECON. 53, 53–54 (2016) ("Intellectual property rights aim to increase private research investments in new technologies by allowing inventors to capture a higher share of the social returns to their inventions.").

12. Cortez, Cohen & Kesselheim, *supra* note 9, at 5; Melanie Cozad & Bruno Wichmann, *Efficiency of Health Care Delivery Systems: Effects of Health Insurance Coverage*, 45 APPLIED ECON. 4082, 4082–83 (2013), http://www.tandfonline.com/doi/abs/10.1080/00036846.2012.750420.

13. Khan, *supra* note 9, at 142–43.

14. *Id.* at 143.

15. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 508 (2009); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 751 (2014).

16. *Compare* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) (placing the cost of developing a new drug at $2.6 billion), *with* Jorge Mestre-Ferrandiz, Jon Sussex and Adrian Towse, *The R&D Cost of a New Medicine,* OFFICE OF HEALTH ECONOMICS 1, 13, 16, 30 (estimating the cost at $1.5 billion), https://www.ncbi.nlm.nih.gov/pubmed/26928437. For my purposes, there is sufficient agreement that drugs are among the most costly technological goods to develop. *See* Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 426, 448–57 (2014).

indispensable tool enabling them to protect their investments in new drugs.[17] Most approved drugs are covered by a number of patents, which cover different aspects of the drug at issue.[18] Core patents typically claim the drug compound itself while secondary patents may cover methods of treatment that use the drug, particular formulations of the drug, or the process of making the drug.[19]

Recent developments in patent law have made it far more difficult for mobile health app developers to achieve the same levels of patent protection that exist in the pharmaceutical context.[20] Specifically, in a series of cases over the past few years, the Supreme Court limited the types of technologies eligible for patent protection under 35 U.S.C. § 101,[21] most recently deciding *Alice Corporation, Ltd. v. CLS Bank International*.[22] CLS Bank had sought a declaratory judgment that several of Alice's patents, directed toward methods of mitigating settlement risk using computers,[23] were invalid under § 101.[24]

Justice Thomas' majority opinion agreed that Alice's specific method claims were invalid.[25] More important, though, was the way Justice Thomas crystallized a two-step process for deciding § 101 cases. The process asks first whether "the claims at issue are directed to [a] patent-ineligible

17. Stuart J.H. Graham et. al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009); Wesley Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 2, 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000).

18. Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make A Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 300–01 (2010).

19. Amy Kapczynski, Chan Park, & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470.

20. *See infra* notes 21–22 and accompanying text.

21. 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."). The Supreme Court has articulated a number of specific exceptions to the broad text of § 101: "[l]aws of nature, natural phenomena, and abstract ideas" are not eligible for patent protection. *See* Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014); *see also* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

22. CLS Bank Int'l v. Alice Corp. Pty., 717 F.3d 1269, 1274 (Fed. Cir. 2013) (en banc) (Lourie, J., concurring) (per curiam).

23. *Id.*

24. *Id.* at 1273–74 (discussing how the en banc Federal Circuit splintered badly, with ten judges issuing seven opinions, none commanding a majority).

25. *Id.* at 2352 (holding further that "merely requiring generic computer implementation fails to transform [Alice's] abstract idea into a patent-eligible invention").

concept[],” and then determines whether there is an “inventive concept” that nonetheless transforms the patent-ineligible natural law into a patent-eligible application thereof.[26] Applying this test to Alice’s claims, Justice Thomas first found that they were directed to an abstract idea—the concept of intermediated settlement, making it a patent-ineligible concept.[27] At step two, Justice Thomas found that merely reciting the existence of a generic computer was insufficient to convert Alice’s patent-ineligible abstract idea into a patent-eligible invention.[28]

Citing *Alice*, lower courts have invalidated patents in almost two hundred and fifty cases since June 2014.[29] Mobile health-related patents have been among those struck down,[30] and lawyers have recognized the increased difficulty of using patents to protect mobile health apps going forward.[31] Although manufacturers of more complex wearable technologies may find it easier to protect aspects of their products, makers of mobile health applications that work with existing phones, tablets, or other technologies will find it difficult to achieve comprehensive patent protection in the way that most drugs or medical devices have.[32]

FDA Regulation. — For at least the last half century,[33] the FDA has played a central role in the regulation of health technologies of all kinds.[34] Its regulation of pharmaceuticals is particularly rigorous, requiring companies to obtain premarket approvals of their technologies by demonstrating both safety and efficacy of the compound in question.[35] The FDA’s regulation of

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26. *Id.* at 2355 (citations omitted).

27. *Id.* at 2356.

28. *Id.* at 2358.

29. Robert R. Sachs, *AliceStorm Update for Fall 2016*, BILSKIBLOG (Oct. 19, 2016), http://www.bilskiblog.com/blog/2016/10/alicestorm-update-turbulence-and-troubles-.html.

30. *See, e.g.*, MobiHealthNews, *What Have We Learned from Four Years of Digital Health Patent Fights?*, MOBIHEALTHNEWS (Aug. 26, 2016), http://www.mobihealthnews.com/content/what-have-we-learned-four-years-digital-health-patent-fights.

31. *See, e.g.*, Douglas H. Pearson et al., *Are You Ready for Digital-Health Patent Disputes?*, JONES DAY DIGITAL HEALTH LAW UPDATE (Aug. 2015), http://www.jonesday.com/files/Publication/6da3b838-431e-4e04-96f0-5c15814e6fd4/Presentation/PublicationAttachment/929ac4d9-b70f-43b8-9776-5ee07cdd7bd1/Digital%20Health%20Vol%20I%20Issue%204.pdf; Brian E. Ferguson & Anish R. Desai, *The Coming Patent War Over Wearable Technologies*, WEIL GOTSHAL (Sept. 2, 2015), http://www.weil.com/articles/the-coming-patent-war-over-wearable-technologies.

32. Douglas H. Pearson et al., *supra* note 31 (“The [*Alice*] test has been applied with devastating effect by district courts and the USPTO to invalidate patents or reject patent claims on grounds that they claim no more than general computer implementations of abstract ideas.”).

33. Kefauver Harris Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

34. Cortez, Cohen & Kesselheim, *supra* note 9, at 372.

35. 21 U.S.C. § 355(b)(1) (2012).

devices—a broad category which encompasses everything from artificial hearts, to tongue depressors, to blood tests—is more tailored and is graduated on the basis of risk, with the highest-risk devices (like the artificial heart) subject to full premarket approval procedures and the lowest-risk devices (like tongue depressors) subject only to "general controls,"[36] including reporting and adherence to good manufacturing practices.[37]

By contrast, the FDA has largely avoided regulating traditional mobile health technologies,[38] opting most importantly only to regulate apps "whose functionality could pose a risk to a patient's safety if the mobile app were not to function as intended."[39] As in the case of traditional medical devices, the FDA's oversight here is risk-based. The FDA has provided a number of examples of apps which pose a "lower risk" to the public and, therefore, over which it has decided to exercise enforcement discretion for the time being.[40]

FDA regulation is often viewed by industry leaders as a hindrance to be surmounted—a process that adds time and expense to the development of a new medical technology, and is therefore a drag on innovation, not an incentive in the way that patents are.[41] However, inherent in the FDA's ability to oversee the approval process is the ability to demand the development and dissemination of information about new medical technologies.[42] Professor Becky Eisenberg has most notably made this argument in the context of pharmaceuticals, arguing that FDA regulation valuably promotes the

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36. 21 U.S.C. § 360c(a)(1)(C) (2012); Replacement Heart Valve, 21 C.F.R. § 870.3925 (2015); 21 U.S.C. § 360c(a)(1)(A) (2012); Tongue Depressor, 21 C.F.R. § 880.6230 (2015).

37. *Id.*

38. William M. Sage, *Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care*, 101 CORNELL L. REV. 609, 698–99 (2016); *see also* Mark Sullivan, *FDA Makes Official Its Hands-Off Approach To Regulating Health Apps and Medical Software*, VENTUREBEAT (Feb. 6, 2015), http://venturebeat.com/2015/02/06/fda-makes-official-its-hands-off-approach-to-regulating-health-apps-and-medical-software/.

39. U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD & DRUG ADMINISTRATION STAFF, 4, 20–21 (Feb. 2015), http://www.fda.gov/downloads/MedicalDevices/. . ./UCM263366.pdf. As a note, the FDA has also declined to regulate apps it does not deem "medical devices." Specifically, the FDA has designated a set of apps that it does not consider to be "medical devices" under the statutory definition. These include apps that provide physicians access to electronic copies of medical reference books, apps that are used for physician or patient training and education, or apps that automate hospital processes like billing and shift management, to name a few. These carve-outs were subsequently codified in large part in the 21st Century Cures Act. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 3060 (2016).

40. U.S. FOOD & DRUG ADMIN., *supra* note 39, at 23–26.

41. INST. OF MED. OF THE NAT'L ACADS., PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS 20–22 (Theresa Wizemann ed. 2010).

42. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 347 (2007).

"development of credible information about the effects of drugs."[43] This insight extends to the device context as well.[44] Although the lack of FDA oversight in the mobile app context means that many companies will be able to come to market more quickly and cheaply, it also means that information about the quality and accuracy of their products will be comparatively lacking.

Insurance Coverage. — Most traditional health care technologies are not marketed or sold directly to patients, but are instead prescribed or administered by a health care professional and purchased with the aid of insurance.[45] Insurers can therefore serve as intermediaries: by refusing to cover technologies until more information about their efficacy has been developed, they can force companies to produce information about their quality, even beyond that required by the FDA.[46] This can serve a valuable role in many cases, such as when medical devices are studied in ideal populations rather than populations which are representative of a disease's sufferers.[47] Therefore, insurance coverage is, in some ways, both innovation-enhancing and access-enhancing. It enhances innovation just as FDA regulation does, by requiring companies to study their products extensively before selling them to consumers. And it enhances access by enabling patients to afford expensive health technologies.

But most patient-facing mobile health technologies are marketed and sold directly to patients, outside of the doctor-patient relationship and without the insurer as intermediary.[48] Helpfully, this does mean that many mobile health apps will be priced affordably and will be accessible without the aid of insurance.[49] More problematically, it also means that the quality control function of insurance coverage is not available for most mobile health technologies.[50] Patients purchasing such apps cannot be sure that trusted

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43. *Id.*

44. *Id.*

45. Jessica Smith & Carla Medalia, U.S. DEP'T. OF COMMERCE: ECON AND STATISTICS ADMIN., HEALTH INSURANCE IN THE UNITED STATES: 2013, at 3 (2014).

46. *See, e.g.*, Liz Richardson, HEALTH AFFAIRS POLICY BRIEF: ALIGNING FDA AND CMS REVIEW 2–3 (Aug. 27, 2015).

47. *Id.* at 3.

48. Derek Newell, *5 Ways Mobile Apps Will Transform Healthcare*, FORBES, (Jan. 26, 2017 12:21 PM), http://www.forbes.com/sites/ciocentral/2012/06/04/5-ways-mobile-apps-will-transform-healthcare/#17a0d18d6509.

49. Isabel de la Torre-Diez et al., *Cost-Utility and Cost-Effectiveness Studies of Telemedicine, Electronic, and Mobile Health Systems in the Literature: A Systematic Review* 21 TELEMEDICINE AND E-HEALTH 81, 82 (2015) (Most research studies in the literature have concluded that telemedicine systems are cost-effective; however, in this article, two studies have been found in which the cost-effectiveness of telemedicine is not an explicit conclusion).

50. *See generally* NAT'L ASS'N OF INS. COMM'RS, EXCHANGES PLAN MANAGEMENT FUNCTION: ACCREDITATION AND QUALITY WHITE PAPER (2012),

physicians or expert intermediaries have signed off on their effectiveness, and so they cannot be sure what the true risks and benefits of the products are.

Patent law, FDA regulation, and insurance coverage simply do not operate on most mobile health technologies in the way that they relate to pharmaceuticals and traditional medical device products. Scholarly literature has explored ways in which the combination of these areas of regulation affects incentives to innovate in pharmaceuticals and traditional medical devices.[51] However, relatively little attention has been paid to the ways in which the *lack of* each of these innovation policy levers may affect innovation patterns in the mobile health sphere,[52] a subject to which I now turn.

II. MOBILE HEALTH RESPONSES TO THE INNOVATION POLICY VACUUM

In the mobile health space, traditional innovation policy levers, such as patent law, FDA regulation, and insurance coverage, have all been turned "off." What effect does this pattern have on companies seeking to innovate in the mobile health space? In a large number of cases, the relative absence of traditional innovation policy levers in the mobile health space has led companies to make a choice.[53] Either a company can engage in what scholars have called "regulatory arbitrage"[54] and construct its business model in a way that will enable it to evade regulatory scrutiny, or the company can choose to emulate traditional medical device companies and undergo FDA and insurer

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http://www.naic.org/documents/committees_b_related_wp_accred_quality.pdf (discussing the quality control function of health insurance providers).

51. *See, e.g.*, Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 19 HEALTH AFF. 119, 120–21 (2001); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 178; Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS. L. REV. 1881, 1929 (2016).

52. Importantly, the lack of these innovation policy levers is the "normal" case. Most consumer products (including most apps) are not heavily regulated in the way that medical technologies are. Viewed from that perspective, drugs and devices are the outliers. But it is important not to view mobile health apps the same as other software products. Not only are the potential implications for consumer well-being more like those in the traditional health technology space, but here companies have the ability to choose between the regulatory systems, as I will now explore.

53. These two stories are not universal. In fact, it is likely that many small start-up companies may proceed without detailed consideration of regulatory barriers that may be years in the future. However, these are two prominent storylines with support from existing literature and adjacent technologies.

54. Victor Fleischer, *Regulatory Arbitrage*, 89 TEX. L. REV. 227 (2010); Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1185 (2012); Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 1, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2774471 (forthcoming 2017).

scrutiny for its products. In either case, the bottom line is that companies are making business decisions shaped by the regulatory options they face.

A. Regulatory Arbitrage

First, a large set of companies has chosen to pursue a strategy of "regulatory arbitrage," in which the company will purposefully design its technology in a way that minimizes or avoids regulatory scrutiny.[55] Professor Nicolas Terry has explored the idea of regulatory arbitrage in the context of mobile health technologies and Health Insurance Portability and Accountability Act (HIPAA) protection.[56] Most health data that is exchanged through, and held by, traditional healthcare providers, such as physicians and hospitals, is subject to HIPAA's protections for privacy and security.[57] Many health technology companies (including pharmaceutical companies and medical device manufacturers) working with these providers may similarly be subject to HIPAA as business associates, by virtue of these connections.[58]

Many mobile health companies have instead chosen to design their systems and interactions with patients to avoid collecting the kind of data, or interfacing with the kind of entities, that would render their technology subject to HIPAA protection.[59] As a result, Professor Terry notes, "the vast majority of health apps are not curated, sold, or implemented by HIPAA 'covered entities."[60] Much of the health data collected by these apps is therefore not protected by HIPAA, and consumers lack the associated privacy and security protections.[61]

This regulatory arbitrage argument extends beyond the HIPAA context to the innovation policy lever analysis described in Part I. A savvy company that is aware of the FDA's decision to exercise enforcement discretion over broad categories of mobile health technologies can construct its products in ways that make them fall outside the FDA's current focus.[62] Keeping development costs low by avoiding FDA regulation is likely to ensure a given

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55. More formally, Professor Victor Fleischer has defined regulatory arbitrage as "the manipulation of the structure of a deal to take advantage of a gap between the economic substance of a transaction and its regulatory treatment." Fleischer, *supra* note 54, at 230.

56. Terry, *supra* note 54, at 44–47.

57. 45 C.F.R. § 160 (2002); 45 C.F.R. § 164 (2002); *see also The HIPAA Privacy Rule*, U.S. DEP'T. HEALTH & HUMAN SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/ (last visited Mar. 2, 2017).

58. 45 C.F.R. § 160 (2002); 45 C.F.R. § 164 (2002).

59. Terry, *supra* note 54, at 38.

60. *Id.* at 37.

61. *Id.* at 37–38.

62. *See generally* U.S. DEP'T HEALTH & HUMAN SERVS. MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015), https://www.fda.gov/downloads/MedicalDevices/. . ./ UCM263366.pdf.

app's affordability without insurance coverage. Although patents may still not be readily available for these technologies, patents may be less essential where the costs of development and time to market are low, as is often true with mobile apps which do not need to surmount regulatory hurdles.[63]

This contention—that mobile health companies observing the regulatory landscape may choose to minimize the amount of regulatory scrutiny to which they are subject—is descriptive, not normative. In this brief essay, I take no position as to whether, on balance, these decisions are positive overall for patients and society. If companies seeking to take advantage of the FDA's enforcement discretion are truly making affordable, low-risk apps which may be beneficial for patients, it would be a positive development. However, if companies are seeking to repackage higher-risk apps in a way that is designed only to avoid FDA scrutiny, risks to patients may increase. Alternatively, if companies opt to develop entirely different, less impactful technologies to avoid FDA scrutiny, patients may lose out on potential health benefits. It is difficult to assess the relative contributions of these potential effects, especially when the very fact of FDA enforcement discretion makes it difficult to determine the size and scope of the mobile app market.

Mobile health technologies would not be the first example of regulatory arbitrage in the health technology space, and other examples are more clearly harmful. Another recent example is from the field of diagnostic technologies.[64] For decades, the FDA decided to exercise its enforcement discretion regarding "laboratory-developed tests" or LDTs, those which are "designed, manufactured, and used within a single laboratory."[65] The FDA

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63. Burk & Lemley, *supra* note 15, at 1618–19, 1622–23 (discussing the characteristics of the business method and software industries which encourage them to innovate without the use of patents); Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 275 (2000) (describing the expense of patents that ultimately transfer a higher price for the consumer); *see also* SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, U.S. DEP'T HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 1 (2010) [hereinafter, SACGHS REPORT ON GENE PATENTS] ("[T]he prospect of patent protection of a genetic research discovery does not play a significant role in motivating scientists to conduct genetic research.").

64. *See generally* U.S. FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUMAN SERVS., FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTS), DRAFT GUIDANCE (2014), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf [hereinafter LDT DRAFT GUIDANCE].

65. *Id.* at 5. Importantly, this does not mean that only one laboratory in the country performs a given test. It certainly can, but it often does not. Many of the most widely available tests are LDTs, precisely because they are simple for every lab to develop and perform independently. Routine laboratory tests like a complete blood count or Pap smear typically qualify as LDTs for this reason. These tests are performed in hundreds or even thousands of labs around the country, but they can still qualify as LDTs as long as there is no test

only exercised its authority over diagnostic tests where a testing company opted to produce a test kit for sale and use in laboratories around the country.[66] Companies responded to the incentives created by this scheme,[67] and estimates suggest that the majority of genetic tests are currently offered as LDTs.[68] However, the FDA has become concerned about increased risk to patients from many of the newer LDTs, and we may see increased regulation in this area going forward.[69]

B. Regulatory Preference

Regulatory arbitrage is only one side of the story. Rather than design their businesses to avoid FDA scrutiny, some companies have chosen to pursue the opposite strategy, leveraging their regulatory sophistication to move fully into the wearable medical device category.[70] These companies welcome FDA regulation and view it as a means of both staving off competition in the market and obtaining a stamp of approval that other companies will lack.[71] Each of these rationales deserves further explication.

First, the FDA is a strong gatekeeper for traditional medical technologies.[72] No pharmaceutical or risky medical device will come to market without FDA clearance.[73] As such, companies running the FDA gauntlet can expect that would-be competitors will also need to expend time

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manufacturer who sells a diagnostic product to other labs.

66. 21 U.S.C. § 321(h) (2012) (The Federal Food, Drug, and Cosmetic Act gives the FDA the authority to regulate any medical device, defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."); SACGHS REPORT ON GENE PATENTS, *supra* note 63, at 61.

67. PRIORITIES FOR PERSONALIZED MED., PRESIDENT'S COUNSEL OF ADVISORS ON SCI. & TECH., 38–39 (2008), http://web.archive.org/web/20090117060516/http://www.ostp.gov/galleries/PCAST/pcast_report_v2.pdf.

68. SACGHS REPORT ON GENE PATENTS, *supra* note 63, at 61.

69. LDT DRAFT GUIDANCE, supra note 64, at 7; *see also generally* U.S. FOOD & DRUG ADMIN., THE PUB. HEALTH EVIDENCE FOR OVERSIGHT OF LABORATORY DEVELOPED TESTS: 20 CASE STUDIES (Nov. 16, 2015), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf.

70. *See* Julie Steenhuysen, *Beyond Fitbit: The Quest to Develop Medical-Grade Wearables*, REUTERS (Dec. 18, 2015), http://www.reuters.com/article/us-usa-health-wearables-insight-idUSKBN0U10G120151218 (last visited Mar. 2, 2017).

71. Bradley Merrill Thompson, SHOULD MHEALTH COMPANIES WANT REGULATION? 6–7 (June 2014), http://www.ebglaw.com/content/uploads/2014/06/37764_mobilehn4b.pdf.

72. *See generally* U.S. FOOD & DRUG ADMIN., FDA'S ROLE IN ENSURING AMERICAN PATIENTS HAVE ACCESS TO SAFE AND EFFECTIVE MEDICAL DEVICE TECHNOLOGY (2015), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM457151.pdf.

73. *See id.*

and money to complete the relevant regulatory processes, and cannot simply free-ride on the first company's investment in clinical trials.[74] In some ways, this gatekeeper function of the FDA partially replicates the function of the patent system.[75] To be sure, it is weaker in some ways (especially for follow-on devices proceeding through the 510(k) pathway), but in others it is stronger.[76] For instance, the FDA gatekeeping authority is automatically enforced—companies do not need to expend resources searching for potential patent infringers on the market, as the FDA will do it for them.[77] If patents are less commonly available for mobile health companies, FDA approval may be one way of partially regaining their function.

Second, FDA approval carries with it an imprimatur of safety and effectiveness that can be highly valuable to a company.[78] Companies can avoid publicly releasing particular types of information, including trade secrets about how their products work, if the FDA has viewed all the relevant information and approved the product on that basis.[79] The FDA is highly respected by both the public and experts in the relevant fields,[80] meaning that its approval decisions are both trusted and important to other decision makers within the health care context.[81] If consumers have a choice between two products—one FDA-approved, recommended by their physician and paid for by their insurer, and another with more limited functionality and no recommendation from a trusted intermediary—they may be inclined toward the former.

One example of this approach is Empatica, a company developing a series of devices that measure and monitor a range of vital signs.[82] Empatica's flagship product, a smart watch called Embrace, was designed primarily for

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74. *See id.* (Noting generally that every new medical technology goes through the relevant regulatory processes).

75. *See* Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals — Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 449–50 (2012).

76. *Id.* at 430–32 (looking at similarities and differences between the patent system and FDA).

77. *Id.* (discussing how the FDA doesn't allow generic drugs to enter the market for a period of 5 years).

78. *See Device Denials, Approvals and Clearances*, U.S. FOOD & DRUG ADMIN. (Apr. 7, 2016), http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/ (noting that FDA approval shows that a medical device is safe and effective for its intended use).

79. Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access To Data on Drug Safety*, 26–2 HEALTH AFFAIRS 483, 484–85 (2007).

80. DANIEL CARPENTER, REPUTATION AND POWER 12 (2010).

81. *Id.*

82. *Embrace: Monitors Seizures, Sleep and Physical Activity*, EMPATICA (2017), https://www.empatica.com/product-embrace (last visited Apr. 7, 2017).

patients with epilepsy.[83] Ideally, Embrace will be able to alert epilepsy patients and caregivers of seizures.[84] Rather than just coming up with an app that tracks sleep and activity or using existing technologies with capabilities in this area (such as fitness trackers like Fitbit or Jawbone), Empatica has invested in its own complex technology.[85] Most importantly, Empatica plans on gaining FDA approval for its products, particularly those which it hopes will be useful in clinical trials.[86] Other companies developing epilepsy sensors, like Smart Monitor, are also conducting studies in preparation for FDA review.[87]

In explaining two of the key ways in which companies have chosen to respond to the landscape of innovation incentives facing mobile health companies, the above stories tell only one side of the innovation puzzle. Equally as important are the decisions being made by agencies about when, why, and how to regulate these technologies. Most interestingly, in the mobile health space there have been several examples of interagency collaboration on innovation and regulation.

III. INTERAGENCY COLLABORATION TO SHAPE MOBILE HEALTH INNOVATION

It is not enough to consider the choices made by any individual administrative agency in the service of innovation and regulation. Their coordinated actions must be considered. Several agencies, which nonetheless lack formally shared regulatory authority over the innovation space, have begun to collaborate in the mobile health space to promote incentives for innovation and regulation. Much of the leading administrative law scholarship on interagency relationships speaks in terms of *coordination*,[88] where the primary goal in situations involving agencies with interacting jurisdictional assignments is to minimize inconsistency.[89] But it is worth distinguishing mere *coordination* from a relationship that rises further to the level of *collaboration*, in which agencies actively work together, exchanging

83. *Advanced Research on Human Behavior*, EMPATICA (2017), https://www.empatica.com/science (last visited Apr. 7, 2017).

84. *Id.*

85. *Id.*

86. Steenhuysen, *supra* note 70.

87. *Id.*

88. *See generally, e.g.*, Freeman & Rossi, *supra* note 54; *see generally* Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421 (2015); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 G.W. L. REV. 1, 21 (2008) (noting that "government agencies often fail to coordinate innovation policy, resulting in incoherence and perhaps bald inconsistency.").

89. Freeman & Rossi, *supra* note 54, at 1146–48.

information and resources, to achieve shared goals.[90] My focus going forward is on this category of true collaboration, although the personal and institutional relationships supporting relationships of mere coordination are often a precondition for collaboration as well.

In another work,[91] I argued that health-related agencies within the Department of Health and Human Services (HHS), such as the FDA, Centers for Medicare and Medicaid Services (CMS), and National Institutes of Health (NIH) engage in collaboration to perform a number of functions.[92] They share information among themselves that can be used to set priorities for research and regulation, engage jointly in research that advances agency priorities, and make decisions more efficiently about product approvals and insurance coverage.[93] Agency collaboration is similarly present in the mobile health context, although thus far observable collaboration has taken a different form: collaboration between traditional health-related agencies and traditional enforcement agencies.[94]

In 2016, the Federal Trade Commission (FTC) worked with HHS and FDA to create and make publicly available an online tool for developers of mobile health apps.[95] The goal of the tool is to "help the developers understand what federal laws and regulations might apply to their apps."[96] The agencies created a clear user interface that marches developers through a series of questions about their product, at each stage providing information about laws that might affect the choice one way or the other.[97] As one example, the app asks developers if their product is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment

90. To be sure, the literature itself—rather than just the terminology it applies—is concerned with both. Requirements for interagency consultation frequently fall into the coordination category, while joint rulemakings are often closer to collaboration, and there are instances of true collaboration. *Id.* at 1157, 1163, 1166.

91. Rachel E. Sachs, *Administering Health Innovation*, 23 (unpublished manuscript) (draft on file with author).

92. *See generally* Sarah Fellay, *Changing the Rules of Health Care: Mobile Health and Challenges for Regulation*, AM. ENTERPRISE INST. (Aug. 4, 2014), http://www.aei.org/publication/changing-the-rules-of-health-care-mobile-health-and-challenges-for-regulation/.

93. Sachs, *supra* note 91.

94. *See generally* Fellay, *supra* note 92.

95. *Mobile Health Apps Interactive Tool*, FED. TRADE COMM'N. (Apr. 2016), https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool.

96. *FTC Releases New Guidance for Developers of Mobile Health Apps*, FED. TRADE COMM'N., (Apr. 5, 2016), https://www.ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps.

97. *Id.*

or prevention of disease."[98] If so, they may be a medical device subject to FDA regulation.[99] These laws—including the Food, Drug and Cosmetic Act, HIPAA, the FTC Act, and others—are the very same ones agencies have made choices to avoid or embrace.[100] The new information from the FTC, HHS, and FDA puts these companies on notice and provides certainty as they move forward.[101]

This questionnaire is the first example of explicit, public collaboration between agencies in the mobile health space. However, I do not believe it is the first example of collaboration. Collaboration between agencies may take place publicly, as with this questionnaire or as with initiatives like the FDA/CMS parallel review program for medical devices.[102] Alternatively, collaboration may take place behind the scenes. While the fact of the collaboration itself may not be public, the existence of collaboration may be the best explanation for a given action taken by an agency—it may be acting to implement another agency's priorities.

In the mobile health space, behind-the-scenes collaboration may be taking place in the context of FTC enforcement actions. To date, the FTC has taken action against a number of mobile health apps it argues are engaging in deceptive advertising practices.[103] The FTC's August 2015 actions against a set of mobile apps that claimed to be able to detect melanoma once users took pictures of their moles[104] is one such example here. Like many federal agencies, the FTC is under-resourced and must set priorities for enforcement. The FDA and FTC have a long-standing relationship of coordination on enforcement actions,[105] and the mobile health space may be the latest example of their work in this area. Since the FDA has opted to exercise their enforcement discretion regarding many of these technologies, FDA officials noticing egregious examples of health-related advertising may request FTC involvement.[106] Of note is the FDA's similar relationship with the SEC, in

98. *Mobile Health Apps Interactive Tool*, *supra* note 95.

99. *Id.*

100. *Id.*

101. *Id.*

102. Program for Parallel Review of Medical Devices, 81 Fed. Reg. 73113, 73114 (Oct. 24, 2016).

103. Fed. Trade Comm'n., *"Melanoma Detection" App Sellers Barred from Making Deceptive Health Claims* (Aug. 13, 2015), https://www.ftc.gov/news-events/press-releases/2015/08/melanoma-detection-app-sellers-barred-making-deceptive-health.

104. *Id.*

105. Freeman & Rossi, *supra* note 54, at 1162; *see also* Anne V. Maher & Lesley Fair, *The FTC's Regulation of Advertising*, 65 FOOD & DRUG L.J. 589, 602 (2010).

106. *Cf.* DAVID C. VLADECK, DIRECTOR, FTC BUREAU OF CONSUMER PROTECTION, COUNCIL FOR RESPONSIBLE NUTRITION ANNUAL SYMPOSIUM FOR THE DIETARY SUPPLEMENT INDUSTRY: PRIORITIES FOR DIETARY SUPPLEMENT ADVERTISING ENFORCEMENT (Oct. 22,

the context of publicly-held pharmaceutical companies who fail to disclose relevant information or who publicly misrepresent their dealings with the FDA.[107]

There are good reasons to make interagency collaborations, both of this and other types, more transparent. First, transparency about agency priorities and enforcement is important to ensure public accountability. These agencies already issue guidance documents (such as the FDA's guidance documents on the regulation of mobile health apps) and rulemakings for public comment for similar reasons.[108] Second and possibly more importantly, transparency about areas of collaborative focus helps scientists and the industry in general plan for the future. The primary point of these collaborations is to improve both regulatory priority-setting and the regulatory process itself, and scientists who are aware of these priorities will make decisions about what technologies to develop and how those technologies will come to market in a more informed, appropriate fashion.

Of course, in many cases collaboration does not occur, even where it might be desirable. There are a range of reasons why this might be true. It may be that one agency's governing statute formally precludes its action or even its collaboration with other agencies on specific issues. For instance, the FDA may hope to regulate in an area, but be hamstrung by its own jurisdictional limitations, as some of the functions implemented by mobile apps may fall under its "practice of medicine" exception.[109]

More commonly, though, the explanation for the failure to collaborate may be less about legal barriers and more about practical obstacles. It is costly—in terms of time, energy, and agency resources, if not in terms of financial resources—to develop and maintain interagency collaborations.[110] Unless staff members have support from agency leaders, it may be difficult for them to identify their counterparts in the relevant agencies, formulate plans for collaboration, and implement those plans.

Helpfully, there are a range of potential procedural mechanisms that could be employed to enhance cooperation between different administrative agencies for the purpose of promoting both innovation and regulation. Many

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2009), https://www.ftc.gov/sites/default/files/documents/public_statements/priorities-dietary-supplement-advertising-enforcement/091022vladeckcrnspeech.pdf.

107. Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1234–36 (2007).

108. *See generally*, CARY COGLIANESE, HEATHER KILMARTIN, AND EVAN MENDELSON, UNIV. OF PA. LAW SCH., TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RULEMAKING PROCESS: A NONPARTISAN PRESIDENTIAL TRANSITION TASK FORCE REPORT (July 2008).

109. *See, e.g.*, Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 430 (2015).

110. Benjamin & Rai, *supra* note 88, at 23–25.

of these tools also have the advantage of directing cooperation to occur in ways that are driven by top-down goals, purposefully and deliberately, rather than opportunistically. Two different examples will illustrate some of the institutional design options available on this issue.

One potential procedural mechanism draws heavily from a proposal first advanced by Professors Arti Rai & Stuart Benjamin, who suggest the creation of an innovation regulator within the executive branch.[111] They consider the advantages (and disadvantages) of centralizing an innovation office and housing it within the Executive Branch, arguing quite rightly that the decentralization we observe at present is a significant problem from an innovation perspective.[112] Interestingly, in keeping with my arguments regarding transparency above, Rai & Benjamin would create a regulator with both "an obligation and an incentive to operate transparently."[113] This proposal is especially well-suited to innovation in mobile health, where potential innovation concerns span multiple independent agencies.[114]

Creating a central innovation office within the White House or even within an existing White House Office, such as the Office of Science and Technology Policy, would be a particularly timely act. Over the past few years, President Obama invested in a series of biomedical research initiatives which all bring together different administrative agencies for innovation purposes.[115] The BRAIN Initiative, the Precision Medicine Initiative, and the Cancer Moonshot are all centrally driven programs.[116] Congress signaled its

111. *Id.* at 6.

112. *Id.* at 57.

113. *Id.* at 78.

114. Sachs, *supra* note 91. Concerning subagencies within HHS—such as CMS, FDA, and NIH—I have elsewhere suggested that creating a separate officer within HHS may be prudent. This proposal may strike a middle-ground between complete centralization and complete decentralization, allowing the officer to develop deeper, more personal connections with the material than would housing them within the executive branch, while at the same time minimizing some of the difficulties of decentralization. Benjamin & Rai, *supra* note 88, at 56–58. Alternatively, creating individual subject matter officers within a more centralized executive branch office may functionally replicate these concerns.

115. *Fact Sheet: BRAIN Initiative*, THE WHITE HOUSE OFF. OF PRESS SEC'Y (Apr. 2, 2013), https://obamawhitehouse.archives.gov/the-press-office/2013/04/02/fact-sheet-brain-initiative [*hereinafter Brain Initiative*]; *Fact Sheet: Vice President Biden Delivers Cancer Moonshot Report, Announces Public and Private Sector Actions to Advance Cancer Moonshot Goals*, THE WHITE HOUSE OFF. OF VP. (Oct. 17, 2016), https://obamawhitehouse.archives.gov/the-press-office/2016/10/17/fact-sheet-vice-president-biden-delivers-cancer-moonshot-report [*hereinafter Vice President Biden Delivers Cancer Moonshot Report*].

116. *See The Precision Medicine Initiative*, THE WHITE HOUSE (2015), https://obamawhitehouse.archives.gov/precision-medicine (last visited Jan. 30, 2017); *BRAIN Initiative*, *supra* note 115; *Vice President Biden Delivers Cancer Moonshot Report*, *supra* note 115.

intention to continue these programs going forward,[117] and a centralized innovation regulator could pull in relevant administrative agencies as necessary.

A second, very different approach would be to involve Congress in the development of innovation policy in this area. Congress might consider creating a non-partisan, independent organization along the lines of MedPAC, the Medicare Payment Advisory Commission.[118] MedPAC is composed of independent experts who advise Congress on potential reforms to Medicare, broadly speaking.[119] These experts are drawn primarily from academia, health care providers, and the health care industry more generally.[120] Such a commission could not only review the individual actions of administrative agencies as they relate to innovation policy, but it could also review the ways in which these agencies relate to each other.

This idea is not merely speculative. An early draft of the 21st Century Cures Act would have created a national Medical Product Innovation Advisory Commission based on MedPAC. The proposed Commission would "analyze medical product innovation in the United States and recommend policies to accelerate the discovery, development, and delivery of new medical products."[121] As such, the Commission would not only be specifically tasked with reviewing policies of the NIH, FDA, CMS, and other agencies, but would also be tasked with "review[ing] the *interaction* of Federal agencies with respect to the discovery, development, and delivery of new medical products and how such interactions influence medical product innovation."[122]

IV. CONCLUSION

In this essay, I considered the ways in which the innovation policy landscape for mobile health technologies affects both the companies choosing whether and how to invest in this space and the administrative

117. Tanya Somanader, *Three Letters That Explain Why President Obama Is Signing the Cures Act*, WHITE HOUSE BLOG (Dec. 13, 2016), https://www.whitehouse.gov/blog/2016/12/12/3-letters-explain-why-president-obama-signing-cures-act.

118. *See* MedPAC, *About MedPAC* (2016), http://www.medpac.gov/-about-medpac-.

119. *See, e.g.*, MEDPAC, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY (March 2016).

120. *Cf.* Benjamin & Rai, *supra* note 88, at 54 ("[A]n innovation regulator that improved congressional decisionmaking would appear quite attractive.").

121. 21st Century Cures Act Discussion Document § 229A (Jan. 26, 2015), https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/Cures/20150127-Cures-Discussion-Document.pdf.

122. *Id.* at § 229A(b)(2)(B) (emphasis added).

agencies setting and implementing the relevant policies. I argued that scholars and policymakers ought to look beyond the capacities of administrative agencies individually to contribute to innovation policy, and instead ought to focus on the potential for collaboration across agencies. There are key areas of collaboration that are almost entirely unexplored, and we ought to consider procedural options for encouraging or requiring such collaboration. The ultimate point, though, is broader. The ways in which these agencies, which have distinct missions regarding overlapping subject matter, collaborate may provide a way forward for innovation policy law and scholarship.