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DIGITAL MEDICINE, THE FDA, AND THE FIRST AMENDMENT

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TABLE OF CONTENTS

I.	INTRODUCTION	935
II.	WHAT IS DIGITAL MEDICINE?	942
	A. AUTOMATED OR DIGITAL REFERENCE MATERIALS AND PREDICTION CALCULATORS (“PHYSICIAN AVATARS”)	942
	B. NON-INVASIVE MEASUREMENT APPLICATIONS	943
	C. INVASIVE MEASUREMENT APPLICATIONS.....	943
III.	THE FDA’S REGULATION OF DIGITAL MEDICINE.....	944
	A. THE FDA’S REGULATION OF MEDICAL DEVICES	946
	B. THE FDA’S REGULATION OF DIGITAL MEDICINE.....	949
IV.	THE FDA’S INTERPRETATION OF § 321(H) VIOLATES THE APA	952
	A. TEXTUAL ANALYSIS OF “MEDICAL DEVICE” UNDER § 321(H).....	953

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B.	THE LEGISLATIVE HISTORY OF § 321(H).....	960
C.	MEDICAL DEVICE MANUFACTURERS	965
V.	THE FIRST AMENDMENT LIMITS ON FDA REGULATION	967
A.	THE FIRST AMENDMENT AND PURE INFORMATION COMMUNICATION APPLICATIONS	971
1.	<i>Pure Information Analysis Applications Are Speech</i>	972
2.	<i>Pure Communications as Used in Digital Medicine Is Protected Speech</i>	974
3.	<i>Under the Applicable Strict Scrutiny Test, the FDA Regulation Fails</i>	976
B.	NON-INVASIVE MEASUREMENT MEDICAL APPLICATIONS	980
C.	INTERMEDIATE SCRUTINY AND DIGITAL MEDICINE.....	987
D.	FINAL FIRST AMENDMENT THOUGHTS: SPEAKER DISCRIMINATION AND PRIOR RESTRAINT	990
VI.	CONCLUSION.....	992

I. INTRODUCTION

In a *Wall Street Journal* opinion piece, Robin Cook and Eric Topol describe “[a] sweeping transformation of medicine . . . that will rival in importance the introduction of anesthesia or the discovery of the germ basis of infectious disease.”¹ They call this transformation “digital medicine.”² Cheaper, computerized DNA sequencers will allow practitioners to figure out which drugs will or won’t work for any particular patient. “[D]igitalization will democratize medicine,” allowing individuals to “control the data about [their] own medical condition [and] analyze it instantly [through] connectivity to the Web,” i.e., individuals may self-diagnose and treat themselves.³

Central to this transformation will be “ever more sophisticated smartphones” which will become “avatar physician[s].”⁴ Drs. Cook and Topol envision this scene:

You wake up at 3 a.m. on Christmas morning with a bout of chest pain. Your smartphone reads your [echocardiogram] and reassures you that you are not having a heart attack—or tells you to call an ambulance and places the call, meanwhile instantly transmitting all the data to a hospital ER. And while you are at the hospital receiving treatment care, your avatar doctor remains at your side as a constant adviser and ombudsman. . . .

[Y]our avatar doctor may be able to warn you days in advance that you are going to have a heart attack by sensing certain genomic signals circulating in your blood stream and sending you to your cardiologist or to the ER. It can tell you if that sore throat you feel coming on is strep, and if it is, automatically send a

¹ Robin Cook & Eric Topol, Op-Ed., *How Digital Medicine Will Soon Save Your Life*, WALL ST. J. (Feb. 21, 2014, 2:07 PM), available at <http://online.wsj.com/news/articles/SB10001424052702303973704579351080028045594>.

² *Id.*

³ *Id.*

⁴ *Id.*

prescription by email to the local pharmacy for an appropriate antibiotic.⁵

And, unlike other medical innovations such as MRIs that have led to higher costs, digital medicine will lower costs by reducing reliance on medicines that do not work, catching disease early, and decreasing demands on healthcare providers.⁶

Already tens of thousands of “mobile medical apps” are available for smartphones. They can monitor “all the physiological data [typically] monitored in a hospital intensive-care unit—including [echocardiogram], blood pressure, pulse, oxygenation, sugar level, breathing rate and body temperature.”⁷ “Doctor Mole” uses an iPhone camera to diagnose the factors indicative of skin cancer;⁸ SpiroSmart allows asthmatics to measure lung function by blowing on their iPhone;⁹ CellScope transforms your smart phone into a digital microscope or macroscope;¹⁰ and, Uchek allows you to check your own urine for a variety of conditions.¹¹ Other apps, such as Caracal Diagnosis,¹² Isabel,¹³ or iLiver,¹⁴ aimed at practitioners but available to all, diagnose disease.

Beyond your smartphone, automated medical services provide information never before accessible to consumers. For instance, 23andMe has used established gene sequencing technology to obtain

⁵ *Id.*

⁶ *See id.*

⁷ *Id.*

⁸ William Cook, *Is that Little Mole a Big Problem? Ask Doctor Mole, the Smartphone App that Checks for Signs of Skin Cancer*, DAILY MAIL (Oct. 4, 2012, 7:02 AM), <http://www.dailymail.co.uk/sciencetech/article-2212200/Doctor-Mole-The-smartphone-app-checks-signs-skin-cancer.html>.

⁹ Hannah Hickey, *App Lets You Monitor Lung Health Using Only a Smartphone*, U. WASH. TODAY (Sept. 18, 2012), <http://www.washington.edu/news/2012/09/18/app-lets-you-monitor-lung-health-using-only-a-smartphone>.

¹⁰ Frank Irving, *Oto: Converting an iPhone into a Digital Otoscope*, MEDICAL PRACTICE INSIDER (Apr. 28, 2014), <http://www.medicalpracticeinsider.com/news/oto-converting-iphone-digital-otoscope>.

¹¹ Jane Wakefield, *TED 2013: Uchek App Tests Urine for Medical Issues*, BBC (Feb. 27, 2013, 7:09 AM), <http://www.bbc.co.uk/news/technology-21586082>.

¹² Stuart Dredge, *Apps Rush Catch-Up: 78 Notable Apps Released in the Last Week*, THE GUARDIAN (June 5, 2012, 7:50 AM), <http://www.theguardian.com/technology/appsblog/2012/jun/05/apps-rush-instagram-anydo-notice#start-of-comments>.

¹³ Stacey Butterfield, *Patients Increasingly Checking ‘Dr. Google,’ ACP INTERNIST*, <http://www.acpinternist.org/archives/2013/11/dr-google.htm> (last visited May 11, 2015).

¹⁴ *About iLiver*, ILIVER, <http://www.iliver.eu/> (last visited May 11, 2015).

genomic information about customers which could reveal tendencies towards certain diseases and therefore prompt customers to make better lifestyle decisions,¹⁵ although it has suspended operation while undergoing the process for FDA regulatory approval.¹⁶

These technologies will expand data gathering from sporadic testing at doctors' offices to enable real-time collection of data from millions of people, both sick and healthy. Such pools of medical data will allow doctors and researchers to personalize medicine, and perhaps give them new ways to examine epidemiology.

For instance, the company, LIONSolver, produced a prototype mobile medical app that recently won the Michael J. Fox Foundation Parkinson's Data Challenge.¹⁷ Its app uses machine learning on data derived from smartphones' 24/7 monitoring of patients to successfully "distinguish [who] had [Parkinson's disease] and predict the progression of the disease over a 90-day timeframe."¹⁸ Although LIONSolver had a only a small pool of data, "[w]ith more data . . . passively collected voice and GPS information might also be helpful in monitoring Parkinson's patients and advising them on drug dosage and eating and sleeping habits."¹⁹ By pooling this data, epidemiologists will be able to measure at a population level the effectiveness of treatments and the genetic and environmental causes of disease.²⁰

In face of these developments, the Federal Drug Administration (FDA) has asserted regulatory authority over mobile medical applications and other digital medical services.²¹ Many, within

¹⁵ *How it Works*, 23ANDME, <https://www.23andMe.com/howitworks/> (last visited May 11, 2015).

¹⁶ *Health: What You Can Learn*, 23ANDME, <https://www.23andMe.com/health> (last visited May 11, 2015).

¹⁷ *\$10,000 Parkinson's Data Challenge*, THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH, <https://www.michaeljfox.org/page.html?parkinsons-data-challenge> (last visited May 11, 2015).

¹⁸ *Dr. Smartphone, What's My Diagnosis?*, ROCK HEALTH (Aug. 22, 2013), <http://rockhealth.com/2013/08/dr-smartphone-whats-my-diagnosis>.

¹⁹ Doug Henschen, *Michael J. Fox Foundation Points Big Data at Parkinson's: Kaggle Challenge Winner Lionsolver Proves that Passive Data Collection Can Improve Patient Care and Medical Research*, INFORMATIONWEEK (July 31, 2013, 10:07 AM), <http://www.informationweek.com/big-data/big-data-analytics/michael-j-fox-foundation-points-big-data-at-parkinsons/d/d-id/1110981?>

²⁰ See *id.* (noting the value of such "vast data sets").

²¹ See *Mobile Medical Applications*, FDA, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/connectHealth/MobileMedicalApplication/ucn255978.htm> (last visited May

legal academia and policy circles, fear that its oversight may chill, if not destroy, this innovation.²² In September 2013, the FDA released formal guidance on the regulation of medical apps, folding them under its regulation of “medical devices.”²³ In a letter dated November 22, 2013, the FDA ordered 23andMe to stop providing its services.²⁴ The action attracted worldwide attention, perhaps because 23andMe is a Silicon Valley company co-founded by Ann Wojcicki, the former wife of Google co-founder Sergey Brin.²⁵ Because the regulations could very well stymie progress in this potentially revolutionary area, the stakes are enormous. Furthermore, if classified as medical devices, medical apps would

11, 2015) (stating that the FDA “has a public health responsibility to oversee the safety and effectiveness of medical devices—including mobile medical apps”).

²² See, e.g., Richard Epstein, Op-Ed., *Manhattan Moment: FDA Overreach Has Heavy Costs*, WASH. EXAMINER (Nov. 29, 2013), <http://washingtonexaminer.com/manhattan-moment-fda-overreach-has-heavy-costs/article/2539939> (asserting that FDA bans of products may harm many patients); Nita Farahany, *FDA Overreach and 23andMe*, THE VOLOKH CONSPIRACY (Nov. 25, 2013, 10:04 PM), <http://www.volokh.com/2013/11/25/fda-overreach/> (questioning whether “information [that] can help in the diagnosis of a medical condition . . . should be considered a ‘medical device’ ”); Walter Olson, *FDA Orders 23andMe to Shut Down Home Genome Test*, OVERLAWYERED (Nov. 26, 2013), <http://overlawyered.com/2013/11/fda-seeks-shut-23andme-home-genome-test/> (noting that home genome testing, such as 23andMe’s testing, “can be hugely valuable”); David Rivkin Jr. & Andrew Grossman, *The FDA Is Blocking 23andMe’s Genome Service. But the Real Target Is Free Speech*, USA TODAY (Dec. 9, 2013, 5:02 PM), <http://www.usatoday.com/story/opinion/2013/12/09/23andme-fda-suit-dna-column/3926589/> (asserting that “[s]hutting a device such as 23andMe is no different from censoring home medical references”).

²³ See FDA, MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 13 (2013), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> [hereinafter FDA GUIDANCE].

²⁴ Letter from Alberto Gutierrez, Director Office of In Vitro Diagnostics and Radiological Health, FDA, to Ann Wojcicki, CEO of 23andMe, Inc. (Nov. 22, 2013), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm>.

²⁵ See Jacob Gershman, *FDA Warning to 23andMe Spawns Class-Action Complaint*, WALL ST. J. (Dec. 3, 2013, 6:44 PM), <http://blogs.wsj.com/law/2013/12/03/fda-warning-to-23andme-spawns-class-action-complaint> (describing a recent class action that accuses the “company of making marketing claims unsupported by scientific evidence”); Ryan Jaslow, *FDA Warns 23andMe, Tells Genetic Testing Firm to Halt Sales*, CBS NEWS (Nov. 25, 2013, 12:57 PM), <http://www.cbsnews.com/news/fda-warns-23andme-tells-genetic-testing-firm-to-halt-sales> (explaining the FDA’s concerns about the company’s products); Claire Cain Miller, *Anne Wojcicki Speaks Out About the F.D.A. Crackdown on 23andMe*, N.Y. TIMES (Dec. 4, 2013, 8:29 PM), <http://bits.blogs.nytimes.com/2013/12/04/anne-wojcicki-speaks-out-about-the-f-d-a-crackdown-on-23andme> (noting that Wojcicki recognized that the company did not respond quickly enough to the FDA’s requests); Dan Munro, *Class Action Law Suit Filed Against 23andMe*, FORBES (Dec. 2, 2013, 11:04 PM), <http://www.forbes.com/sites/danmunro/2013/12/02/class-action-law-suit-filed-against-23andme>.

face the new medical device tax under the Patient Protection and Affordable Care Act (Obamacare).²⁶

Building on the large, growing legal literature on mobile medical applications and other aspects of digital medicine,²⁷ this Article argues that the FDA stands on firm legal ground regulating medical devices that invasively measure bodily functions or take actual physical specimens. On the other hand, the FDA's exercise of jurisdiction over applications that simply process information, such as Isabel, or use approved medical devices to provide medical information raises serious legal concerns. These devices are what this Article calls "avatar physicians,"²⁸ a phrase coined by Drs. Cook and Topol that refers to digitized medical reference materials or prediction calculators. They provide information that books also provide, but use screens rather than pages, or they analyze information derived from approved FDA devices.²⁹ For instance, 23andMe analyzes results from the gene sequencer, the Illumina

²⁶ See 26 U.S.C. § 4191 (2012) (imposing a tax on certain medical devices).

²⁷ See, e.g., Eric D. Hargan, *The Internet, Information Technology, and the FDA*, in RECENT DEVELOPMENTS IN FOOD AND DRUG LAW 27 (Ellie Fournier ed., 2012) (describing recent developments in medical technology and FDA regulations); Vernessa T. Pollard & Chandra Branham, *FDA Medical Device Requirements: A Legal Framework for Regulating Health Information Technology, Software, and Mobile Apps*, RECENT DEVELOPMENTS IN FOOD AND DRUG LAW 91 (Eddie Fournier ed., 2012) (describing the FDA's "regulatory approach to health information technology . . . and the emerging rules and compliance issues for companies"); Tatiana Melnik, *There's an App for That! The FDA Offers a Framework for Regulating Mobile Health*, 13 J. HEALTH CARE COMPLIANCE 45–46 (2011) (describing contributions by the federal government and the private sector to the growth of mobile health); Deborah Runkle, *The mHealth Revolution*, 9 ABA SCITECH LAW. 24–25 (2013) (describing innovations such as apps that record heart rate or blood glucose levels); Nicolas P. Terry, *Information Technology's Failure to Disrupt Health Care*, 13 NEV. L.J. 722, 756–57 (2013) (assessing the impact of health information technology on health care delivery); Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7, 9 (2013) (advocating for "more sophisticated utilization of [health information technology] in exchange for" government subsidies); Julie Tibbets, Paula Stannard & Brendan Carroll, *FDA's "Mobile Medical Apps" Guidance: What's In? What's Out?*, 18 CYBERSPACE LAW. 15 (summarizing the impact of the FDA's Final Guidance). For more background material, see generally Alex Krouse, Note, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731 (2012) (providing an overview of the mobile health industry); Daniel F. Schulke, Note, *The Regulatory Arms Race: Mobile-Health Applications and Agency Posturing*, 93 B.U. L. REV. 1699 (2013) (proposing different regulatory systems for the mobile health industry).

²⁸ Cook & Topol, *supra* note 1.

²⁹ See, e.g., *id.* ("A device worn on the wrist, called Visi, has been approved by the FDA for hospital use that can measure [various bodily functions], and transmit the data wirelessly.")

HumanOmniExpress-24 format chip.³⁰ One could search the Internet to find explanations of its output without using 23andMe.³¹ 23andMe simply makes that process easier.³² As such, medical applications such as 23andMe and other automated references and prediction calculators stand beyond the FDA's regulatory reach and within the First Amendment's protection.

The Article proceeds as follows. Part II describes digital medicine and the mobile medical application industry, the potential of this industry to transform medicine, and the FDA's regulation of it under the Federal Food, Drug, and Cosmetic Act³³ (FDCA) as well as its recently published guidance on mobile medical applications.³⁴ Part III examines the basis for the FDA's assumption of jurisdiction over digital medicine under the "medical devices" provision of 21 U.S.C. § 321(h).³⁵ Though this definition encompasses a broad expanse of items, this Part concludes that the statute excludes items that have no direct physical effect in the world—like smartphone apps or automated references. This Article concludes that the FDA only has jurisdiction over devices that physically measure or directly and affect the human body.

This conclusion is consistent with the statutory prohibition against the FDA's regulation of medicine.³⁶ As Drs. Cook and Topol point out, digital medicine is not a device; it is an "avatar physician."³⁷ If avatar physicians are practicing medicine, regulatory authority resides with the States, which regulate professional practice, not the FDA. More fundamentally, it is far from clear whether avatar physicians in fact are practicing

³⁰ *How it Works*, *supra* note 15.

³¹ See, e.g., *DNA Sequencing Results Analysis*, THE CHEN LABORATORY, MOLECULAR AND CELLULAR BIOCHEMISTRY DEPARTMENT, INDIANA UNIVERSITY BLOOMINGTON, http://sites.bio.indiana.edu/~chenlab/protocol_files/sequence_analysis.htm (last visited Feb. 1, 2015) (providing instructions for analyzing gene sequences using various software programs).

³² See *How it Works*, *supra* note 15 (explaining that a customer's "DNA sample is processed by a team of expert technicians once it arrives at the lab").

³³ 21 U.S.C. §§ 301–399f (2012).

³⁴ See generally FDA GUIDANCE, *supra* note 23.

³⁵ 21 U.S.C. § 321(h) (2012).

³⁶ See *id.* § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device . . .").

³⁷ Cook & Topol, *supra* note 1.

medicine. After all, courts still have not decided whether LegalZoom and other automated legal services practice law.³⁸

Part IV conducts a First Amendment critique of the FDA's regulation of medical applications and concludes that regulating items that simply involve informational inputs and outputs or that use approved FDA devices to do so—like automated reference materials or prediction calculators—should receive strict scrutiny. The FDA's regulation is also speaker discriminatory because it exempts physician-made medical applications. Under this standard of review, the FDA's regulation is unconstitutional.

This Article also adds to the large and important First Amendment debate on the status of information and computer code as protected speech. A voluminous literature exists on the protected status of information and computer code.³⁹ Building on the landmark Supreme Court decision, *Sorrell v. IMS Health Inc.*,⁴⁰ which ruled healthcare information to be protected speech, and *Brown v. Entertainment Merchants Ass'n*,⁴¹ which ruled video games and video interaction to be protected speech, this Article shows how computer code and applications which create healthcare information are similarly protected. Given their capacity to produce pools of data that researchers can mine to find clinical and epidemiological insights, medical applications are scientific speech deserving of the greatest protection. Because government now controls nearly two-thirds of healthcare

³⁸ See Isaac Figueras, Comment, *The LegalZoom Identity Crisis: Legal Form Provider or Lawyer in Sheep's Clothing?*, 63 CASE W. RES. L. REV. 1419, 1431–37 (2013) (discussing cases challenging LegalZoom, an online legal service, for unauthorized practice of law).

³⁹ See, e.g., Jane Bambauer, *Is Data Speech?*, 66 STAN. L. REV. 57, 64 (2014) (asserting that “data should receive speech protection anytime it is regulated as information”); Stuart Minor Benjamin, *Algorithms and Speech*, 161 U. PA. L. REV. 1445, 1492–94 (2013) (outlining the Free Speech protections available to algorithm-based decisions); Amanda Beshears Cook, *Copyright and Freedom of Expression: Saving Free Speech from Advancing Legislation*, 12 CHI.-KENT J. INTELL. PROP. 1, 26 (2013) (exploring the tension between federal copyright legislation and the Free Speech Clause); Andrea M. Matwysyn, *Hacking Speech: Informational Speech and the First Amendment*, 107 NW. U. L. REV. 795, 830–40 (2013) (proposing a new approach to instructional speech that uses four factors to determine a speaker's communicative intent); Andrew Tutt, *The New Speech*, 41 HASTINGS CONST. L.Q. 235, 242 (2014) (suggesting that “placing unfettered discretion into the hands of powerful digital intermediaries threatens to erode access to knowledge” on the internet).

⁴⁰ 131 S. Ct. 2653, 2659 (2011).

⁴¹ 131 S. Ct. 2729, 2733 (2011).

expenditures⁴²—and healthcare consumes almost eighteen percent of GDP,⁴³ healthcare information implicates speech about vital political issues and should receive the fullest First Amendment protection. Finally, digital medicine's power to increase control over our lives and make better choices about our most intimate concerns merits constitutional protection.

II. WHAT IS DIGITAL MEDICINE?

At its broadest, digital medicine computerizes processes that human beings once performed. Of course, medicine has been automating for decades. The FDA has long attempted to regulate computerized medicine through its authority to regulate “medical devices,”⁴⁴ although its previous efforts have proved largely unsuccessful.⁴⁵ Digital medical services can be grouped into three categories: data analysis, non-invasive mobile data collection and analysis, and invasive mobile data collection. The FDA regulation, discussed below, tracks these distinctions.

A. AUTOMATED OR DIGITAL REFERENCE MATERIALS AND PREDICTION CALCULATORS (“PHYSICIAN AVATARS”)

Those applications that provide medical services which healthcare providers previously performed are automated medicine—i.e., physician avatars. Diagnostic programs or risk calculators, like Isabel and iLiver, fall within this category. One simply inputs information and receives a diagnosis or risk estimate. One could, at least in theory, obtain such information

⁴² See Chris Conover, *Takeover: Government on Track to Make up 66% of Healthcare Spending*, FORBES (Aug. 7, 2012, 9:21 AM), <http://www.forbes.com/sites/chrisconover/2012/08/07/takeover-government-on-track-to-make-up-66-of-healthcare-spending-obamacare/> (“In 2009, federal, state, and local governments accounted for more than 60 percent of all healthcare spending.”).

⁴³ Shirley S. Wang, *U.S. Health Spending: One of These Things Not Like Others*, WALL ST. J. (July 23, 2013, 2:05 PM), <http://blogs.wsj.com/economics/2013/07/23/u-s-health-spending-one-of-these-things-not-like-others/> (noting that the United States spent nearly 18% of its GDP on healthcare in 2011, almost double the next highest spender).

⁴⁴ 21 U.S.C. § 321(h) (2012).

⁴⁵ For example, see *Medical Devices; Medical Device Data Systems*, 76 Fed. Reg. 8637 (Feb. 15, 2011) (proposed to be codified at 21 C.F.R. pt. 880), which the FDA withdrew in the face of criticism.

with a library card or internet access. Physician avatars simply make this process easier.

B. NON-INVASIVE MEASUREMENT APPLICATIONS

Beyond analysis, mobile medical applications can, often non-invasively, collect information from the body, such as heart beat,⁴⁶ blood pressure,⁴⁷ glucose (using a contact lens),⁴⁸ echocardiogram information,⁴⁹ brain waves,⁵⁰ and breath.⁵¹ Like the data analyzers, these mobile applications allow individuals to perform functions, such as echocardiograms, which previously required doctors and technicians.

Often, these types of applications can work in conjunction with other devices. For instance, 23andMe uses (in theory, if not in practice) an approved gene sequence to obtain the basic genetic information. Like iLiver or Isabel, 23andMe simply provides a medical prognosis or prediction based upon informational inputs.

C. INVASIVE MEASUREMENT APPLICATIONS

Medical mobile applications can also be invasive, taking measurements within the body rather than simply detecting and measuring physical outputs. Consumer-marketed invasive measurements are not new. Diabetics have been testing their blood for decades. However, invasive mobile applications, which often attach to smartphones or can be worn, can enable 24/7 data collection.

⁴⁶ Chenda Ngak, *Smartphone Apps Help Track Steps, Heart Rate and Sleep*, CBS NEWS (Jan. 17, 2014, 9:57 AM), <http://www.cbsnews.com/news/smartphone-apps-help-track-steps-heart-rate-and-sleep>.

⁴⁷ Benny Evangelista, *Dad Inspires App-Linked Blood Pressure, Heart Monitors*, SAN FRANCISCO CHRON. (Jan. 11, 2004, 4:00 PM), <http://www.sfgate.com/technology/article/Dad-inspires-app-linked-blood-pressure-heart-5134844.php>.

⁴⁸ FOX NEWS, *Google Announces "Smart" Contact Lenses that Monitor Glucose Levels* (Jan. 16, 2014), <http://www.foxnews.com/tech/2014/01/16/google-announces-contact-lens-glucose-monitor>.

⁴⁹ Todd Neale, *Cardiac Echo: There Is an App for that*, MEDPAGE TODAY (Sept. 23, 2011), <http://www.medpagetoday.com/Cardiology/Arrhythmias/28698>.

⁵⁰ Matt Blake, *The App that Can Read Your Mind: iPhone Brainwave Detector Arrives (it Was Only a Matter of Time)*, DAILY MAIL (Jan. 14, 2011, 10:56 PM), <http://www.dailymail.co.uk/sciencetech/article-1346900/The-app-read-mind-iphone-brainwave-detector-matter-time.html>.

⁵¹ Hickey, *supra* note 9.

Medical mobile applications have the potential to radically transform medical practice by letting consumers obtain and analyze information without using doctors or healthcare providers. These medical applications' ability to collect data on a 24/7 basis also could transform the study of disease. Computers could analyze this data to find patterns that predict disease and determine effective treatments.

For instance, LIONsolver's experiment app diagnoses Parkinson's disease and predicts its progression by analyzing data collected from a mobile medical device.⁵² The LIONsolver program uses smart phones with an accelerometer, comparing small variations in movements of individuals with Parkinson's with those of healthy individuals.⁵³ Using machine learning, the program discovers "hidden and novel relationships" between differences in the way healthy people move compared to those suffering from Parkinson's.⁵⁴ Similar approaches could be applied to myriad diseases. Medical mobile applications, therefore, open the window to an entire new way of diagnosing and eventually treating disease.

III. THE FDA'S REGULATION OF DIGITAL MEDICINE

The FDA's assertion of jurisdiction over medical applications highlights the difficulty of applying the approval process for traditional medical devices to digital medicine. The FDA envisions the creation of a stent, artificial heart valve, or other fixed item that will remain the same for its entire product lifetime. The approval process can take over five months, on average, even to approve a device that is simply a newer version of an already approved device (a so-called 510(k) clearance)⁵⁵ and even for devices that pose little to no threat to human health.⁵⁶

⁵² See *Dr. Smartphone, What's My Diagnosis?*, *supra* note 18.

⁵³ Henschen, *supra* note 19.

⁵⁴ *Predicting Parkinson's Disease Progression with Smartphone Data*, KAGGLE (Mar. 27, 2013), <http://www.kaggle.com/c/predicting-parkinson-s-disease-progression-with-smartphone-data>.

⁵⁵ *How Long to Clear a 510(k) Submission?*, EMERGO GROUP, <http://www.emergogroup.com/resources/research/fda-510k-review-times-research> (last visited May 11, 2015).

⁵⁶ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-418, *MEDICAL DEVICES: FDA HAS MET MOST PERFORMANCE GOALS BUT DEVICE REVIEWS ARE TAKING LONGER 21-25* (2012), available at <http://www.gao.gov/assets/590/588969.pdf> (noting that the FDA met most of its goals for normal product submissions but not for expedited ones).

Applying this paradigm to computer software could chill innovation. The FDA could conceivably require approval for every new computer version or update, slowing development or even crushing it. Indeed, the FDA medical device approval regime—which assumes unitary versions of devices—seems completely inappropriate for the “version 2.0” world of computer applications, let alone the culture of consumer-created hacks. Technology markets often involve investors making high-risk investments and accepting high rates of failure in the hope of finding the super app, like Google or Facebook, that outperforms all others. Adding a thick layer of regulatory uncertainty may make medical application investment simply too risky and chill a potential realm of P2P consumer innovation.

Recent FDA performance indicates that its regulatory apparatus may not be up to the challenge. According to iMedicalApps, a leading online review of medical applications, as of July 2013, “the Google Play store list[ed] approximately 8,000 medical apps, while the iTunes store ha[d] almost 20,000 medical apps.”⁵⁷ On the other hand, according to MobiHealthNews, as of the end of 2013, the FDA listed more than 103 mobile medical apps in databases for approved Class I, Class II, and Class III devices.⁵⁸ The FDA’s regulatory burdens are not trivial—many argue they are threatening innovation in medical technology in the United States.⁵⁹

As mentioned above, the FDA’s power to regulate automated medicine stems from its authority to regulate medical devices under section 321(h) of the FDCA, a definition that dates from the original Federal Food, Drug, and Cosmetic Act of 1938⁶⁰ and which the 1976 Amendments changed slightly. The FDA has power to approve the

⁵⁷ Timothy Aungst, *Apple App Store Still Leads Android in Total Number of Medical Apps* (July 12, 2013), <http://www.imedicalapps.com/2013/07/apple-android-medical-app/>.

⁵⁸ See *103 FDA Regulated Mobile Medical Apps*, MOBIHEALTHNEWS (2013), <http://mobihealthnews.com/research/103-fda-regulated-mobile-medical-apps/>.

⁵⁹ See, e.g., Bonnie Scott, *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, 66 FOOD & DRUG L.J. 377, 378 (2011) (“Clogged by layers of procedural red tape, FDA denies millions of U.S. citizens quick access to beneficial medical devices, suppresses the development of new device technologies and forces manufacturers to travel abroad to develop their products. While FDA does not intend to stifle innovation or access, its premarket approval programs accomplish this end through their very existence.” (footnotes omitted)).

⁶⁰ See Federal Food, Drug, and Cosmetic Act of 1938, §§ 501, 502, 52 Stat. 1049–51 (codified as amended at 21 U.S.C. § 321(h) (2012)).

marketing of medical devices,⁶¹ classify devices into different classes,⁶² and place different safety and approval requirements on devices depending upon the class into which the FDA places them.

Beyond initial approval, there are numerous other requirements, such as registration,⁶³ reporting,⁶⁴ adulteration,⁶⁵ and branding⁶⁶ requirements imposed on manufacturers of medical devices. Finally, as a third major element of regulation, the FDA requires that medical devices must be efficaciousness.⁶⁷

A. THE FDA'S REGULATION OF MEDICAL DEVICES

Pursuant to the Medical Device Amendments of 1976,⁶⁸ as amended by the Safe Medical Devices Act of 1990 (the SMDA),⁶⁹ the FDA groups devices into three classes—Class I, Class II, and Class III.⁷⁰ Class I devices have the lowest risk and include surgeon's gloves,⁷¹ tongue depressors,⁷² eye pads,⁷³ certain types of syringes⁷⁴ and catheter equipment.⁷⁵ Class I devices are generally not relied upon to support or sustain human life.⁷⁶ The FDA mandates only that these devices comply with its "general controls,"⁷⁷ which include the prohibitions on adulteration⁷⁸ and misbranding,⁷⁹ registration requirements for device manufacturers,⁸⁰ premarket

⁶¹ 21 U.S.C. § 360e (2012).

⁶² *Id.* § 360bbb-2.

⁶³ *Id.* § 360.

⁶⁴ *Id.* § 360i.

⁶⁵ *Id.* § 351.

⁶⁶ *Id.* § 352.

⁶⁷ See 21 C.F.R. § 860.7 (2014) (listing factors that classification panels must consider in determining the safety and effectiveness of a device).

⁶⁸ Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in 21 U.S.C. § 360c (2012)).

⁶⁹ Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified as amended in 21 U.S.C. § 360c (2012)).

⁷⁰ 21 U.S.C. § 360c (2012).

⁷¹ 21 C.F.R. § 878.4460 (2014).

⁷² *Id.* § 880.6230.

⁷³ *Id.* § 878.4440.

⁷⁴ *Id.* § 880.6960.

⁷⁵ *Id.* § 880.5210.

⁷⁶ 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (2012).

⁷⁷ *Id.* § 360c(a)(1)(A).

⁷⁸ *Id.* § 351.

⁷⁹ *Id.* § 352.

⁸⁰ *Id.* § 360.

notification for new devices (§ 510(k)),⁸¹ requirements for notification to users of problems,⁸² and the duty to produce extensive adverse event reports.⁸³ Quality System (QS) regulations also place manufacturing requirements on Class I medical devices.⁸⁴

The § 510(k) notification process is one of the more burdensome obligations potentially applicable to Class I devices. It requires manufacturers to show that their device is as safe and effective—or to use the regulatory term, “substantially equivalent” (SE)—to a legally marketed device that has already been demonstrated to be safe and effective.⁸⁵ While the FDA exempts most Class I devices from these requirements, the FDA does require such Class I devices to receive § 510(k) notification clearance if the device meets certain criteria—i.e., it is “intended for a use which is of substantial importance in preventing impairment of human health, or [it] presents a potential unreasonable risk of illness or injury.”⁸⁶ As mentioned above, this process averages five months.⁸⁷

The FDA classifies devices with medium risk as Class II devices, and examples of such devices include pediatric hospital beds,⁸⁸ implantable staples,⁸⁹ dental cement,⁹⁰ teething rings,⁹¹ and electrocardiographs.⁹² Like Class I devices, Class II devices are subject to general controls.⁹³ Yet unlike Class I devices, Class II devices are rarely exempt from 510(k) premarket notification requirement.⁹⁴

While a finding of substantial equivalence does not typically require a manufacturer to conduct clinical testing, it does require that the proposed device have

⁸¹ *Id.* § 360(k).

⁸² *Id.* § 360h.

⁸³ *Id.* § 360i.

⁸⁴ See generally 21 C.F.R. § 820 (2014).

⁸⁵ 21 U.S.C. § 360(o)(1)(A) (2012).

⁸⁶ *Id.* § 360(l).

⁸⁷ See *supra* notes 55–56 and accompanying text.

⁸⁸ 21 C.F.R. § 880.5140 (2014).

⁸⁹ *Id.* § 878.4750.

⁹⁰ *Id.* § 872.3275.

⁹¹ *Id.* § 872.5550.

⁹² *Id.* § 870.2340.

⁹³ 21 U.S.C. § 360c(a)(1)(B) (2012).

⁹⁴ See *id.* (noting that to be eligible for Class II status, a device must have generated sufficient information to trigger § 510(k)).

“the same intended use as the predicate device[,] . . . the same technological characteristics as the predicate device . . . [and] not raise different questions of safety and efficacy than the predicate device.”⁹⁵

In addition to the general controls, Class II devices are subject to “special controls.”⁹⁶ The FDA can make up specialized requirements for each device, such as “performance standards, postmarket surveillance, patient registries,” special labeling requirements, and premarket data requirements.⁹⁷

Finally, Class III devices include devices that “support[] or sustain[] human life or [are] for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury.”⁹⁸ Examples include implantable pacemakers,⁹⁹ heart valves,¹⁰⁰ cerebellar stimulators,¹⁰¹ certain types of hip joint replacements,¹⁰² and female condoms.¹⁰³ Class III devices must receive approval through the premarket approval (PMA) process, in which manufacturers must provide “reasonable assurance” that their devices are safe and effective for their intended uses.¹⁰⁴ Clinical data must be provided, and often randomized control studies must be performed.¹⁰⁵ To perform these studies, manufacturers must receive initial approval to conduct them through the investigational device exemption (IDE) process.¹⁰⁶ The PMA

⁹⁵ Scott, *supra* note 59, at 381 (alteration in original) (footnote omitted) (quoting 21 U.S.C. § 360 (2006)) (citing Jeffrey Zigler, John Walsh & Jack Zigler, *Medical Device Reporting: Issues with Class III Medical Devices*, 62 FOOD DRUG COSM. L.J. 573, 573–74 (2007)).

⁹⁶ 21 U.S.C. § 360c(a)(1)(B) (2012).

⁹⁷ *Id.*

⁹⁸ *Id.* § 360(a)(1)(C).

⁹⁹ 21 C.F.R. § 870.3610 (2014).

¹⁰⁰ *Id.* § 870.3925.

¹⁰¹ *Id.* § 882.5820.

¹⁰² *Id.* § 888.3300.

¹⁰³ *Id.* § 884.5330.

¹⁰⁴ 21 U.S.C. § 360e(c)(2)(A)(xi) (2012).

¹⁰⁵ *Id.* § 360e(d)(6)(B).

¹⁰⁶ See 21 C.F.R. § 812.1 (2014) (outlining the process by which “a device that otherwise would be required to comply with a performance standard or to have premarket approval [may] be shipped lawfully for the purpose of conducting investigations of that device”).

process, given its potential for requiring controlled, clinical trials, can take many years.

B. THE FDA'S REGULATION OF DIGITAL MEDICINE

In the FDA Guidance for mobile medical applications, the FDA presents an outline of how it will regulate mobile medical applications, which suggests its framework for a more general regulation of digital medicine.¹⁰⁷ First, the FDA will regulate “[m]obile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.”¹⁰⁸ The FDA provides the following examples: “remote display of data from bedside monitors, display of previously stored EEG waveforms, and display of medical images directly from a Picture Archiving and Communication System (PACS) server, or similar display functions.”¹⁰⁹ These also include applications “that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform.”¹¹⁰

Second, the FDA will regulate “[m]obile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.”¹¹¹ Examples include

attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; or attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; a mobile app that uses the built-in accelerometer on a

¹⁰⁷ See FDA GUIDANCE, *supra* note 23, at 13 (addressing applications “that are medical devices [under the FDCA] and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended”).

¹⁰⁸ *Id.* at 14 (footnotes omitted).

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

mobile platform to collect motion information for monitoring sleep apnea; a mobile app that uses sensors (internal or external) on a mobile platform for creating [an] electronic stethoscope function . . . and similarly a mobile app that displays radiological images for diagnosis[, which] transforms the mobile platform into a class II Picture Archiving and Communications System (PACS) under 21 CFR 892.2050.¹¹²

This category of medical applications will no doubt include both what this Article terms invasive and non-invasive measurement applications.¹¹³ These would include heartbeat monitors, brain wave monitors, and the muscle monitor discussed in the Introduction, which is used to diagnose Parkinson's and predict its impact.

Third, the FDA will regulate “medical device (software) [that] perform[s] patient-specific analysis and provide[s] patient-specific diagnosis, or treatment recommendations.”¹¹⁴ Here, the FDA asserts authority over automated reference materials and prediction calculators—physician avatars discussed earlier. The FDA gives few examples: “apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software (CAD); image processing software; and radiation therapy treatment planning software.”¹¹⁵ In practice, this regulation will capture virtually the entire swath of information and diagnostic applications—i.e., all avatar physicians.

The FDA also gives examples of medical applications for which it was exercising regulatory forbearance. Note that these are medical applications that fall under the medical devices definition, but that the FDA will not regulate. These include “healthy living” medical applications that “provide or facilitate” care through reminding or prompting people to eat well, exercise, or follow pre-determined medication dosing.¹¹⁶

¹¹² *Id.* at 15.

¹¹³ See *supra* notes 46–54 for an overview of these two categories.

¹¹⁴ FDA GUIDANCE, *supra* note 23, at 15.

¹¹⁵ *Id.* (footnotes omitted).

¹¹⁶ *Id.* at 16.

The FDA will also exercise forbearance over medical applications that give people “simple tools . . . to organize and track health information *without providing recommendations to alter or change a previously prescribed treatment.*”¹¹⁷ These include applications that allow people to track their blood pressure or manage diabetes.¹¹⁸ The FDA will thus forbear from regulating mobile applications that provide information about certain conditions and those that help communicate with health care providers, such as “videoconferencing portals . . . for medical use.”¹¹⁹ The FDA will also forbear from regulating “[m]obile apps that perform simple calculations routinely used in clinic practice,” such as “Body Mass Index (BMI)[,] Total Body Water / Urea Volume of Distribution[,], [m]ean arterial pressure[,], Glasgow Coma Scale score[,], APGAR score[,], NIH Stroke Scale[, and] [d]elivery date estimator.”¹²⁰ Finally, the FDA will refrain from regulating “[m]obile apps that enable individuals to interact with” electronic record keeping.¹²¹

Last, the FDA provides examples of items it does not consider to be medical devices under 21 U.S.C. § 321(h). The FDA excludes “electronic ‘copies’ (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.”¹²² The FDA further excludes “educational tools” such as “[q]uestion/[a]nswer quiz apps; [i]nteractive anatomy diagrams or videos; [s]urgical training videos; [m]edical board certification or recertification preparation apps; [and] [g]ames that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.”¹²³ And, the FDA excludes “[m]obile apps that are generic aids or general purpose products. These apps are not considered devices because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”¹²⁴

¹¹⁷ *Id.* at 17 (emphasis added).

¹¹⁸ *See id.*

¹¹⁹ *Id.*

¹²⁰ *Id.* at 17–18.

¹²¹ *Id.* at 18.

¹²² *Id.* at 20.

¹²³ *Id.*

¹²⁴ *Id.* at 21–22.

It seems an intractable inconsistency that electronic books are *not* medical applications, but electronic books or programs that give individual patient diagnoses are. The FDA does not explain why a book form of a physician avatar is not a regulated device but an easier-to-use automated version of that book is a regulated physician avatar. Both e-books and the medical applications make recommendations; the only difference is the speed by which they provide them. Why should an individual be permitted to read a book and learn about its assertions concerning the relationship between symptoms and a disease, but not be permitted to use a computer program that does *precisely the same* thing? The following Part shows that once one accepts that books are not medical devices, then all automated medicine falls out of the FDA's jurisdiction. Because it does not put forth a coherent definition of medical devices that explains why physician avatars, but not e-books, are regulated, the FDA's interpretation of § 321(h) is not reasonable and violates the APA as the next section discusses.¹²⁵

IV. THE FDA'S INTERPRETATION OF § 321(H) VIOLATES THE APA

The previous Part described the burdens placed on an item the FDA classifies as a medical device. This key regulatory term is, of course, defined in the statute. The pertinent section of the FDCA, codified as 21 U.S.C. § 321(h), defines the term device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory” that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,” or is “intended to affect the structure or any function of the body of man or other animals.”¹²⁶

The definition is quite broad and, as one senator who voted for the original 1938 act commented, it can include virtually

¹²⁵ See Administrative Procedures Act, 5 U.S.C. § 706(2)(A) (2012) (requiring reviewing courts to invalidate arbitrary and capricious agency actions).

¹²⁶ 21 U.S.C. § 321(h) (2012).

anything.¹²⁷ Indeed, one searches in vain in the dozens of cases reviewing challenges to the FDA's classification of an item as a medical device for a court overturning the FDA's classification of an item as a device. As a general matter of administrative law, the *Chevron* doctrine requires courts to defer to an agency's reasonable interpretations of its statute.¹²⁸ In addition to this deference, the Supreme Court has stated that "the Food, Drug and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . ."¹²⁹

Courts might also increase deference for fear of limiting regulation of some potentially injurious item. The injuries from an unregulated device can be dramatic, and the connection between the judge and injuries are clearly drawn. No judge wants to be known as the person who stopped the FDA from saving sick children from some horrible fate. As one commenter has written, the "FDA has been highly successful in expanding its jurisdiction."¹³⁰ This success may stem from judges' "desire to 'prevent trouble before it starts,' rather than [from] any technical principles of [statutory] construction."¹³¹ On the other hand, the injuries from over-regulation of innovation, which prevent sick people from using new, highly beneficial devices, often remain invisible.

A. TEXTUAL ANALYSIS OF "MEDICAL DEVICE" UNDER § 321(H)

Regardless of the broad definition and broad implementation, medical device cannot refer to everything, or Congress would simply have said just that in § 321(h). A coherent statutory definition must have a limiting principle. As the canon of

¹²⁷ See *United States v. 25 Cases, More or Less, of an Article of Device*, 942 F.2d 1179, 1182 (7th Cir. 1991) ("One senator opined on the floor of the Senate that '[t]he language [of the bill] is broad enough to cover any device . . .'" (quoting 79 Cong. Rec. 4841 (1935))).

¹²⁸ See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) ("[C]onsiderable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer . . .").

¹²⁹ *United States v. An Article of Drug . . . Bacto-Unidesk . . .*, 394 U.S. 784, 793 (1969).

¹³⁰ Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 807-08 (1993).

¹³¹ Jay M. Zitter, *What Is "Device" Within Meaning of § 201(h) of Federal Food, Drug, and Cosmetic Act (21 USCS § 321(h))*, 129 A.L.R. FED. 343, 353 (1996).

statutory construction *expressio unius exclusio alterius* states, a statute's use of one word implies a legislative intent to *not* use another, even related, word.¹³² Logic, or in particular *reductio ad absurdum*, also requires a limit. The medical device definition—"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease"¹³³—could include, for example, medical office furniture, eyeglasses used by physicians, or air conditioning units marketed to hospitals. Lastly, the FDCA states explicitly that the FDA may not regulate the practice of medicine.¹³⁴ Thus, a device that constitutes the practice of medicine cannot be considered a medical device. As this Article will show, a physician avatar practices medicine, and may therefore stand beyond the FDA's regulation.

What limiting principle does § 321(h) imply? Courts have not been helpful. In the approximately forty-three opinions reviewed, none have explicitly rejected FDA jurisdiction over an item claimed to be a device.¹³⁵ The one case that questioned FDA

¹³² BLACK'S LAW DICTIONARY 661 (9th ed. 2009).

¹³³ 21 U.S.C. § 321(h) (2012).

¹³⁴ See *id.* § 396 (prohibiting the FDA from "interfere[ing] with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease").

¹³⁵ See *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 800 (1969) (subjecting an antibiotic sensitivity disk to FDA regulation even though it was a drug, not a device); *United States v. Bowen*, 172 F.3d 682, 686, 688 (9th Cir. 1999) (holding that a dental hand piece sterilizer and its accessory were devices subject to premarket approval); *Anguiano v. E.I. Du Pont de Nemours & Co.*, 44 F.3d 806, 811 (9th Cir. 1995) (holding polytetrafluoroethylene was an ingredient in the manufacture of Teflon-based temporomandibular joints and therefore was not subject to the Medical Device Amendments of 1976); *United States v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026, 1029 (10th Cir. 1994) (holding specimen collection containers were devices, but were not subject to premarket approval); *Alabama Tissue Ctr. of Univ. of Alabama Health Serv. Found., P.C. v. Sullivan*, 975 F.2d 373, 378 (7th Cir. 1992) (holding that a heart valve allograft was a medical device); *United States v. 25 Cases, More or Less, of an Article of Device*, 942 F.2d 1179, 1180, 1183 (7th Cir. 1991) (holding that a latex bag filled with silicone lubricant, which was intended to increase a woman's ability to feel abnormalities during breast self-examinations, was a device); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (holding that a manufacturer had no duty under Indiana law to issue warnings to certain users of a catheter even though it was a medical device under the FDCA); *United States v. An Article of Device . . . "Toftness Radiation Detector"*, 731 F.2d 1253, 1261-62 (7th Cir. 1984) (holding a chiropractic instrument was a misbranded device); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) (holding that a regulatory letter was not a final agency determination and therefore that the case at hand was not ripe for judicial review); *United States v. Dianovin Pharmaceuticals, Inc.*, 475 F.2d 100, 103 (1st

Cir. 1973) (holding that the court had jurisdiction to permanently enjoin a drug manufacturer's activities, which were violating the FDCA); *United States v. Articles of Device* * * * "KuF Diathera-Puncteur, etc. * * * Detecteur Niboyet GMG Schmidt D'Acupuncture," 481 F.2d 434, 437-38 (10th Cir. 1973) (holding that an acupuncture machine was a device, and its accompanying literature did not constitute adequate labeling); *Church of Scientology of California v. Richardson*, 437 F.2d 214, 217 (9th Cir. 1971) (holding that a court could consider a party's publications that discussed the applications of a device to determine whether the FDCA applied); *United States v. Ellis Research Labs., Inc.*, 300 F.2d 550, 555 (7th Cir. 1962) (upholding an injunction against shipping misbranded devices in interstate commerce); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (concluding that violation of the FDCA was negligence per se in Virginia); *Drown v. United States*, 198 F.2d 999, 1005 (9th Cir. 1952) (finding sufficient evidence to support a finding that a sale occurred in interstate commerce, which triggered the FDCA); *United States v. 23, More or Less, Articles*, 192 F.2d 308, 309 (2d Cir. 1951) (holding that a phonograph record that was intended for the alleviation of insomnia was a device); *United States v. 4 Devices, Labeled in Part "Color-Therm."*, 176 F.2d 652, 654 (10th Cir. 1949) (concluding that four devices were misbranded); *United States v. Ghadiali*, 165 F.2d 957, 958 (3d Cir. 1948) (holding that defendants introduced misbranded devices into interstate commerce in violation of the FDCA); *United States v. Olsen*, 161 F.2d 669, 670-71 (9th Cir. 1947) (holding that a Spectro-Chrome was a device that entered into interstate commerce, and thus was subject to the misbranding analysis); *United States v. One Device, Intended for Use as a Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947) (holding that a colonic irrigator was a misbranded device); *PREVOR v. FDA*, 895 F. Supp. 2d 90, 100-01 (D.D.C. 2012) (holding that a spray canister was not a drug and device combination product because the FDA failed to articulate proper reasoning); *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1393-97 (M.D.N.C. 1997) (holding that the FDA can regulate tobacco products under the FDCA), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 175-76 (4th Cir. 1998) (holding that tobacco products were not devices because while they affected a structure or function of the body, they were not intended for use or intended to affect the structure of any function of the body within the meaning of the FDCA), *aff'd*, 529 U.S. 120 (2000); *United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less, "The Ster-o-Lizer MD-200 * * *, . . . Halogenic Prods. Co."*, 941 F. Supp. 1086, 1095-96 (D. Utah 1996) (holding that a company and its principal agent in criminal contempt for continuing to market and introduce devices into interstate commerce without premarket approval), *aff'd sub nom. United States v. Themy-Kotronakis*, 140 F.3d 858 (10th Cir. 1998); *United States v. One Unlabeled Unit, More or Less, of an Article of Device & Promotional Brochures*, 885 F. Supp. 1025, 1028-29 (N.D. Ohio 1995) (holding that a bed was a device and that its seizure did not violate due process); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1285-86 (D. P.R. 1992) (holding that latex gloves were adulterated devices due to a failure to follow good manufacturing practices); *United States v. Various Articles of Device Identified in Attachment "A."*, 814 F. Supp. 31, 31 (E.D. Tenn. 1992) (recognizing that disinfecting products were devices); *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 665, 668 (D. Md. 1989) (holding that the FDCA and Medical Device Amendments did not preempt state tort actions); *United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less, * * * "The Ster-O-Lizer MD-200 * * *"*, 714 F. Supp. 1159, 1166 (D. Utah 1989) (holding that a sterilizer was a device despite the existence of an implicit exemption because the FDA's interpretation of the FDCA deserved deference where Congress had not previously acted); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1525-26 (E.D.N.Y. 1984) (holding that defendants were criminally liable for

jurisdiction only did so with respect to the classification of an implantable disk that delivered antibiotics as a device.¹³⁶

The definition of medical devices, as one congressman commented, can include virtually anything:

adulteration and misbranding where they sealed intraocular lenses into containers that were marked as sterile, but were actually contaminated); *United States v. Articles of Device* [Acuflex; Pro-Med], 426 F. Supp. 366, 371 (W.D. Pa. 1977) (holding that an acupuncture device was a misbranded device); *United States v. An Article or Device "Hubbard Electrometer,"* 333 F. Supp. 357, 365 (D.D.C. 1971) (holding that a device could be used for religious but not secular purposes as long as explicit warnings were present); *United States v. Relaxacizor, Inc.,* 340 F. Supp. 943, 947 (C.D. Cal. 1970) (holding that an electrical muscle stimulator was a misbranded device); *United States v. An Article of Device Consisting of Approximately 46 Devices, "Dynatone,"* 315 F. Supp. 588, 591 (D. Minn. 1970) (holding that facial exercisers were misbranded devices); *AMP Inc. v. Gardner,* 275 F. Supp. 410, 413-14 (S.D.N.Y. 1967) (holding that a hemostat and associated nylon ligature loop and nylon lock were drugs, not devices, because the essential element of the products was "a container for and method of applying a suture"); *United States v. An Article of Device Consisting of 4 Devices, More or Less, and Component Parts for 6 Additional Devices,* 261 F. Supp. 243, 246 (D. Neb. 1966) (holding that machines used in treatment of eye malfunctions and diseases were misbranded devices because they lacked sufficient labeling); *United States v. An Article or Device Consisting of 2 Devices, More or Less,* 255 F. Supp. 374, 382 (W.D. Ark. 1966) (holding FDA had no jurisdiction to regulate the use of ultrasounds as devices because the FDA could not regulate the practice of medicine in Arkansas), *rev'd sub nom.* *United States v. Shock,* 379 F.2d 29 (8th Cir. 1967); *United States v. 2000 Plastic Tubular Cases, More or Less, Each Containing 2 Toothbrushes,* 231 F. Supp. 236, 240 (M.D. Pa. 1964) (holding that a toothbrush was a misbranded device because its accompanying literature asserted a false claim); *United States v. One Device, More or Less, The Ellis Micro-Dynameter,* 224 F. Supp. 265, 268 (E.D. Pa. 1963) (concluding that a device was misbranded because it "was admittedly incapable of all uses claimed for it"); *United States v. An Article or Device Consisting of 31 Units,* 180 F. Supp. 52, 53 (E.D. Mich. 1959) (holding that a device could not be condemned under the FDCA because it had not entered interstate commerce); *United States v. 22 Devices, More or Less, Halox Therapeutic Generator,* 98 F. Supp. 914, 919 (S.D. Cal. 1951) (holding that a Halox Therapeutic Generator was a device and that it must therefore have adequate instructions for use); *United States v. One Article of Device Labeled Spectrochrome,* 66 F. Supp. 754, 757-58 (D. Or. 1946) (holding that the Fourth Amendment prevents the FDA from entering a person's home to seize and destroy a mechanical object that was not inherently dangerous), *rev'd sub nom.* *United States v. Olsen,* 161 F.2d 669 (9th Cir. 1947); *United States v. 6 Devices, "Electreat Mechanical Heart,"* 38 F. Supp. 236, 238 (W.D. Mo. 1941) (holding that the "Electreat Mechanical Heart" was a misbranded device); *Retkwa v. Orentreich,* 579 N.Y.S.2d 577, 581 (N.Y. Sup. Ct. 1991) (holding that importing industrial grade liquid silicone into the state, recompounding it, and using it to treat patients, with FDA approval, nevertheless violated the FDCA and was a sufficient basis for medical malpractice). See generally Zitter, *supra* note 131 (collecting a majority of the cases cited above).

¹³⁶ See *Bacto-Unidisk*, 394 U.S. at 799 (holding that an antibiotic sensitivity disc was a drug, not a device, but concluding that the drug was nevertheless subject to regulation under the FDCA).

The term “devices” itself is confusing. It is defined as any “instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to affect the structure of any function of the body of man or other animals.” That to me sounds very confusing. Is that simple language in the eyes of a bureaucrat?¹³⁷

In fact, examples of judicial approval of seemingly absurd extensions of the FDA’s authority abound. For instance, the Seventh Circuit upheld the FDA’s ruling that “the ‘Sensor Pad,’ consist[ing] of a flat, circular latex bag filled with a layer of silicone lubricant,” which was “intended to be placed over the breast during self-examinations to improve the woman’s ability to feel abnormalities beneath the skin”¹³⁸ constituted a “device.”¹³⁹ Similarly, courts have upheld the FDA’s claims of jurisdiction over urine and saliva specimen containers,¹⁴⁰ “a vinyl covered bed with audio speakers mounted on its side,”¹⁴¹ and even toothbrushes.¹⁴²

The FDA provides one clue as to where the limit lies: we know from the Guidance on Medical Mobile Applications that an “electronic book,” such as an electronic version of the Physician Desk Reference, is not a medical device,¹⁴³ even though it is arguably an apparatus or instrument. A book is an item intended for the diagnosis of disease; that is how doctors use it all the time. The FDA, however, has never stated what about books makes them *not* medical devices or announced a rule of law to justify this line-drawing; it simply gave particular examples. Without

¹³⁷ 122 CONG. REC. 5851 (1976) (statement of Rep. James Collins).

¹³⁸ *United States v. 25 Cases, More or Less, of an Article of Device*, 942 F.2d 1179, 1180 (7th Cir. 1991).

¹³⁹ *Id.* at 1180–83.

¹⁴⁰ *United States v. An Undetermined No. of Unlabeled Cases*, 21 F.3d 1026, 1029 (10th Cir. 1994).

¹⁴¹ *United States v. One Unlabeled Unit, More or Less, of an Article of Device & Promotional Brochures*, 885 F. Supp. 1025, 1027–28 (N.D. Ohio 1995).

¹⁴² *United States v. 2000 Plastic Tubular Cases, More or Less, Each Containing 2 Toothbrushes*, 231 F. Supp. 236, 238 (M.D. Pa. 1964).

¹⁴³ See FDA GUIDANCE, *supra* note 23, at 20.

forward-looking reasoned principles, this FDA's regulation "by example" seems arbitrary.

The FDA's inability, or unwillingness, to state the distinction points to a limiting principle to the meaning of "medical device." Books, unlike the terms in § 321(h),¹⁴⁴ have no direct physical effect. In contrast, medical devices of the sort Congress intended include birth control implements, heart stents, and monitors or tubes that directly measure the human body physically, or affect or touch the human body.

On the other hand, to affect the world, books require an individual guided by what he or she has learned in the book. The textual meaning of a phrase—which is an incorporeal thing—guides physical action. And like automated digital reference materials, prediction calculators and physician avatars answer questions, provide information, and lack any direct physical effect in the world. Like books, they are not medical devices under 21 U.S.C. § 321(h) and should not be classified as such.

A textual analysis of § 321(h) reinforces this conclusion. Certainly the phrase "instrument, apparatus, implement, machine, contrivance, implant, [and] in vitro reagent"¹⁴⁵ refers to things that have physical effects in the world. An instrument is defined as "a tool or device used for a particular purpose; *especially*: a tool or device designed to do careful and exact work."¹⁴⁶ A tool in turn is defined as "a handheld device that aids in accomplishing a task" or "something (as an instrument or apparatus) used in performing an operation or necessary in the practice of a vocation or profession."¹⁴⁷ An apparatus similarly is defined as "a tool or piece of equipment used for specific activities."¹⁴⁸ Finally, a device is defined as "an object, machine, or

¹⁴⁴ 21 U.S.C. § 321(h) (2012).

¹⁴⁵ *Id.*

¹⁴⁶ *Instrument*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/instrument> (last visited May 11, 2015).

¹⁴⁷ *Tool*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/tool> (last visited May 11, 2015).

¹⁴⁸ *Apparatus*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/apparatus> (last visited May 11, 2015).

piece of equipment that has been made for some special purpose.”¹⁴⁹

The definitions of these terms point to items that have physical effects in the world. Secondary definitions of these words can point to non-physical matters. For instance, one could speak of the “machinery of government” or the “apparatus of society.”¹⁵⁰ These usages are less common and metaphorical. No one believes that there is a physical government machine, and there is no indication that Congress intended such a use in § 321(h). Scholarly and technical writers concur in this conclusion. For instance, G.R. Higson writes “medical devices generally have only physical effects on the body.”¹⁵¹

Beyond dictionary definitions, accepted canons of statutory construction point to the conclusion that the term medical device refers to items with direct physical effects. Under *noscitur a sociis* (“it is known by its associates”),¹⁵² lists of words are read in relation to each other.¹⁵³ In other words, their shared meaning limits their reference. The Supreme Court and other courts routinely rely on *noscitur a sociis* to decide similar cases.¹⁵⁴

Here, all common and plain meanings of the terms taken together—instrument, apparatus, implement, machine, contrivance, implant, and in vitro reagent—refer to physical items with direct physical effects in the world. This common meaning connects these terms, reflecting congressional intention.

¹⁴⁹ *Device*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/device> (last visited May 11, 2015).

¹⁵⁰ *Apparatus*, *supra* note 148.

¹⁵¹ GORDON R. HIGSON, *MEDICAL DEVICE SAFETY: THE REGULATION OF MEDICAL DEVICES FOR PUBLIC HEALTH AND SAFETY* 4 (2001).

¹⁵² BLACK'S LAW DICTIONARY 1224 (10th ed. 2014).

¹⁵³ See *Babbitt v. Sweet Home Chapter of Cmty. for a Great Oregon*, 515 U.S. 687, 694 (1995) (“*Noscitur a sociis* . . . holds that a word is known by the company it keeps.”).

¹⁵⁴ See, e.g., *Maracich v. Spears*, 133 S. Ct. 2191, 2201 (2013) (concluding that the phrase “in connection with” litigation does not include solicitation of clients); *Freeman v. Quicken Loans, Inc.*, 132 S. Ct. 2034, 2042 (2012) (reasoning that the term “percentage” means a part of a whole because it was grouped with the words “portion” and “split”); *United States v. Williams*, 553 U.S. 285, 294–95 (2008) (finding the words “promotes” and “presents” to have a “transactional connotation” when grouped “in a list that includes ‘solicits,’ ‘distributes,’ and ‘advertises’”); see also *Env'tl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007) (“A given term in the same statute may take on distinct characters from association with distinct statutory objects calling for different implementation strategies.”).

Lastly, the catch-all term at the end of the definition, “or other similar or related article, including any component, part, or accessory,”¹⁵⁵ would refer to items with physical effect in the world based on the construction canon of *ejusdem generis*. Under this canon, terminal catch-all phrases are read in light of the preceding list.¹⁵⁶ Again, this is a canon upon which the Supreme Court often relies.¹⁵⁷

The difference between books and devices exists. While both can be “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man,”¹⁵⁸ books are not physical artifacts that directly affect the world; they provide information. Devices have a direct affect on the physical world. Similarly, digital medicine, which simply provides information, is not a device.

B. THE LEGISLATIVE HISTORY OF § 321(H)

The legislative history reinforces the interpretation of “devices” as articles with physical effects in the world that do more than simply provide information. Digital medicine did not exist either in 1938 when Congress passed the original FDCA or in 1976 when it passed the Medical Device Amendments. Congress, therefore, could never have contemplated regulating it.¹⁵⁹ At neither time did computers have sufficient power to give information or particularized diagnostic advice to patients.¹⁶⁰ Instead, it is

¹⁵⁵ 21 U.S.C. § 321(h) (2012).

¹⁵⁶ See BLACK'S LAW DICTIONARY 631 (9th ed. 2014).

¹⁵⁷ See, e.g., *Bullock v. BankChampaign, N.A.*, 133 S. Ct. 1754, 1760 (2013) (relying on this canon to interpret the statutory term “defalcation”); *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2160 (2012) (using the canon to interpret the phrase “other disposition”); *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (noting that the statute applies where “a general authorization and a more specific, limited authorization exist side-by-side”); *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2330 (2011) (refusing to “read a ‘catchall’ provision to impose general obligations that would include those specifically enumerated”); *Sossamon v. Texas*, 131 S. Ct. 1651, 1662 (2011) (employing the canon to construe a residual clause in a statute).

¹⁵⁸ 21 U.S.C. § 321(h)(2) (2012).

¹⁵⁹ See Kunio Doi, *Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential*, 31 *COMPUTERIZED MED. IMAGING & GRAPHICS* 198, 198 (2007) (stating that computer-aided diagnosis became the subject of “serious and systematic investigation” in the 1980s).

¹⁶⁰ See *id.* (noting that attempts in the 1960s to use “automated computer diagnosis” were unsuccessful).

obvious that what Congress had in mind in its definition of medical devices was items with physical effects in the world, not items that merely process or provide information.

The original 1906 Pure Food Act,¹⁶¹ a triumph of the Progressive Movement and one of the first major federal health regulatory regimes, failed to include in its regulatory mandate devices used to diagnose illnesses or affect the body's structure. The FDCA, in contrast, passed in 1938 had the following definition of medical device:

The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.¹⁶²

The legislative history of this section is quite interesting as it tracks almost identically the definition of "drug," which is as follows:

The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3) of this paragraph; but does not include devices or their components, parts, or accessories.¹⁶³

¹⁶¹ Pure Food Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified as amended at 21 U.S.C. §§ 301-399f (2012)).

¹⁶² Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(h), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321(h) (2012)).

¹⁶³ *Id.* § 201(g).

The legislative history shows that the need to set apart certain physical devices from the definition of "drug" compelled the separate definition. In original drafts of the FDCA, "drugs" were meant to include devices. But, as the Supreme Court later explained, congressmen balked at "the incongruous result of calling the following items 'drugs': shoulder braces, radium belts, electrical devices, bathroom weight scales, and hospital air conditioning apparatus. The opposition finally settled on 'crutches' to signify the ultimate absurdity of the drug definition's broad coverage."¹⁶⁴ Congress therefore created another term, "devices." Its definition simply replaced "articles" with "instruments, apparatus, and contrivances."¹⁶⁵

Congress intended, as far as the legislative history can show, that drugs and devices refer to physical items with direct physical effects upon the world. The Supreme Court has recognized that conclusion, as shown in *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, where the Court interpreted the FDCA's intent in the following manner:

the legislative history, read in light of the statute's remedial purpose, directs us to . . . confine the device exception as nearly as is possible to the types of items Congress suggested in the debates, such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches. . . . [T]he exception was created primarily for the purpose of avoiding the semantic incongruity of classifying as drugs (1) certain quack contraptions and (2) basic aids used in the routine operation of a hospital—items characterized more by their purely mechanical nature than by the fact that they are composed of complex chemical compounds or biological substances.¹⁶⁶

¹⁶⁴ *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 796 (1969) (footnotes omitted) (citations omitted).

¹⁶⁵ *Id.* at 799.

¹⁶⁶ *Id.* at 799–800.

Thus, as the Supreme Court recognized, medical devices are “items purely mechanical in nature,” and physician avatars do not qualify.

The 1976 Amendments did not disrupt the Supreme Court’s understanding of medical device as a physical item. Rather, responding to *Bacto-Unidisk*, Congress intended to amend the definition to clearly separate the concept of medical device from drug.¹⁶⁷ Under the original act, the FDA had much more authority to regulate drugs than devices. Courts complained about these confusing overlapping definitions, and Congress intended the changed definition to remedy the situation, as the following quotation from the legislative history indicates.

As noted earlier in this report, considerable legal controversy has ensued over the past decade as to which articles constitute medical devices subject to regulation under the Federal Food, Drug, and Cosmetic Act. Existing statutory definitions of “device” and “drug”, although legally mutually exclusive, are functionally overlapping and, thus confusing to the device industry, the general public and the courts.

Because of FDA’s current limited statutory authority over medical devices, the agency has attempted to regulate as “drugs” some articles commonly considered to be “devices” in order to subject them to more extensive regulation under the Act, including requirements for premarket testing. In most instances, the courts have upheld FDA’s attempts, although, as the Supreme Court has observed, “. . . it must be conceded that the language of the [Federal Food, Drug, and Cosmetic Act] is of little assistance in determining precisely what differentiates a ‘drug’ from a ‘device.’”

The Committee proposal amends the existing definition of “device” in section 201(h) of the Act to draw a clear distinction between a “device” and a “drug.”¹⁶⁸

¹⁶⁷ See H.R. REP. NO. 94-853, at 14 (1976) (noting that the Committee proposal would amend the existing definition to provide a “clear distinction”).

¹⁶⁸ *Id.* at 13–14 (quoting *Bacto-Unidisk*, 394 U.S. at 799).

Beyond this exchange, the legislative history makes clear that Congress did not intend in the 1976 Act to upset the original understanding in the 1938 Act: devices would refer to physical contrivances that directly physically affect the body like drugs, but through non-chemical means.¹⁶⁹ There is no evidence that Congress intended to expand the definition to information-providing items, i.e., prediction calculators or physician avatars. The Committee Report states:

The Committee recognizes that there is confusion at the present time about whether certain articles are to be treated as devices or drugs under the Food, Drug and Cosmetic Act. Therefore, the Committee reported bill has carefully defined "device" so as to specifically include implants, in vitro diagnostic products and other similar or related articles. In vitro diagnostic products include those products which are not ingested and which are used to assist in the diagnosis of disease or other conditions of the body.¹⁷⁰

In short, the 1976 amendments were intended to clarify and expand the FDA's jurisdiction over medical devices, not alter the understanding that devices were physical objects with direct physical effects in the world.

Finally, it was the controversy surrounding the Dalkon shield, a birth control device that injured many women, which prompted Congress to pass the 1976 Amendments.¹⁷¹ Congress intended to

¹⁶⁹ See *id.* at 14 (explaining that under the amended definition, a device does not achieve its purpose through chemical action within the body).

¹⁷⁰ S. REP. NO. 94-33, at 17 (1975), reprinted in 1976 U.S.C.C.A.N. 1070.

¹⁷¹ See Gary L. Wilson, *Listen to the FDA: The Medical Device Amendments Do Not Preempt Tort Law*, 19 HAMLINE L. REV. 409, 409 (1996) ("Defective medical devices have been injuring consumers for decades. Between 1960 and 1970, at least 10,000 consumers were injured by devices used to treat health conditions. In response to public outcry against this carnage, and in particular the injuries caused by the Dalkon Shield intrauterine device (IUD), Congress passed the Medical Device Amendments of 1996. . . ." (footnote omitted)); see also RONALD HAMOWY, GOVERNMENT AND PUBLIC HEALTH IN AMERICA 206 (2007) ("The Congress was finally impelled to action by the FDA's order that the Dalkon Shield, an interuterine device implicated in the deaths of several women, be recalled."); David B. Klein & Alexander Tabarok, *History of Federal Regulation: 1902-Present*, FDAREVIEW, <http://www.fdareview.org/history.shtml#twelfth> (last visited May 12, 2015) ("The FDA first tried to regulate these

expand the FDA's authority over medical devices in light of the catastrophic effects of the Dalkon shield.¹⁷² This historical impetus further reinforces the conclusion that Congress conceived of "medical devices" as physical objects with direct physical effects in the world, such as the Dalkon shield. Digital medicine was simply not on Congress's radar and was not an intended object of FDA regulation.

C. MEDICAL DEVICE MANUFACTURERS

The FDA's definition of "manufacturers" may have as important an impact on the development of medical applications as the FDA's classifications of medical devices. The FDA classifying an item as a medical device requires the item's manufacturer to jump through the hoops discussed above in Part III.A. However, device manufacturers also face additional requirements. These include, *inter alia*, requirements for proper branding,¹⁷³ making premises available for inspection and labeling,¹⁷⁴ recordkeeping,¹⁷⁵ and annual registration.¹⁷⁶ Much turns, therefore, on how the FDA defines a manufacturer.

But, it is not clear who or what "manufactures" a medical application under the relevant statute and regulations. This

new products by reclassifying them as drugs, but in the usual story it took a tragedy, this time over the faulty Dalkon Shield IUD, to generate [the Medical Device Amendments of 1976].").

¹⁷² See Wilson, *supra* note 171 ("The [Medical Device Amendments] brought medical devices under the provinces of the Food Drug and Cosmetic Act and, for the first time, regulation by the [FDA].").

¹⁷³ See 21 U.S.C. § 352 (2012) (prohibiting "misbranded drugs and devices"); 21 C.F.R. § 1.20 (2014) (establishing "General Laboratory Requirements," including the requirement of label information and disclosure of material facts).

¹⁷⁴ See 21 U.S.C. § 374 (establishing rules regarding inspections, including the right of agents to enter a premises); 21 C.F.R. §§ 1.20–24 (regulating proper labeling), 1.83–.99 (establishing regulations regarding imports and exports of devices).

¹⁷⁵ See 21 U.S.C. § 360i(a) ("Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness."); see also 21 C.F.R. pts. 803, 806 (2014) (setting specific requirements for "Medical Device Reporting").

¹⁷⁶ See 21 U.S.C. § 360(b)(2) ("During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments."); see also 21 C.F.R. pt. 807 (setting specific registration requirements).

difficulty stems from the wording of § 321(h), which defines a device as “intended for use in . . . diagnosis.”¹⁷⁷ End users of medical applications create, generate, and control the information that makes a computer useful for medical diagnosis. Before end users enter this data, the medical application could simply be a general application computer program, like a book.

In its *Guidance*, the FDA asserts that software becomes a “medical device” when it performs “patient-specific analysis”:

Mobile apps . . . become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved.

Examples of mobile apps that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device include: apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.¹⁷⁸

The FDA’s reliance on the addition of “patient-specific” information to render an automated medical reference or risk calculator a medical device creates a serious regulatory problem in defining a manufacturer of a medical application. Physician avatars could serve to answer questions in the abstract or answer questions about hypothetical symptoms—just like a book answers questions in the abstract or specific. Under the FDA’s definition, however, only when a consumer enters his or her data does the program “become” a medical device.¹⁷⁹ The end user, therefore, would become the manufacturer under the FDA’s definition.¹⁸⁰ In this respect, medical applications blur the line between producer

¹⁷⁷ 21 U.S.C. § 321(h)(2).

¹⁷⁸ FDA GUIDANCE, *supra* note 23, at 15 (emphasis omitted).

¹⁷⁹ *See, e.g.*, at 14–15 (describing how mobile platforms are transformed into regulated medical devices).

¹⁸⁰ *See id.* at 9 (reasoning that “any person or entity” that modifies a mobile medical app software system can be a manufacturer).

and consumer—a line that P2P file sharing crossed in copyright¹⁸¹ and 3D printing may cross in patent.

Despite this inconsistency, the FDA attempts to elucidate what constitutes a manufacture of a medical app, but its efforts simply underscore the intractable nature of this problem. The FDA states that a person who “[c]reates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components” may be a manufacturer.¹⁸²

Under this definition, anyone who hacks or builds upon an application using open source code could be a manufacturer subject to the myriad regulations mentioned above.¹⁸³ Given the fluid and collaborative nature of much computer programming, such a rule would stifle innovation.

Last, the FDA explicitly exempts applications created by “[l]icensed practitioners, including physicians, dentists, and optometrists, who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice.”¹⁸⁴ As discussed below, this exemption dovetails with the FDCA prohibition against the FDA regulating the practice of medicine.¹⁸⁵ This exemption means that a doctor can make an app and give it to his or her friends or anyone he or she declares part of his or her practice—but the reader (if he or she does not have an M.D.) may not. However, if an application *is* speech, then the FDA is engaging in impermissible discrimination under the First Amendment by favoring one type of speaker over another.¹⁸⁶ It is to these constitutional arguments that we now turn.

V. THE FIRST AMENDMENT LIMITS ON FDA REGULATION

There have been no First Amendment challenges to the FDA’s classification of computer programs or applications as medical

¹⁸¹ See, e.g., *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936–37 (2005) (holding that distributors of certain devices may be liable for the resulting copyright infringement of third parties).

¹⁸² FDA GUIDANCE, *supra* note 23, at 15.

¹⁸³ See *supra* notes 173–76 and accompanying text.

¹⁸⁴ FDA GUIDANCE, *supra* note 23, at 11.

¹⁸⁵ See *infra* note 246 and accompanying text.

¹⁸⁶ *Members of City Council of L.A. v. Taxpayers for Vincent*, 466 U.S. 789, 804 (1984) (“In the realm of private speech or expression, government regulation may not favor one speaker over another.”).

devices, although some experts have discussed the possibility in light of the recent 23andMe letter.¹⁸⁷ On the other hand, successful First Amendment challenges have been launched against state laws prohibiting the marketing of physician prescription information in the landmark *Sorrell* case.¹⁸⁸ There, the Supreme Court ruled that healthcare information is protected speech and restrictions on the dissemination of such information are subject to strict scrutiny.¹⁸⁹

Similarly, courts have rejected FDA efforts to limit speech concerning off-label usage of drugs.¹⁹⁰ Courts have struck down regulation of manufacturers' sponsorship of continuing medical education seminars,¹⁹¹ requirements on FDA-mandated labeling for cigarettes,¹⁹² prohibition on compounding pharmacies advertising,¹⁹³ and, most significantly, regulation of drug companies' promotion of off-label drug uses.¹⁹⁴ While these cases involve different aspects of the FDA's regulatory scheme, they do show that courts are far from loath to apply the First Amendment to FDA regulations.

Relying on the taxonomy set forth in the Introduction, this Part argues for a different First Amendment analysis for different types of digital medicine. First, the First Amendment prohibits the FDA from regulating pure information analysis such as automated medical reference, prediction calculators, or physician avatars in general.¹⁹⁵ These items are pure speech.¹⁹⁶ Pure information is

¹⁸⁷ See, e.g., Saurabh Jha, *The FDA and 23andMe Puts a Libertarian in a Dilemma*, KEVINMD (Jan. 25, 2014), <http://www.kevinmd.com/blog/2014/01/fda-23andMe-puts-libertarian-dilemma.html> (arguing that the outright ban on 23andMe's genetic testing is excessive); see also *supra* note 22 and accompanying text (summarizing commentary about the chilling effect of the FDA's action).

¹⁸⁸ *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

¹⁸⁹ *Id.* at 2672.

¹⁹⁰ Off-label uses are legal uses of drugs for purposes not approved by the FDA. *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012).

¹⁹¹ *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998), *judgment vacated on other grounds*, *Washington Legal Found. v. Henney*, 202 F.3d 331, 337 (D.C. Cir. 2000).

¹⁹² *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1222 (D.C. Cir. 2012), *overruled by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22–23 (D.C. Cir. 2014) (en banc).

¹⁹³ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 376–77 (2002).

¹⁹⁴ *Caronia*, 703 F.3d at 168–69.

¹⁹⁵ See discussion *infra* at Part V.A.1 (reasoning that such information analysis is protected speech).

communicative because the computer application expresses an opinion in reaction to users' input, and this input, in turn, can be communicated to large data pools usable for further analysis. Mobile applications are useful because they provide high value scientific speech, usable for both individual diagnosis and epidemiological research.

In *Sorrell*, the Supreme Court explicitly recognized the value of information about healthcare.¹⁹⁷ This information is also expressive; it says something about one's desire to seek medical treatment or control one's health in a new, different way outside of typical healthcare channels. In that vein, the speech is also political, especially in the age of the PACA.¹⁹⁸ Because the government spends almost one half of all healthcare dollars,¹⁹⁹ alternate ways of receiving medical information may be seen as political. Strict scrutiny applies, and renders the FDA's regulation unconstitutional.

Second, some pure information analysis devices—automated medical reference, prediction calculators, or physician avatar applications—rely on other medical devices, such as 23andMe.com.²⁰⁰ They use another medical device to collect information and then provide an informational output.

¹⁹⁶ See *infra* notes 213–15 and accompanying text (discussing the elements of speech that receive strict scrutiny).

¹⁹⁷ “A ‘consumer’s concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.’ That reality has great relevance in the fields of medicine and public health, where information can save lives.” *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011) (quoting *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977)) (internal citation omitted).

¹⁹⁸ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S.C.).

¹⁹⁹ See *supra* note 42 and accompanying text.

²⁰⁰ 23andMe's situation is a little complicated. It uses a sequencer, the Illumina HumanOmniExpress-24, which is not approved. Illumina has just received approval for a sequencer, the MiSeqDx platform, which has the same functions as the Illumina HumanOmniExpress-24. Thus, in theory, 23andMe could use an approved device, but currently it does not. See Jennifer K. Wagner, *What Does the FDA Approval of the MiSeqDx Platform Mean for DTC?*, GENOMICS LAW REPORT (Dec. 31, 2013), <http://www.genomicslawreport.com/index.php/2013/12/31/what-does-the-fda-approval-of-the-miseqdx-platform-mean-for-dtc/> (discussing whether 23andMe could avoid FDA scrutiny by switching to the MiSeqDx platform).

Third, there are non-invasive medical measurement devices. Examples might include Doctor Mole,²⁰¹ Spiro Smart,²⁰² Cell Scope,²⁰³ and uChek.²⁰⁴ They present a closer issue than the first two categories of digital medicine because they are, in fact, devices. Beyond simply providing information, they do something in the world; they transform light waves or sound waves or some other sensory data into binary code that computers can analyze.

These non-invasive measurement devices raise several issues. First, gathering the information is like taking a picture. The transformation is clearly expressive for all the reasons discussed above, and should receive full First Amendment protection. Second, communicating information about health symptoms is protected speech. The more difficult question is the intermediate step: whether computer codes' transformation of the photographic image (or sound wave or other sensory data) into binary code suitable for computer program analysis is protected.

This question raises an old question of whether the First Amendment protects computer code. Most courts have answered "yes," particularly if the code is more expressive in nature than functional.²⁰⁵ The constitutional standards for code are ambiguous but most courts agree that code with some expressive aspects should receive some degree of protection.²⁰⁶ This precedent, combined with growing recognition that information is protected, as in *Sorrell*,²⁰⁷ leads to the conclusion that the First Amendment protects the transformation of photographs, sound recordings, and

²⁰¹ See Cook, *supra* note 8 (explaining how the "Doctor Mole" smartphone app helps users identify signs of skin cancer).

²⁰² See Hickey, *supra* note 9 (highlighting a mobile app that allows users to monitor lung function with their smartphone).

²⁰³ See Megan McCrea, *The CellScope: Not Just for James Bond Any More*, HEALTHLINE NEWS, <http://www.healthline.com/health-news/cellscope-introduced-in-the-classroom-121712> (last visited May 11, 2015) (explaining an app that uses magnifying optical equipment to diagnose diseases).

²⁰⁴ See Wakefield, *supra* note 11 (discussing an app that uses a phone's camera to analyze urine and check for twenty-five different health issues).

²⁰⁵ See *e.g.*, *University City Studios, Inc. v. Corley*, 273 F.3d 429, 451 (2d Cir. 2001).

²⁰⁶ See *id.* at 450–51 (reasoning that the level of protection depends on part of the degree to which the speech is expressive).

²⁰⁷ *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011) ("This court has held that the creation and dissemination of information are speech within the meaning of the First Amendment.").

other sensory data into binary code readable by computer programs used in digital applications.

Finally, several other considerations put the FDA regulations in doubt. First, the entire regulatory regime constitutes prior restraint, which occurs when the government reviews speech before punishing it. This is highly disfavored under First Amendment law.²⁰⁸ Second, the regulations, which allow physicians to design their own applications without FDA approval, constitute speaker discrimination of the sort that courts have rejected in other First Amendment challenges to FDA actions.²⁰⁹

A. THE FIRST AMENDMENT AND PURE INFORMATION COMMUNICATION APPLICATIONS

As discussed above, physician avatars are devices that simply communicate informational outputs in response to inputs, such as the diagnostic apps Caracal Diagnosis,²¹⁰ Isabel,²¹¹ or iLiver.²¹² In addition, they also could include 23andMe, which uses an informational input from another FDA device.²¹³ These devices communicate consumers' symptoms to the application, which then churns out information, and often places the data in a database for later use.²¹⁴ To show that pure information communication applications should receive strict scrutiny, it must first be shown

²⁰⁸ See, e.g., *Org. for a Better Austin v. Keefe*, 402 U.S. 415, 419 (1971) ("Any prior restraint on expression comes to this Court with a 'heavy presumption' against its constitutional validity."); *Carroll v. President & Comm'rs of Princess Anne*, 393 U.S. 175, 181 (1968) (emphasizing the "heavy presumption" against the constitutionality of prior restraints on expression (quoting *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963))); see also *Near v. Minnesota*, 283 U.S. 697, 721–23 (1931) (holding unconstitutional a state abatement statute under which the government had prevented the publication of certain material by a newspaper).

²⁰⁹ See, e.g., *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012) (characterizing the prohibition as content-based because it distinguished between favored and disfavored speech).

²¹⁰ See *Dredge*, *supra* note 12 (explaining that this app "tak[es] in signs, symptoms and lab results, and suggest[s] what disease or condition may be at work").

²¹¹ See *Butterfield*, *supra* note 13 (discussing Isabel, which asks patients to identify symptoms, and then provides diagnostic suggestions).

²¹² See *iLIVER*, *supra* note 14 ("[iLiver] delivers instant medical information and clinical recommendations to medical experts . . . specifically related to liver disease.").

²¹³ See *How It Works*, *supra* note 15 (describing the company's use of the Illumina Human Omni Express-24 format chip in its DNA analysis service).

²¹⁴ See *supra* notes 18–19 and accompanying text (discussing, as an example, the benefits of one company's pooling of user data related to Parkinson's disease).

that they are speech. Information is only speech if it is communicative, which means that the speaker must intend to convey a message and that the audience will likely understand the message.²¹⁵ Second, it must be shown that the speech is protected because it involves core political, scientific, or other valued expression.²¹⁶ Third, the regulations must be content-based.²¹⁷ Under strict scrutiny, the FDA regulations fail.

1. *Pure Information Analysis Applications Are Speech.* Because they simply provide words in response to other words, physician avatars, automated medical references, and prediction calculators are protected speech; indeed, they are “pure speech” entitled to the highest protections.²¹⁸ Items that receive information about given medical conditions and then provide a suggested diagnosis or prognosis about the likelihood of future health pass the legal test for pure speech: they provide words in exchange for words. Because they are simply words and thus pure speech, they are “entitled to comprehensive protection under the First Amendment.”²¹⁹

The Supreme Court’s test for pure speech is straightforward.²²⁰ Supreme Court precedents “strongly imply that a court need only assess the expressiveness of conduct in the absence of ‘the spoken

²¹⁵ See *Texas v. Johnson*, 491 U.S. 397, 404 (1989).

²¹⁶ See, e.g., *Roth v. United States*, 354 U.S. 476, 483 (1957) (“[I]t is apparent that the unconditional phrasing of the First Amendment was not intended to protect every utterance.”).

²¹⁷ See, e.g., *United States v. Playboy Entm’t Grp., Inc.*, 529 U.S. 803, 813 (2000) (“Since [the statute] is a content-based speech restriction, it can stand only if it satisfies strict scrutiny. If a statute regulates speech based on its content, it must be narrowly tailored to promote a compelling Government interest.” (citation omitted)).

²¹⁸ See *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 505–06 (1969) (“‘[P]ure speech’ . . . is entitled to comprehensive protection under the First Amendment.”).

²¹⁹ *Id.* at 506; see also Jorge R. Roig, *Decoding First Amendment Coverage of Computer Source Code in the Age of YouTube, Facebook, and the Arab Spring*, 68 N.Y.U. ANN. SURV. AM. L. 319, 395 (2012) (arguing that the First Amendment should extend to computer source code because it is “sufficiently communicative . . . as either a kind of written word or as an activity that carried with it sufficient social conventions to convey messages understandable by others”).

²²⁰ See, e.g., *Virginia v. Hicks*, 539 U.S. 1113, 1124 (2003) (distinguishing pure speech, which involves the spoken or written word, from expressive conduct); see also BLACK’S LAW DICTIONARY 1529 (9th ed. 2009) (defining such speech as “[w]ords or conduct limited in form to what is necessary to convey an idea”).

or written word.’”²²¹ Automated medical reference services and prediction calculators are simply words and thus are pure speech because they communicate verbal responses to verbal inputs.

However, one could argue that “talking” to a medical application is not really protected speech because one does not communicate; there is only one speaker. For instance, some courts, reasoning that purposeless photography of public spaces without intention to communicate to others lacks communicative content, have concluded that such photography is not speech.²²² As one court put it: “[t]o achieve First Amendment protection, a plaintiff must show that he possessed: (1) a message to be communicated . . . and (2) an audience to receive that message, regardless of the medium in which the message is to be expressed.”²²³

This analysis does not apply to automated medicine. The Supreme Court ruled in *Brown v. Entertainment Merchants Ass’n* that video games are expressive.²²⁴ In that context, individuals only “communicate” with a program, yet the court found them expressive, analogizing videogames to literary or artistic works.²²⁵

²²¹ *Bernstein v. U.S. Dep’t of State*, 922 F. Supp. 1426, 1434 (N.D. Cal. 1996) (quoting *Texas v. Johnson*, 491 U.S. 397, 404 (1984)); see also Norman Andrew Crain, Commentary, *Bernstein, Karn, and Junger: Constitutional Challenges to Cryptographic Regulations*, 50 ALA. L. REV. 869, 886 (1999) (“The [Supreme] Court reasoned that even nonverbal conduct can be expressive when the intent to convey a particularized message is present, and it is likely that the message will be understood by those who view it.” (citing *Johnson*, 491 U.S. at 404, 417)).

²²² See *Porat v. Lincoln Towers Cmty. Ass’n*, No. 04 Civ. 3199(LAP), 2005 WL 646093, at *5 (S.D.N.Y. Mar. 21, 2005) (concluding that the photography at issue was not expressive since the plaintiff “effectively disclaim[ed] any communicative property of his photography as well as any intended audience by describing himself as a ‘photo hobbyist’”), *aff’d*, 464 F.3d 274 (2d Cir. 2006); see also *Texas v. Johnson*, 491 U.S. 397, 405 (1989) (“We have not automatically concluded, however, that any action taken with respect to our flag is expressive. Instead, in characterizing such action for First Amendment purposes, we have considered the context in which it occurred.”); *Carson v. Cnty. of Stanislaus*, No. 1:10-cv-02133-OWW-SMS, 2011 WL 1532533, *2 (E.D. Cal. Apr. 20, 2011) (“To the extent Plaintiff’s [First Amendment] claim is that his use of a camera was itself protected speech, the complaint is insufficient because it does not allege facts that give rise to an inference that Plaintiff had the intent to convey a particular message, or that his actions would be understood by the viewer to be communicative.”); *Larsen v. Fort Wayne Police Dep’t*, 825 F. Supp. 2d 965, 979–80 (N.D. Ind. 2010) (denying First Amendment protection to videography of a dance recital to be used for private archival purposes).

²²³ *Porat*, 2005 WL 646093, at *4 (citing *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 568 (1995)).

²²⁴ 131 S. Ct. 2729, 2733 (2011).

²²⁵ See *id.* (“Like the protected books, plays, and movies that preceded them, video games communicate ideas—and even social messages—through many familiar literary devices . . . and through features distinctive to the medium . . .”).

In the same way, the creator of a medical application is creating an expressive work.

Further, the creators of a medical application and the consumer are engaged in a communicative exchange. Unlike photography, which is taken solely for an individual's enjoyment,²²⁶ information in a medical application is exchanged with the creators of the program. Lastly, data, as with the Michael J. Fox Foundation's LIONSolver app,²²⁷ is collected into pools of data used for later analysis.

2. *Pure Communications as Used in Digital Medicine Is Protected Speech.* Of course not all speech receives First Amendment protection. As many have pointed out, much speech, such as threats, criminal solicitation and conspiracy, use of copyrighted material, or unauthorized practice of medicine or law, are clearly communicative and expressive speech but receive no protection.²²⁸ The question is whether discussion about medical conditions constitutes protected speech.

The best argument that automated medicine is *not* protected speech asserts that automated medicine constitutes unauthorized practice of medicine—which is, of course, illegal and not protected speech.²²⁹ Of course, the problem with that argument is that the FDCA prohibits the FDA from regulating the practice of medicine.²³⁰ Thus, the FDA cannot regulate medical devices in the context of the practice of medicine. The States have power to regulate digital medicine.

Digital medicine touches on important First Amendment issues, which the Supreme Court has defined as the “core” of messages informing the debate on “public issues”²³¹ and the “interchange of

²²⁶ See *Porat*, 2005 WL 646093, at *4 (characterizing photography as non-communicative when undertaken merely as a hobby).

²²⁷ See Henschen, *supra* note 19 (discussing the app's use of data pools to identify Parkinson's disease).

²²⁸ See, e.g., FREDERICK F. SCHAUER, *FREE SPEECH: A PHILOSOPHICAL ENQUIRY* 92 (1982) (noting that these categories are speech “in the ordinary sense, yet are not ‘speech under any conception of freedom of speech’”).

²²⁹ See, e.g., N.Y. EDUC. LAW § 6512 (McKinney 2015) (criminalizing the unauthorized practice of medicine).

²³⁰ 21 U.S.C. § 396 (2012).

²³¹ *McIntyre v. Ohio Elections Comm'n*, 514 U.S. 334, 346 (1995) (quoting *Buckley v. Valeo*, 424 U.S. 1, 14 (1976)).

ideas for the bringing about of political and social changes.”²³² Given the role of federal, state, and local government payment for medical services, which was more than \$2.9 trillion in 2013 alone,²³³ and will only increase under the PACA,²³⁴ alternate ways of rendering health care can bring about a profound public impact. Illustrating and even creating alternative ways to diagnose disease and manage health is therefore highly political and can adversely affect the great “social changes” the Supreme Court identified in *Roth*.²³⁵

More recently, the Supreme Court in *Sorrell* went even further. It found that even if the dissemination of health care information were equivalent to “a mere ‘commodity’ with no greater entitlement to First Amendment protection than ‘beef jerky’” it would still be protected against content based restrictions.²³⁶ The Court stated explicitly that information about healthcare deserved the highest protection, stating: “The First Amendment protects even dry information, devoid of advocacy, political relevance, or artistic expression’ Facts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs.”²³⁷

In *Sorrell*, the information involved prescribing practices of physicians—important information, but limited in its potential to transform medicine.²³⁸ Since digital medicine, as discussed above, offers new ways of understanding and diagnosing diseases and

²³² *Roth v. United States*, 354 U.S. 476, 484 (1957).

²³³ *National Health Expenditures 2013 Highlights*, CENTERS FOR MEDICARE AND MEDICAID SERVICES, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited May 11, 2015).

²³⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of the U.S.C.); see also Jessica Banthin & Sarah Masi, *CBO's Estimate of the Net Budgetary Impact of the Affordable Care Act's Health Insurance Coverage Provisions Has Not Changed Much over Time*, CONGRESSIONAL BUDGET OFFICE (May 14, 2013), <http://www.cbo.gov/publication/44176> (explaining that the statute's health insurance provisions will cost \$710 billion over a five-year period).

²³⁵ *Roth*, 354 U.S. at 484; see also *id.* (“All ideas having even the slightest redeeming social importance—unorthodox ideas, controversial ideas, even ideas hateful to the prevailing climate of opinion—have the full protection of the guaranties, unless excludable because they encroach upon the limited area of more important interests.”).

²³⁶ *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2666 (2011) (quoting *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 53 (1st Cir. 2008)).

²³⁷ *Id.* at 2666–67 (quoting 630 F.3d 263, 271–72 (2d Cir. 2010)).

²³⁸ *Id.* at 2659.

advancing epidemiology, the Supreme Court's reasoning applies with even greater force in this context.

Digital medicine is scientific speech—not simply information—and therefore enjoys a high, if not the highest, level of protection.²³⁹ It permits individuals to diagnose disease; allows for the creation of huge pools of data from which epidemiologists can gain new understandings of disease; and, as with the Michael J. Fox Foundation for Parkinson's Research, points to new ways of diagnosing and understanding disease.²⁴⁰

Finally, automated medicine is highly protected self-expression. It reflects a way of living in which individual consumers take charge of their healthcare and bodies. Indeed, its capacity to promote individual autonomy resonates with the Fourteenth Amendment's guarantees of individual liberty and autonomy.²⁴¹

3. *Under the Applicable Strict Scrutiny Test, the FDA Regulation Fails.* As discussed above, regulation in this context would receive the greatest First Amendment protection. And “[i]f a statute regulates speech based on its content, it must be narrowly tailored to promote a compelling Government interest. [Also,] [i]f a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative.”²⁴² In the context of the First Amendment, narrowly tailored means the regulation “targets and eliminates no more than the exact source of the ‘evil’ it seeks to remedy.”²⁴³

Here, there is no doubt that the regulation is content based as it singles out certain kinds of speech—those relating to diagnosis

²³⁹ See Christopher P. Guzelian, *Scientific Speech*, 93 IOWA L. REV. 881, 910–11 (2008) (arguing that objectively unverifiable scientific speech should be entitled to less First Amendment protection).

²⁴⁰ See *supra* notes 18–20 and accompanying text.

²⁴¹ The central cases for expressive behavior are *United States v. O'Brien*, 391 U.S. 367, 377 (1968) (“Whatever imprecision inheres in these terms, we think it clear that a government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.”), and *Spence v. Washington*, 418 U.S. 405, 410–11, 415 (1974) (extending First Amendment protection to the display of a United States flag with a peace symbol affixed to it).

²⁴² *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 813 (2000) (citation omitted).

²⁴³ *Frisby v. Schultz*, 487 U.S. 474, 485 (1988) (citing *City Council of Los Angeles v. Taxpayers for Vincent*, 466 U.S. 789, 808–10 (1984)).

and treatment of disease.²⁴⁴ Thus, to survive scrutiny, the FDA would have to point to a compelling interest that could only be furthered through its regulation; indeed, the government would likely have to show that its regulations would be the least restrictive way of achieving its goals. This is a very tall order, as courts rarely, if ever, uphold restrictions on speech under the strict scrutiny test.²⁴⁵ “To date, the only case in the campaign finance law context to uphold a restriction under strict scrutiny is *Austin*, which *Citizens United* reversed.”²⁴⁶

Naturally, protecting health is an important government interest, and courts have so recognized it in a variety of contexts.²⁴⁷ However, the interest in prohibiting “risk calculators” and automated reference materials is more attenuated. Assuming the applications are accurate, the interest in restricting avatar physicians is that people may make wrong decisions based on that information. But, self-diagnosis is not against the law—the government has no basis to restrict that. To the contrary, the Supreme Court has stated explicitly that the First Amendment does not exist to protect people from their own bad decisions.²⁴⁸ To the degree there is an interest in prohibiting the unauthorized practice of medicine, this is a matter, as discussed above, for States, not the FDA.²⁴⁹

Conceding some legitimate state interest in restricting avatar physicians, any interest in restriction must be balanced against

²⁴⁴ See *supra* Part III.B.

²⁴⁵ Kathleen Sullivan, *Post-Liberal Judging: The Roles of Categorization and Balancing*, 63 U. COLO. L. REV. 293, 296 (1992) (“If strict scrutiny is applied, the challenged law is never supposed to survive . . .”).

²⁴⁶ Matt A. Vega, *The First Amendment Lost in Translation: Preventing Foreign Influence in U.S. Elections After Citizens United v. FEC*, 44 LOY. L.A. L. REV. 951, 1011 (2011) (“[I]f a content-based restriction on speech involves core First Amendment rights, it must pass strict scrutiny, which means it will almost never be upheld.”)

²⁴⁷ See, e.g., Dayna B. Royal, *The Skinny on the Federal Menu-Labeling Law & Why it Should Survive a First Amendment Challenge*, 10 FIRST AMEND. L. REV. 140, 186 n.242 (2011) (collecting cases holding that the governmental interest in public health and safety is substantial). Among the cases that Royal cites for this proposition are *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 296 (2000); *Jaffee v. Redmond*, 518 U.S. 1, 11 (1996); *Florida Bar v. Went for it, Inc.*, 515 U.S. 618, 625 (1995); and *Friedman v. Rogers*, 440 U.S. 1, 15 (1979).

²⁴⁸ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 359 (2002) (noting the court’s rejection of the notion that a legislature may regulate because of “a fear that people would make a bad decision”).

²⁴⁹ See 21 U.S.C. § 396 (2012) (forbidding the FDA from interfering with the practice of medicine).

the greater access to medical information that medical applications provide in any strict scrutiny analysis. Consider apps like Dr. Mole that identify moles. According to one study that dermatologists conducted, the best three out of four programs tested were only 70% effective in identifying cancerous moles, compared to dermatologists who were roughly 90% effective.²⁵⁰ General practitioners, interestingly enough, are between 60% and 75% accurate in identifying cancerous moles.²⁵¹

So let us assume you have a suspicious-looking mole. Not everyone is going to run to a dermatologist. In fact, it is reasonable to assume that many more people would prefer an app than make an appointment with a dermatologist, sit for two hours in a waiting room, and endure the indignity of getting undressed in front of a dermatologist, his or her assistant, and a random assortment of medical students.

Assume 20% of people will go to the dermatologist; however, 50% will consider using an app.²⁵² Let us say 10% of all suspicious moles are cancerous, a higher than realistic number that makes the arithmetic easier.

Take two groups of 1,000 people each in which all the people have suspicious moles. One hundred (10%) will have cancer in each group. Group One has no access to apps, so 200 (20%) go to the dermatologist, with 20 of these people (10%), in fact, having cancer. Of these 200, 180 get properly diagnosed with 18 having

²⁵⁰ See Joel A. Wolf et al., *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, 149 J. AM. MED. ASSOC. DERM. 422, 422, 424 (2013), available at <http://archderm.jamanetwork.com/article.aspx?articleid=1557488> (stating that the performance of smartphone apps in the study was “highly variable” in terms of measuring melanoma risk); Christopher Weaver, *Apps Aim to Detect Skin Cancer*, WALL. ST. J. (Jan. 13, 2013, 4:54 PM), <http://www.wsj.com/articles/SB10001424127887323783704578245973988828066> (summarizing the Wolf study).

²⁵¹ See Tracy Wolff et al., *Screening for Skin Cancer: An Update of the Evidence for the U.S. Preventive Services Task Force*, in EVIDENCE SYNTHESSES 67 (2009) (surveying research and finding that most studies show average general practitioners’ ability to correctly identify malignant moles at under 70%); Weaver, *supra* note 250 (noting that apps generally “compare[] well with the detection skills of unspecialized family doctors”).

²⁵² This higher number is supported by the extent to which people will use the Internet to obtain healthcare. See Michelle Castillo, *More than One-Third of U.S. Adults Use Internet to Diagnose Medical Condition*, CBS NEWS (Jan. 15, 2013 11:54 AM), <http://www.cbsnews.com/news/more-than-one-third-of-us-adults-use-internet-to-diagnose-medical-condition> (“Thirty-five percent of U.S. adults have gone online to self-diagnose a medical condition that they or someone they knew had . . .”).

cancer. Assuming random distribution, 2 with cancer will be incorrectly diagnosed (“false negatives”) and 18 without cancer will be incorrectly diagnosed (“false positives”). Group Two only has access to apps. Five hundred people use the app, which is 70% accurate, so 350 are correctly diagnosed—or 35 of the 100 people with cancer detected. Of the 150 incorrectly diagnosed, 15 are false negative and have cancer. These 15 people, therefore, are lulled into false security.

In sum, the apps will catch 35 of the cancers, while the dermatologists catch 18. Comparing the two diagnostic modes, the apps result in nearly twice as many properly diagnosed. On the other hand, the apps provide 15 false negatives compared to the 2 false negatives from the dermatologists.

The app’s better catch rate comes at a price: a higher “false negative rate” of 15 compared to 2. But, if you deduct the false negatives from the correct “catches,” the apps still come out ahead. Further, the apps’ higher false negative rates could be mediated by strong warnings of the tests inconclusiveness—warnings physicians rarely give to the tests they administer.

Figure 1

Group 1 (Dermatologists)		Group 2 (Medical Applications)	
Total in Group	1000 people	1000 people	Total in Group
20% go to dermatologist	200 people	500 people	50% use an app
Accuracy	90%	70%	Accuracy
Results	180 proper diagnosis	350 proper diagnosis	Results
	20 improper diagnosis <ul style="list-style-type: none"> • 18 with no cancer (“false positives”) • 2 with cancer (“false negatives”) 	150 improper diagnosis <ul style="list-style-type: none"> • 135 with no cancer (“false positive”) • 15 with cancer (“false negatives”) 	
	800 do not know status	500 do not know status	

While this illustration is simplistic, it demonstrates that the FDA cannot say that banning medical applications—even those that perform less well than physicians—further public health. To the contrary, such bans may *harm* human health, provided that the test is not completely inaccurate.

At the very least, this calculation shows that digital medicine involves a tradeoff between a medical app's greater ability to diagnose and those people lulled into a false sense of security. Under strict scrutiny, the FDA's regulations do not advance the government's stated goal, improved health. It is reasonable to prefer a medical application's increased numbers of correct diagnoses, even considering its high number of false negatives.

Further, strict scrutiny of content-based speech typically requires the government to adopt the least restrictive regulatory alternative.²⁵³ If the concern is preventing medical apps from lulling people into false positives, there are certainly less restrictive ways to achieve that end. Most obviously, mandated disclosures would achieve this goal.

In any case, courts rarely, if ever, uphold a content-based restriction on speech that involves core First Amendment rights.²⁵⁴ Strict scrutiny in the context of FDA content-based regulations would therefore almost surely be fatal.

B. NON-INVASIVE MEASUREMENT MEDICAL APPLICATIONS

These applications present a different set of legal questions. Consider Dr. Mole, which takes a digital photograph of a mole, transforms the digital picture using some algorithm into various values, and then puts these values into another algorithm to make a prediction or diagnosis.²⁵⁵ The process starts with taking a photograph and then uses a computer algorithm to produce communicative speech: you have a certain risk of cancer (or you do not). The process may be broken into three steps: Dr. Mole takes a

²⁵³ See *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 816 (2000) ("When a plausible, less restrictive alternative is offered to a content-based speech restriction, it is the Government's obligation to prove that the alternative will be ineffective to achieve its goals.").

²⁵⁴ See *supra* notes 246–46 and accompanying text (explaining that such scrutiny is almost always fatal).

²⁵⁵ See *Doctor Mold Features*, DOCTOR MOLE SKIN CANCER APP, <http://www.doctormole.com> (last visited May 12, 2015).

digital photograph, applies the photo's information to an algorithm, and verbally communicates a conclusion about the mole. Each step implicates a different First Amendment analysis.

First, there is the question of the photograph (or digital sound recording). The taking of photographs for communicative or expressive purposes receives First Amendment protection and its regulation would receive strict scrutiny in most situations.²⁵⁶ Second, the transformation of the photograph by computer algorithm receives First Amendment protection, although likely less protection.²⁵⁷ Courts have not fully answered the question of whether computer code is protected although, as the following discussion shows, the weight of precedent supports at least some intermediate protection. And third, the verbal communication is entitled to full protection.

There is no doubt that a photographic image of a mole, or for that matter an audio recording or other reproduction of a heartbeat, like an ECG, qualifies as protected speech. As the Supreme Court has stated, “[a]s with pictures, films, paintings, drawings, and engravings, both oral utterance and the printed word have First Amendment protection until they collide with the long-settled position of this Court that obscenity is not protected by the Constitution.”²⁵⁸

There are cases that have concluded that photographs without political, artistic, or communicative purposes are not speech.²⁵⁹ Specifically, there are cases in which courts have upheld bans on

²⁵⁶ See *infra* notes 258–63 and accompanying text.

²⁵⁷ See, e.g., Lee Tien, *Publishing Software as a Speech Act*, 15 BERKELEY TECH. L.J. 629, 654–55 (2000) (reasoning that “software speech acts,” as opposed to “mundane software acts,” “are covered by the First Amendment”).

²⁵⁸ Kaplan v. California, 413 U.S. 115, 119–20 (1973); see also *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495, 502 (1952) (“[E]xpression by means of motion pictures is included within the free speech and free press guaranty of the First and Fourteenth Amendments.”).

²⁵⁹ See, e.g., *Porat v. Lincoln Towers Cmty. Ass’n*, No. 4 Civ. 3199 (LAP), 2005 WL 646093, at *4–5 (S.D.N.Y. Mar. 21, 2005), *aff’d*, 464 F.3d 274 (2d Cir. 2006) (rejecting a First Amendment claim on the basis that the plaintiff was acting as a “photo hobbyist,” instead of intending to communicate a message); see also *Texas v. Johnson*, 491 U.S. 397, 404 (1989) (explaining how courts should analyze the communicative elements of expressive conduct); *Carson v. Cnty. of Stanislaus*, No. 1:10-cv-02133-OWW-SMS, 2011 WL 1532533, at *1–3 (E.D. Cal. Apr. 20, 2011) (dismissing a First Amendment claim because an inference about a particularized message could not be drawn from a lawyer’s attempt to take a photograph of a district attorney investigator).

the taking of pictures on public property.²⁶⁰ However, in these cases, the photographer's only stated purpose was hobbyism.²⁶¹ There was no stated communicative or expressive purpose. Most recently, this issue has emerged in citizens taking photographs and recordings of police officers. Courts have found this activity protected.²⁶²

Applying this precedent to our situation, photographs or other recordings that medical applications produce are likely protected. They have a clear communicative purpose since they relate information to a computer program and, very possibly, as with 23andMe, contribute to a larger pool of information usable to research scientists. These medical app photographs are expressive—and for all the reasons discussed above—expressive about scientific and political matters.

Just as the first step of the Dr. Mole process is protected, so is the last. Communicating information about health conditions is protected for all the reasons discussed previously in Part V.C. Verbal communications almost always receive the highest protections.²⁶³

The toughest question is whether, or to what degree, the First Amendment protects the second step: the code's transformation of the photograph or recorded sound into a diagnosis or other medical device. Courts have not definitively determined the question of whether, and to what degree, code receives First Amendment protection.²⁶⁴ But, as the following analysis suggests, precedent grants more protection to code to the extent that it is expressive.

²⁶⁰ See, e.g., *Larsen v. Fort Wayne Police Dep't*, 825 F. Supp. 2d 965, 979–80 (N.D. Ind. 2010) (finding that a father's attempt to video record his daughter's choir concert does not communicate an idea for First Amendment purposes). Cf. *Gilles v. Davis*, 427 F.3d 197, 212 n.14 (3d Cir. 2005) (reasoning that "videotaping or photographing" certain events, such as "the police in the performance of their duties on public property may be a protected activity").

²⁶¹ See *Porat*, 2005 WL 646093, at *5 (characterizing the plaintiff as a "photo hobbyist" with regard to his taking of pictures in front of a building).

²⁶² See *Am. Civil Liberties Union of Illinois v. Alvarez*, 679 F.3d 583, 595–98 (7th Cir. 2012), cert. denied, 133 S. Ct. 651 (2012).

²⁶³ See *supra* Part V.A.1 (discussing the high protection traditionally afforded to "pure speech").

²⁶⁴ See, e.g., *Junger v. Daley*, 209 F.3d 481, 484–85 (6th Cir. 2000) (explaining that "[t]he issue of whether or not the First Amendment protects encryption is a difficult one" and holding that computer source code is protected because it "is an expressive means for the exchange of information and ideas").

The code in digital medicine is expressive and therefore likely to receive full protection with strict scrutiny, and certainly at least intermediate scrutiny.

Medical applications are both expressive and functional and, therefore, the First Amendment applies, but in uneven ways. They are purely expressive when they analyze information.²⁶⁵ They are functional when they take measurements in the world—whether color strips from uChek or pictures of skin as does Dr. Mole—and convert them into information. The former is purely expressive and entitled to full protection. In pure informational analysis, medical applications have a pure communicative function and, therefore, are entitled to full protection.

The recent Supreme Court case *Brown v. Entertainment Merchants Ass'n*, ruled that California's laws concerning the distribution of violent video games violated the First Amendment.²⁶⁶ To arrive at that conclusion, the Supreme Court had to rule that a video game, i.e., a collection of code, constitutes protected speech. And it did. In an important passage, the Court states:

California correctly acknowledges that video games qualify for First Amendment protection. The Free Speech Clause exists principally to protect discourse on public matters, but we have long recognized that it is difficult to distinguish politics from entertainment, and dangerous to try Like the protected books, plays, and movies that preceded them, video games communicate ideas—and even social messages—through many familiar literary devices (such as characters, dialogue, plot, and music) and through features distinctive to the medium (such as the player's interaction with the virtual world). That suffices to confer First Amendment protection And whatever the challenges of

²⁶⁵ See *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 452–58 (2d Cir. 2001) (analyzing speech (expressive) and nonspeech (functional) elements of computer decryption code).

²⁶⁶ See 131 S. Ct. 2729, 2742 (2011) (holding that the California legislation could not survive strict scrutiny); see also *Junger*, 209 F.3d at 484–85 (holding that “source code has both an expressive feature and a functional feature” and should receive First Amendment protection).

applying the Constitution to ever-advancing technology, “the basic principles of freedom of speech and the press, like the First Amendment’s command, do not vary” when a new and different medium for communication appears.²⁶⁷

Digital medicine is speech as is a video game. It is expressive for reasons discussed above. Indeed, as its expression touches on vital political and scientific questions, automated medicine is arguably closer to the “discourse of public matters” mentioned by the Court in *Brown* than is entertainment. Therefore, it should be entitled to greater protection.

Brown may not settle the matter. There, the question was whether the First Amendment allowed the government to regulate the violent *content* of computer games.²⁶⁸ Here, the question is whether government can regulate a function on which automated medicine relies: translating sound or light waves used in measuring the human body into data. While *Brown* may therefore be highly dispositive, other cases from lower courts also shed light.

For almost two decades, lower courts have struggled with defining when code should receive protection. Some courts maintain that when code is purely functional, meaning it just does a job rather than express an idea, it should receive no First Amendment protection.²⁶⁹ Thus, some courts have found code non-expressive, despite differing precedent.²⁷⁰ In *Universal City Studios, Inc. v. Corley*, the Second Circuit held that DVD decryption software, a program that allows users to make illegal copies of DVDs, was speech entitled to protection but could be regulated

²⁶⁷ *Brown*, 131 S. Ct. at 2733 (quoting *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495, 503 (1952)).

²⁶⁸ *Id.* at 2732.

²⁶⁹ See *Universal City Studios, Inc. v. Reimerdes*, 82 F. Supp. 2d 211, 222 (S.D.N.Y. 2000) (extending a lower level of protection to the code at issue because its “expressive aspect appears to be minimal when compared to its functional component”); Roig, *supra* note 219, at 323 n.9 (collecting federal court cases grappling with the extent of protection the First Amendment provides for computer source code).

²⁷⁰ Compare *Junger*, 209 F.3d at 485 (concluding that “computer source code is an expressive means for the exchange of information”), and *Universal Studios, Inc. v. Reimerdes*, 111 F. Supp. 2d 294, 327 (S.D.N.Y. 2000) (reasoning that computer code “is a means of expressing ideas”), *aff’d sub nom.*, *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 449 (2d Cir. 2001), with *Reimerdes*, 82 F. Supp. 2d at 222 (balancing the expressive nature of the computer code at issue against its functional elements).

pursuant to intermediate scrutiny.²⁷¹ The court ruled that the decryption program, used to circumvent DVD protections against unauthorized copying, “can instantly cause a computer to accomplish tasks and instantly render the results of those tasks available throughout the world via the Internet.”²⁷² “These realities of what code is and what its normal functions are require a First Amendment analysis that treats code as combining nonspeech and speech elements, *i.e.*, functional and expressive elements.”²⁷³

The *Universal City Studios* case reflects the majority rule that encryption software is speech, entitled to at least intermediate scrutiny.²⁷⁴ For instance, in *Bernstein v. United States Department of Justice*, the Ninth Circuit concluded that the computer source code at issue, again used for encryption, should receive First Amendment protection because computer programmers and cryptographers use it as “the preferred means” of communication.²⁷⁵ Similarly, in *Universal City Studios, Inc. v. Reimerdes*, the Southern District of New York ruled that “[c]omputer code is expressive” and thus “a matter of First Amendment concern” in that respect, but “not purely expressive.”²⁷⁶ Like *Bernstein*, the *Universal City Studios* court found intermediate scrutiny appropriate.²⁷⁷

One case deserves special attention. *Commodity Futures Trading Commission v. Vartuli*²⁷⁸ raised the question of whether a computer program offering advice is protected under the First Amendment. The case involves a firm, AVCO Financial Corp. and its principals, who marketed software called “Recurrence” and fraudulently claimed that it provided profitable trading strategies for currency futures.²⁷⁹ The program gave its users precise

²⁷¹ 273 F.3d at 449–51.

²⁷² *Id.* at 451.

²⁷³ *Id.* (citing *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 386 (1969)); *see also Junger*, 209 F.3d at 484–85 (holding that “source code has both an expressive feature and a functional feature” but is nonetheless entitled to First Amendment protection).

²⁷⁴ The scholarly consensus also views computer code as protected. *See Tien, supra* note 257, at 681 (stating that under most instances code should be treated as speech for First Amendment purposes); *see also Robert Post, Encryption Source Code and the First Amendment*, 15 BERKELEY TECH. L.J. 713, 719–20 (2000) (agreeing that code is part of public dialogue).

²⁷⁵ 176 F.3d 1132, 1141 (9th Cir. 1999), *reh’g granted, opinion withdrawn*, 192 F.3d 1308.

²⁷⁶ 111 F. Supp. 2d 294, 304 (S.D.N.Y. 2000).

²⁷⁷ *Id.* at 329.

²⁷⁸ 228 F.3d 94 (2d Cir. 2000).

²⁷⁹ *Id.* at 98–100.

commands for when to buy and sell futures.²⁸⁰ AVCO argued that its program was protected speech under the First Amendment.²⁸¹

The Second Circuit rejected the claim that the computer program was speech.²⁸² It reasoned that AVCO marketed the program in the following way:

“The system [was] automatic,” with “NO complicated rules to follow. NO calculations to make. NO fundamentals to analyze. And NOTHING to interpret.” Users were told they must “follow the signals with no second-guessing.” When Recurrence displayed a “sell” signal, the customer was supposed to sell; when it flashed “buy” the customer was supposed to buy The customer or “client” was to be an automaton, mechanically following Recurrence’s commands.²⁸³

Because the AVCO system simply involved the issuance of commands, the court concluded that AVCO was not speech.²⁸⁴ Rather, because the “language at issue . . . was to be used in an entirely mechanical way,” the court found that the program could not “convey information or . . . assert values.”²⁸⁵ Because AVCO simply

induce[d] action without the intercession of the mind or the will of the recipient[,] [it implicated] [n]one of the reasons for which speech is thought to require protection above and beyond that accorded to non-speech behavior—the pursuit of truth, the accommodation among interests, the achievement of social stability, the exposure and deterrence of abuses

²⁸⁰ *Id.* at 111.

²⁸¹ *Id.* at 109.

²⁸² *See id.* at 111 (holding that the program operated “without engaging in constitutionality protected speech”).

²⁸³ *Id.*

²⁸⁴ *See id.*

²⁸⁵ *Id.* (quoting Kent Greenawalt, *Speech and Crime*, 4 AM. B. FOUND. RES. J. 645, 680 (1980)).

of authority, personal autonomy and personality development, or the functioning of a democracy²⁸⁶

The *Vartuli* precedent does not control digital medicine because medical applications do simply provide commands in a non-interactive way. They are meant to complement the user's "mind" and "will" and, in fact, engage an individual in an open manner. The thoughtless (and apparently fraudulent) commands in the trading program from the *Vartuli* case simply lacks the same First Amendment significance. Medical applications are not mindless commands; rather, they analyze symptoms, sift through information, and often provide sophisticated, nuanced advice.

Further, unlike futures trading, which is very private and limited in its impact, medical applications and digital medicine implicate First Amendment values in myriad ways as discussed above in Part V.A. Their capacity to collect and analyze information—and allow individuals to take control of their health and lives—has profound implications for our government as well as personal autonomy.

In conclusion, there is an argument that the computer code translation of a body reading, which is either a visual image or a sound recording, into code or information does not constitute speech alone but may also have a large functional input. However, encryption has a non-communicative function—it makes information hard to get. It is like using a lock on a diary or locking a filing cabinet. By contrast, translation of information about the world, such as a heartbeat or a mole, into information readable by a medical application seems essentially expressive. It is an ineluctable step in using computers to engage information about the world—not simply in digital medicine—but in every aspect of life today.

C. INTERMEDIATE SCRUTINY AND DIGITAL MEDICINE

Courts have ruled that computer code has essential functional aspects as discussed above. They have also ruled that regulation of codes' non-expressive aspect can be considered content-neutral

²⁸⁶ *Id.*

regulation.²⁸⁷ Either analysis leads to examining the regulation using at least intermediate scrutiny.

Under that standard, the FDA must show that the challenged provisions advance “an important or substantial government interest unrelated to the suppression of free expression, and [that] the incidental restrictions on First Amendment freedoms are no greater than essential to the furtherance of that interest.”²⁸⁸ The government must “demonstrate that the recited harms are real, not merely conjectural, and that the regulation will in fact alleviate these harms in a direct and material way.”²⁸⁹ “[C]ourts must accord substantial deference to the predictive judgments of Congress,” since “[a]s an institution . . . Congress is far better equipped than the judiciary to ‘amass and evaluate the vast amounts of data’ bearing upon an issue as complex and dynamic as that presented [in many cases.]”²⁹⁰

Under intermediate scrutiny, it is unclear how regulating pure information processing items or items that process information from approved devices furthers any governmental interest. The purpose of the 1976 Medical Device Amendments is to ensure safe devices. That is evident from the legislative history.²⁹¹ As discussed above, courts also have recognized safety as the goal of the 1976 Amendments.²⁹² However, neither pure information

²⁸⁷ See, e.g., *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 454 (2d Cir. 2001) (finding injunction prohibiting the posting of decryption software on a website to be content-neutral, and therefore subject to intermediate scrutiny); *321 Studios v. Metro Goldwyn Mayer Studios*, 307 F. Supp. 2d 1085, 1100–01 (N.D. Cal. 2004) (concluding that intermediate scrutiny is the appropriate standard in reviewing a regulation that suppresses speech “only because of the way in which th[e] code, when executed, operates”); *United States v. Elcom Ltd.*, 203 F. Supp. 2d 1111, 1128–29 (N.D. Cal. 2002) (applying intermediate scrutiny because the statute regulates “what the code does,” not “what the code says”).

²⁸⁸ *Elcom*, 203 F. Supp. 2d at 1129.

²⁸⁹ *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 664 (1994).

²⁹⁰ *Id.* at 665–66 (quoting *Walters v. Nat’l Ass’n of Radiation Survivors*, 473 U.S. 305, 331 n.12 (1985)).

²⁹¹ See S. REP. NO. 94-33, at 17 (1975), reprinted in 1976 U.S.C.C.A.N. 1070 (expressing concern about the safety of medical devices).

²⁹² See, e.g., *Gen. Med. Co. v. FDA*, 770 F.2d 214, 218 (D.C. Cir. 1985) (“We uphold as a permissible statutory interpretation the FDA’s position that the Amendments allow it to require a showing of safety and effectiveness before conceding that the particular device at issue here does not present a potential unreasonable risk of illness or injury.”); *Contact Lens Mfrs. Ass’n v. FDA*, 766 F.2d 592, 594 (D.C. Cir. 1985) (“Congress’ new prescription for the FDA divided the world of medical devices into three classes, according to the degree of

processors nor information processors that use outputs from approved devices can directly cause an injury. Like a book or other reference, they require the intercession of a doctor administering drugs or other treatment in order to cause any harm in the real world.

Of course, the government might claim that its interest is to protect individuals from incorrect information that, in turn, causes individuals to make poor medical decision that cause harm. But, beyond the prohibition of unauthorized practice of medicine, there is no government interest in protecting people against bad suggestions about their health.²⁹³ If there were, then the government could probably shut down most health sections in magazines as well as censor a large portion of normal conversation, which tends to center around the discussion of health, especially as we age. As the Court stated in *Sorrell*,

[t]hose who seek to censor or burden free expression often assert that disfavored speech has adverse effects. But the “fear that people would make bad decisions if given truthful information” cannot justify content-based burdens on speech. “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”²⁹⁴

The government might also claim that it is trying to protect individuals against self-diagnosis. But again, this is not a crime; indeed, it is arguably a right.²⁹⁵ Therefore, it is not a legitimate government goal.²⁹⁶

regulation thought necessary to provide reasonable assurance of each device’s ‘safety and effectiveness.’ ”).

²⁹³ See, e.g., *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2670–71 (2011) (reasoning that the Free Speech guarantee does not only protect what many might view as good advice).

²⁹⁴ *Id.* (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (plurality opinion)).

²⁹⁵ See Jacqueline A. Greff, *Regulation of Cosmetics that Are Also Drugs*, 51 *FOOD & DRUG L.J.* 243, 247 (1996) (“Consumers who use OTC drugs generally have the ability to accurately diagnose and safely treat the condition at issue themselves.”).

²⁹⁶ See *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 66–67 (1983); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980).

Even if there were some legitimate governmental interest in protecting people from bad information outside of the unauthorized practice of medicine, the interest would be limited to some baseline review of effectiveness. Intermediate scrutiny requires restrictions “no greater than is essential to the furtherance of” valid governmental interests.²⁹⁷ As the discussion above indicates, this is a high burden for the government. Because they create much greater access, the medical applications will improve health outcomes—even given less accuracy than medical doctors.²⁹⁸

D. FINAL FIRST AMENDMENT THOUGHTS: SPEAKER DISCRIMINATION AND PRIOR RESTRAINT

The FDA’s regulatory scheme faces additional First Amendment hurdles. First, the Supreme Court has made clear, particularly in the context of health care information, that a state may not discriminate among speakers by engaging in speaker discrimination.²⁹⁹ In *Sorrell*, the Supreme Court rejected a Vermont law that treated drug “detailers . . . who promote brand-name drugs” differently from other speakers, finding the treatment unconstitutional as it “‘goes even beyond mere content discrimination, to actual speaker discrimination.’”³⁰⁰

Other courts, building on *Sorrell*, have ruled unconstitutional FDA regulations that impose discriminatory speech burdens. For instance, courts have overturned the FDA’s restriction on truthful marketing of off-label drug use by drug marketers.³⁰¹ Key to these courts’ reasoning has been that physicians may engage in same speech that drug companies and their marketers may not.³⁰²

²⁹⁷ *United States v. O’Brien*, 391 U.S. 367, 377 (1968).

²⁹⁸ *See supra* Part V.A.3.

²⁹⁹ *See, e.g., Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2663 (2011) (condemning a regulation imposing “speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information”).

³⁰⁰ *Id.* (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 391 (1992)).

³⁰¹ *See United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012).

³⁰² *See id.* at 153 (observing that the “FDA generally does not regulate how physicians use approved drugs”).

Courts have found this discriminatory treatment unsupportable under the First Amendment.³⁰³

The FDA's regulation suffers from similar speaker discrimination, as it exempts physician-made medical applications from regulation. Specifically, the FDA explicitly exempts applications created by "[l]icensed practitioners, including physicians, dentists, and optometrists, who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice."³⁰⁴ Just as with speech concerning off-label drug usage, the FDA's special treatment of physicians cannot be supported under the First Amendment. Anyone can utter truthful speech, even in the healthcare context, as *Sorrell* makes clear.

Lastly, the FDA's regulatory regime, which often requires premarket notification under § 512, constitutes prior restraint. Medical applications and other digital programs are speech. Yet before one distributes a medical application, one must first receive approval from the FDA or obtain confirmation that approval is not required, which given the vagueness of the regulations also presents concerns.

Courts have ruled that prior restraints using mandatory *ex ante* approval or licensing of speech receive special scrutiny under the First Amendment.³⁰⁵ Indeed, scholars have long recognized that prior restraint, due to its potential to silence speech even before it enters the public domain, constitutes a chief evil against which the First Amendment was intended to protect.³⁰⁶

Licensing schemes that regulate speech must therefore have "narrow, objective, and definite standards to guide the licensing authority."³⁰⁷ Any such scheme must meet three requirements:

³⁰³ See *id.* at 168 ("[P]rohibit[ing] manufacturer promotion [of off-label uses] alone . . . would unconstitutionally restrict free speech.").

³⁰⁴ FDA GUIDANCE, *supra* note 23, at 11.

³⁰⁵ See *Alexander v. United States*, 509 U.S. 544, 550 (1993) ("The term 'prior restraint' is used 'to describe administrative and judicial orders *forbidding* certain communications when issued in advance of the time that such communications are to occur.'" (quoting MELVILLE B. NIMMER, *NIMMER ON FREEDOM OF SPEECH* § 4.03 (1984))); see also IOANNIS G. DIMITRAKOPOULOS, *INDIVIDUAL RIGHTS AND LIBERTIES UNDER THE U.S. CONSTITUTION: THE CASE LAW OF THE U.S. SUPREME COURT* 531–32 (2007).

³⁰⁶ THOMAS I. EMERSON, *THE SYSTEM OF FREEDOM OF EXPRESSION* 504 (1970).

³⁰⁷ *Shuttlesworth v. Birmingham*, 394 U.S. 147, 150–51 (1969); see also *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 335, 340 (2010) ("[P]rior restraint [is] analogous to licensing laws implemented in 16th- and 17th-century England, laws and governmental

(1) the government must bear the burden of proving the speech should be prohibited, (2) the initial restraint must be only as long as necessary to allow the parties to obtain judicial review of the government's censorship, and (3) the review process must ensure a prompt, final judicial resolution.³⁰⁸

The FDA's licensing scheme fails these requirements. First, there are no "narrow, objective, and definite standards." As discussed in Part III, it is far from clear whether the FDA will categorize a medical application as a Class I, II, or III device.³⁰⁹ A prospective medical application device developer faces vast regulatory uncertainty. Second, given all the showings a manufacturer of medical applications must make, the burden is clearly on the manufacturer. Last, given the months that FDA approval requires, without mentioning judicial appeal, there is no prompt resolution to charges of censorship.

VI. CONCLUSION

In recent decades, information technologies have radically disrupted centuries-old regulatory regimes in areas as diverse as copyright, patent, and the law of police search by dramatically changing the cost and mode of production. For instance, peer-to-peer file-sharing changed copyright but the VCR did not. This is probably because file-sharing is so much easier, quicker and cheaper than copying VCR tapes.³¹⁰ Similarly, 3-D printing makes

practices of the sort that the First Amendment was drawn to prohibit . . . Premised on mistrust of governmental power, the First Amendment stands against attempts to disfavor certain subjects or viewpoints.").

³⁰⁸ *Freedman v. Maryland*, 380 U.S. 51, 58–59 (1965).

³⁰⁹ See *supra* notes 70–106 and accompanying text (discussing the three classes of medical devices and their respective regulations).

³¹⁰ See Michael A. Carrier, *Copyright and Innovation: The Untold Story*, 2012 WIS. L. REV. 891, 947–48 ("This opportunity has been seized, with several respected scholars pointing to technological change in calling for a more aggressive approach to the law of secondary liability. They have claimed that the Supreme Court's decision in *Sony Corporation of America v. Universal City Studios, Inc.*, which had found that the manufacturer of the videocassette recorder (VCR) was not secondarily liable because the device was 'capable of substantial noninfringing uses,' was the product of an earlier era. Because p2p developers have greater control over their products, these scholars have advocated heightened monitoring obligations." (quoting *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 442 (1984))); Lital Helman & Gideon Parchomovsky, *The Best Available Technology Standard*, 111 COLUM. L. REV. 1194, 1238 (2011)) (arguing that advancing technologies for filtering should guide copyright infringement rules); Douglas Lichtman & William Landes,

physical objects easier to reproduce, transforming patent law, trade dress law, and even gun control laws.³¹¹ And, Eric Snowden has brought to the forefront of public attention the ability of computer tracking to transform policing and to even alter the relationship between the individual and the state.

These great technology-induced disruptions of the law often result in overreaches. For instance, Congress's reaction to peer-to-peer file sharing, the Digital Millennium Act, has often been criticized as a power grab that dramatically shifts the balance of power in favor of the recording music industry.³¹² And, the narrowly defeated Stop Online Piracy Act and Protect IP Act bills³¹³ suggest the content industry may shift the balance further in its favor.³¹⁴ Recent, highly criticized regulatory action by the State Department foreshadows similar struggles over 3-D printing.³¹⁵

In contrast, a careful application of First Amendment principles avoids both FDA regulation that could crush innovation and dangerous medical apps that could injure health. By recognizing the limits of FDA jurisdiction as set forth in § 321(h) as well as the First Amendment limits on FDA power, effective regulation of

Indirect Liability for Copyright Infringement: An Economic Perspective, 16 HARV. J.L. & TECH. 395, 405–06 (2003) (noting the uncertainty faced by producers in the application of copyright rules to p2p technology).

³¹¹ See Davis Doherty, Note, *Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution*, 26 HARV. J.L. & TECH. 353, 354 (2012) (“But if one of these designs happens to infringe on an existing patent, 3D printing also enables widespread patent infringement in the form of digital downloads in much the same manner that the advent of digital music enabled widespread copyright infringement.”).

³¹² See, e.g., Olivera Medina & Kaiser Wahab, *Does Liability Enhance Credibility?: Lessons from the DMCA Applied to Online Defamation*, 25 CARDOZO ARTS & ENT. L.J. 237, 258–63 (2007) (providing an overview of criticism of the DMCA, including the arguments that it chills speech and creates a duty to police for infringement).

³¹³ Stop Online Piracy Act, H.R. 3261, 112th Cong. (2011); Protect IP Act of 2011, S. 968, 112th Cong. (2011).

³¹⁴ See Adam Candeb, *Transparency in the Administrative State*, 51 HOUS. L. REV. 385, 394–95 (2013) (“As many have lamented, intellectual property laws are the product of . . . political pressure and capture. Many expected a PIPA or SOPA-like bill to pass given the past success of the content industry’s similar legislation, such as the Digital Millennium Copyright Act of 1998.” (footnotes omitted)).

³¹⁵ See Andy Greenberg, *State Department Demands Takedown of 3D-Printable Gun Files for Possible Export Control Violations*, FORBES (May 9, 2013, 2:36 PM), <http://www.forbes.com/sites/andygreenberg/2013/05/09/state-department-demands-takedown-of-3d-printable-gun-for-possible-export-control-violation/> (describing actions taken by the State Department to conceal blueprints of a 3D-printable handgun).

digital medicine can emerge that encourages innovation and furthers health and safety.