# The Federal Trade Commission and Consumer Protections for Mobile Health Apps

Jennifer K. Wagner

# I. Introduction

The mobile health (mHealth) industry is no longer "emerging." Ready or not, for better or worse, it is here. According to the PEW Research Center, more than three-quarters of Americans now have a smartphone<sup>1</sup> and more than half of smartphone users are collecting "health-associated information" in some way with those smartphones.<sup>2</sup> There has been a proliferation of mHealth apps. Reports indicate more than 325,000 of them are available via the Google Play Store, Apple App Store, and elsewhere,<sup>3</sup> and projections for the global mHealth app market - of which North American is considered the leading region and the U.S. is the leading country within that region – are that it will generate more than \$111 Billion U.S. dollars by 2025.4 The mHealth apps are diverse and have been described as falling into one of four different types: informational, diagnostic, control, and adapter apps.<sup>5</sup> Through mHealth apps and other apps not typically considered by users to be health-related, personal data are being generated and aggregated at unprecedented levels. The data flow in and out of the mHealth apps, connecting with gadgets and online platforms. Researchers have been able to leverage

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The Federal Trade Commission (FTC) is the bestsuited agency in the United States to provide both well-calibrated and well-timed governmental protections for technology consumers in modern society, yet it remains remarkably under-appreciated. This commentary explores the consumer protections for mHealth apps and related technologies provided by the FTC, describing in Part II key aspects of the FTC's structure and authority, highlighting in Part III the recent activities to promote competition and consumer protection with mHealth apps and enforcement actions the FTC has taken against app developers, and proposing in Part IV modest policy recommendations to strengthen its powers as a formidable consumer watchdog.

# II. FTC Structure and Consumer Protection Authority

The FTC — or Federal *Technology* Commission as it has been dubbed critically on occasion<sup>s</sup> — has a 105-year-old history<sup>9</sup> that illustrates it is, by design, poised and primed to address the rapidly changing and emerging technologies and accompanying uncer-

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tainty. Indeed, the FTC has, since its inception, been the arbiter of technology. As legal scholar Christopher Hoofnagle has remarked, "Saying that the FTC has suddenly become a technology regulator is ... ahistorical. It treats technology as something that exists today, forgetting the innovation and social implication of technology from decades past."<sup>10</sup>

The FTC was created in 1914 with the enactment of the Federal Trade Commission Act<sup>11</sup> and began its work six months later in March 1915.<sup>12</sup> Organizationally, the FTC consists of the Bureau of Competition, Bureau of Consumer Protections, and Bureau of Economics<sup>13</sup> and is led by a bipartisan group of five commissioners (no more than three may be affiliated with the same political party) who are appointed by the President subject to confirmation by the Senate to serve seven-year, staggered terms.<sup>14</sup> The creation of Technology – Personal Information Security Specification). While this attention is merited and while the FTC can enforce data privacy and security via the FTCA, the consumer protections afforded by the FTC go far beyond privacy and data-related issues.

With the creation of the FTC in 1914, Congress charged the agency with an inherently compound mission: to promote fairness and competition in the marketplace. Initially Section 5 of the FTCA focused the FTC on the prevention of "unfair methods of competition in commerce." In 1931 the U.S. Supreme Court narrowly interpreted this phrasing to imply that the statute protected businesses (not consumers directly) and thwarted FTC action against unfair business tactics (no matter how repugnant or egregious) unless there was corresponding harm to business competitors.<sup>20</sup> Congress responded in 1938 with passage of the Wheeler-

Pressure for federal privacy policy reform in the U.S. is arising domestically from the individual states setting their own consumer privacy (e.g., California) and data broker transparency (e.g., Vermont) approaches and internationally from countries setting their own data protection approaches (e.g., the European Union's General Data Protection Regulation and China's Cybersecurity Law and Information Security Technology — Personal Information Security Specification). While this attention is merited and while the FTC can enforce data privacy and security via the FTCA, the consumer protections afforded by the FTC go far beyond privacy and data-related issues.

the FTC has itself been described as a "radical innovation,"<sup>15</sup> given the breadth of powers (a mix of judicial, legislative, and executive functions) that were entrusted and delegated to a single governmental agency to carry out its mission.<sup>16</sup>

Scholars and policymakers have been giving fresh attention to the FTC's ability to serve as the nation's primary privacy regulator, increasingly recognizing that the deluge of data raises important questions about appropriate limits on data practices and whether the sector-specific federal approach to privacy rights in the United States<sup>17</sup> remains workable. Pressure for federal privacy policy reform in the U.S. is arising domestically from the individual states setting their own consumer privacy (e.g., California)<sup>18</sup> and data broker transparency (e.g., Vermont)<sup>19</sup> approaches and internationally from countries setting their own data protection approaches (e.g., the European Union's General Data Protection Regulation and China's Cybersecurity Law and Information Security Lea Amendments that specifically allowed the FTC to prevent not only "unfair methods of competition" but also "unfair or deceptive acts or practices."21 By maintaining broad statutory language in Section 5 even with these changes, Congress reiterated its commitment to empowering the FTC to be adaptive, able to - on a moment's notice - promote competition and protect consumers as new circumstances require. According to Hoofnagle, skeptics of entrusting the agency with so much power were persuaded by limits imposed by the agency's purpose being "preventative, cooperative, and not penal."22 The FTC was further strengthened in the 1970s by judicial rulings affirming its broad powers to define unfair practices<sup>23</sup> and by additional legislation<sup>24</sup> enabling, for example, the agency to appear in court on its own behalf and take action against practices "in or affecting commerce." Congress pushed back and adjusted the agency's powers in 1980 when it perceived the FTC to be overzealous in its efforts, imposing limitations on the FTC's rulemaking authority, asserting the potential for legislative veto, and declining to reauthorize the agency until 1994.  $^{\rm 25}$ 

This historical context of how the current FTCA prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce"<sup>26</sup> and the refinement of the FTC's powers over time makes abundantly clear that the FTC is the agency uniquely situated, capable, and qualified to address the challenges raised by technological innovations. Whenever Congress is either oblivious to the issues, at an impasse over how to address them, or perhaps even distracted by unrelated pressing matters, the FTC has existing statutory authority to take the first steps. This is what distinguishes the FTC from other agencies that have to wait for congressionally delegated powers to respond to most technological innovations. For example, in the absence of congressional action, the Food and Drug Administration (FDA) has performed mental gymnastics to contort direct-to-consumer genomic interpretation and predictive algorithms as "medical devices" in order to act within the boundaries of its authority specifically defined in the Food Drug and Cosmetic Act (FD&C Act).<sup>27</sup> Similarly, in the area of wearables and other "internet of things" consumer products, the Consumer Product Safety Commission (CPSC) has a limited focus on protecting consumers from physical injuries only.<sup>28</sup> In this extraordinary and essential "first responder" role, the FTC should be brave and bold, taking swift and decisive actions that promote businesses and protect consumers. This approach allows technologies and industries to mature without extensive governmental meddling and allows a better assessment of whether existing laws are sufficient or whether new specific legislation is necessary.

The FTC's Bureau of Competition and Bureau of Consumer Protection work in tandem to "facilitate the exercise of consumer sovereignty," with the former ensuring that business practices do not artificially restrict options available to the consumers and the latter ensuring that business practices do not obstruct the consumers' abilities to choose from among the available options.<sup>29</sup> Importantly, with its preventative mission, the FTC is able to take action even before harms occur from practices violating the FTCA. Furthermore, the FTC has numerous tools at its disposal, including the ability to host workshops; conduct research; generate reports and white papers; publish consumer advisories, brochures, and educational materials; file amicus briefs; investigate individual corporations to gain insights about specific industries and otherwise hidden business practices; develop formal rules and standards for entire industries; issue guidance; publish press releases; monitor consumer complaints; prosecute alleged violations; adjudicate matters; and supervise business compliance with contracts.<sup>30</sup> Through its enforcement of Section 5 of the FTCA, the FTC works to ensure that business practices are free from a wide variety of undesired conduct, including unfairness, deception, unsubstantiated claims, false advertising, and anti-competitive activities.<sup>31</sup> Examples of violations include price fixing, predatory pricing, anticompetitive mergers, unreasonable horizontal or vertical restraints, overt coercion, undue influence, deception, and incomplete or confusing information.<sup>32</sup>

In the mHealth app space, anti-competitive practices relate to platform dynamics (e.g., Apple, Google, etc.) and how a powerful few corporations might hold consumers captive, monopolize the entirety of a mobile device user's experience, control consumer access to apps or data they generate, limit the rate of innovation or app options by dictating app features, and more.33 FTC commissioners have acknowledged, for example, that "[d]ata are a competitive asset" and that network effects can "lead to barriers to entry that grow over time rather than diminishing."34 The FTC watches out for methods of competition that would lower the quality, raise the prices, reduce choices, and reduce rates of innovation. Unfairness in the mHealth app space includes (but is not limited to) lax data security and privacy measures.35 While the FTC has underutilized the unfairness doctrine in the past 20 years, it is particularly poised for a comeback<sup>36</sup> and would proceed in predictable ways given the standard is codified (enabling the FTC to act when an act or practice "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition.").<sup>37</sup> Importantly for mHealth app developers, the FTC continues to show a tendency to use deception principles,38 and the FTC's standard for proving deception does not require the agency to establish intentions to deceive or actual deception; rather, the FTC must show that a material representation, omission, or practice is likely to mislead a consumer and this standard is viewed from the perspective of a reasonable consumer.<sup>39</sup> Substantiation of claims is related to deceptive practices and false advertising, and the FTC will consider numerous factors to determine the veracity of a claim.<sup>40</sup> In the mHealth space, this could include the FTC specifying the science<sup>41</sup> that must be available at the time a claim is made to support purported health benefits.

# III. FTC Enforcement Activities Involving mHealth Apps

As briefly summarized in this section, the FTC has been relatively active in its approach to mHealth apps,

UNREGULATED HEALTH RESEARCH USING MOBILE DEVICES • SPRING 2020 The Journal of Law, Medicine & Ethics, 48 S1 (2020): 103-114. © 2020 The Author(s) engaging in targeted enforcement against app developers who engage in deception and false advertising; providing guidance and interactive tools to assist app developers; issuing relevant reports; and hosting a range of topical workshops and hearings.

# A. Cases and Proceedings Involving mHealth Apps The FTC has taken selective enforcement action against at least seven mHealth app providers.

### 1. ACNEAPP AND ACNE PWNER

The FTC's first case involving mHealth apps occurred in 2011 (when the FTC was chaired by Jon Leibowitz) and involved apps known as "AcneApp" and "Acne Pwner."42 The matter was handled as an administrative matter, a proposed consent agreement was filed concurrently with the administrative complaint, and the final settlement was approved unanimously (5-0) by the commissioners a month later.<sup>43</sup>According to the FTC, the AcneApp was sold deceptively in the Apple iTunes Store for \$1.99 and was downloaded 11,600 times, and the Acne Pwner app was sold in the Google Android Marketplace for \$0.99 and downloaded 3,300 times.<sup>44</sup> The apps instructed consumers to hold their smartphone display against their skin for a few minutes daily so that the app could emit blue and red alternating lights,45 and the marketing statements and depictions claimed or suggested the apps cured acne, were developed by a dermatologist, and backed by a published scientific study.46 The terms of the settlement agreement barred the developers from making any acne-treatment claims about their apps and from misrepresenting science and required the developers to pay the FTC a combined amount of \$15,994 (i.e., \$14,294 to be paid by one defendant and \$1,700 to be paid by the other).<sup>47</sup> The FTC noted that substantiation of any health-related claims for the apps could only be made if the claims were substantiated by "competent and reliable scientific evidence" consisting of "at least two adequate and well-controlled human clinical studies" that were "conducted by different researchers."48 Notably, the display screen for the AcneApp prior to purchase instructed consumers to use the app "to improve skin health" and included a disclaimer that the app was "for entertainment purposes only."49

# 2. MELAPP AND MOLE DETECTIVE

The second case and proceeding taken by the FTC against mHealth app developers occurred four years later (when the FTC was chaired by Edith Ramirez) and also involved deceptive dermatological claims. The FTC commission voted 4-1 on these enforcement actions against MelApp and Mole Detective.<sup>50</sup> The

actions against the developer of MelApp were handled administratively<sup>51</sup> whereas the actions against the providers of Mole Detective were handled in federal court.<sup>52</sup> According to the FTC, the apps were sold for up to \$4.99 in the Google and Apple app stores; consisted of using a smartphone camera to take a photograph of any moles and input relevant consumerprovided-information into the app to assess whether the mole had a low, medium, or high risk of melanoma and detect melanoma at early stages.<sup>53</sup> The FTC argued that the claims were deceptive and unsubstantiated, and the settlement terms entered a total monetary judgment to the FTC from the app providers for \$62,553.42 collectively (\$58,623.42 from one provider and \$3,930 from the others) and banned the app providers from making any health-related claims unless they are supported by "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields..."54 Commissioner Maureen K. Olhausen dissented, expressing her belief that the FTC's order imposed an excessive substantiation requirement when applied to the claims made by the developers and without extrinsic evidence as to how consumers interpreted the claims (e.g., whether they expected the app to be as accurate as a medical professional in diagnosis of melanoma) and that this requirement would ultimately have a chilling effect on mHealth apps and useful health information for consumers.<sup>55</sup> She warned that the FTC should not assume that an mHealth app has been or would be interpreted by consumers to be a suitable substitute for professional medical care unless there are "express claims, clearly implied claims, or extrinsic evidence" to that effect.56

# 3. ULTIMEYES

In late 2015, the FTC initiated an administrative enforcement action (with the commissions in unanimous, 4-0, agreement) against the providers of Ultimeyes, an online and mobile app that involved visual exercises, was advertised as "scientifically shown to improve vision" and as reducing the need for wearing corrective lenses, and was sold for between \$5.99 and \$9.99 on the company's website and in the Apple App Store and Google Play Store.<sup>57</sup> Again, the central focus of the FTC was on the deceptive and unsubstantiated health-related claims that were made. The final settlement, which was approved in February 2016, required the providers to stop marketing the app with health claims unless they possessed "competent and reliable scientific evidence" (i.e., "randomized, double-blind, and adequately controlled" studies) supporting the claims; to pay \$150,000 to the FTC, to disclose any affiliations that the company has with any researchers of studies purporting to support their claims and with any individuals providing endorsements for their app.<sup>58</sup> The proposed settlement of this matter prompted dozens of comments from experts who expressed concern about the FTC's insistence on double blinded studies to prove health claims, although Commissioner Ohlhausen explained in a concurring statement that the settlement agreement is not as rigid or onerous as commenters worry.<sup>59</sup>

#### 4. LUMOSITY

In 2016 the FTC took enforcement action against the Lumos Labs, the provider of Lumosity.60 The FTC challenged the company's sales pitch (which was promoted widely on radio, television, and online media) that suggested consumers who play one of its 40 games, sold via online and mobile subscriptions (e.g., a monthly subscription for \$14.95 or a one-time "lifetime" subscription for \$299.95), would experience improved work or school performance and avoid memory loss or age-related cognitive decline and also took issue with the company's failure to disclose that testimonials were solicited with prizes.<sup>61</sup> The commissioners unanimously (4-0) agreed to the FCT action filed in federal court and to the settlement that required the company to pay \$2 million dollars, required the company to notify existing customers to give them an easy way to cancel their subscriptions to avoid auto-renewal charges, and barred the company from making similar deceptive claims in the future by requiring any claims to have proper substantiation.62 Commissioner Julie Brill filed a concurring statement underscoring her concern that consumers of "brain training" products in particular could be easily misled by advertising messages regarding their efficacy and that rigorous scientific proof is required for healthrelated claims to be supported properly.63

#### 5. INSTANT BLOOD PRESSURE APP

Despite vacancies at the Commission,<sup>64</sup> the FTC continued to pay attention to mHealth apps and, in December 2016, took unanimous (3-0) action in federal court against the providers of the Instant Blood Pressure (IBP) app.<sup>65</sup> According to the complaint, the app was sold online and via the Apple App Store and Google Play Marketplace for \$3.99 or \$4.99 and generated over \$600,000 in sales over a one-year period. To measure blood pressure with this app, a user was to place the right index finger on the smartphone's camera while holding the base of the smartphone over the heart.<sup>66</sup> The FTC argued the app was deceptive in its claims that the app could measure blood pressure as accurately as a traditional cuff method and

also deceptive in its use of endorsements that failed to disclose affiliations that the individuals endorsing the app had to the company (e.g., 5-star app ratings were given by the CEO/President and by the Chairman of the board and co-founder), which affect the credibility of the endorsements.<sup>67</sup> The stipulated settlement required the providers to (1) stop marketing their app as measuring blood pressure or being suitable as a replacement for a traditional blood pressure cuff unless they have, at the time of making the claim, scientific evidence demonstrating the claim is true; (2) stop misleading consumers with endorsements lacking clear and conspicuous disclosures of any affiliations between the individuals providing the endorsement and the app company; and (3) pay \$595,945.27 to the FTC.68

#### 6. BREATHOMETER APPS

In 2017 the FTC took unanimous (3-0) action in federal court against the providers of the Breathometer Original and Breeze apps.<sup>69</sup> The Original and Breeze apps and related accessories (the former connecting through the audio jack and the latter being Bluetoothenabled) appeared on the television show "SharkTank," were sold online by Amazon, BestBuy, and Brookstone for \$49.99 and \$99.99, respectively, and ultimately generated gross sales of \$5.1 million dollars (\$3.1 million for the Original and \$2 million for the Breeze).<sup>70</sup> This breathalyzer mHealth technology instructed users to connect the device to their smartphone, download the app, and blow into the device, and purported to display the blood alcohol content (BAC) of the consumer within five seconds.71 The FTC challenged the company's claims that the app had "government-lab grade testing" accuracy and alleged the app developers knew that the mHealth technology under-estimated BAC, had no way to calibrate the mHealth technology in the field to correct the problem, continued allowing retailers to sell the tests and keeping the app live even after the problem was discovered, and failed to notify retailers and consumers.72 The settlement bars the mHealth technology providers from re-enabling their app's breathalyzer functions and bars them from making any claims that the technology has been scientifically or clinically proven or that they claims have been proven by government lab-grade testing; and requires the providers to notify consumers and issue refunds to those requesting the refund (and to pay the FTC the difference between \$1million and the amount of consumer refunds processed).<sup>73</sup> For claims about the breathalyzer's accuracy being as accurate as "law-enforcement grade" products to be truthful and substantiated, the settlement further specified that the demonstration of accuracy must be shown via the

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Department of Transportation's *Model Specifications for Devices to Measure Breath Alcohol*, and Commissioner Ohlhauser issued a concurring statement to explain that this settlement did not establish an industry-wide substantiation standard.<sup>74</sup>

#### 7. PACT APP

The FTC was down to only a pair of Commissioners by the time it took action against the providers of the Pact App in September 2017.75 The FTC handled this matter in district court, filing the complaint and the proposed settlement the same day.<sup>76</sup> According to the FTC, the Pact App was designed to help consumers commit to diet and exercise, enabling users to set weekly goals (which would carry over week-to-week unless settings were changed by the user) and subsequently imposing positive or negative reinforcement of behavior that fulfilled or fell short of the goals set: users who missed their weekly goals were to be penalized with a fee of between \$5 and \$50 for each activity missed, while those who met their weekly goals were to be rewarded with a share of the proceeds collected by those penalized.77 The gist of the FTC's complaint was that the operators of the Pact App were misleading in their billing and rewards scheme and that they did not live up to their promises and billed users even when goals were met, technical problems were experienced, or accounts were deleted.78 The complaint alleged violations of the FTCA as well as the Restore Online Shoppers' Confidence Act, a statute barring the use of negative options (i.e., wherein continued acceptance of the provision of goods or services is assumed by a consumer's silence) unless the material transaction terms are "clearly and conspicuously" disclosed upfront and also alleged that the app's operators were aware of billing problems.79 The settlement bars the app providers from making misrepresentations about how they charge consumers, bars them from charging consumers unless they have "the consumers' express, informed consent"; requires them to make specific disclosures in order to provide negative options; and requires them to pay a \$1.5 million settlement fee with \$948,788 to be issued as refunds to consumers who have already complained about billing problems they experienced.<sup>80</sup>

In sum, these seven distinct enforcement activities, while not an exhaustive review of all enforcement efforts related to the Office of Technology Research and Investigation,<sup>\$1</sup> reveal recurrent themes. The FTC has focused on preventing consumers of mHealth apps from (1) being misled by false or deceptive advertising, (2) being fooled by app ratings and endorsements made by individuals with conflicts of interest, (3) being misled by misrepresentations of the science; (4) incurring unexpected fees charged in confusing ways; and (5) being kept in the dark about technical problems interfering with the app's performance or recalibration. The FTC has not yet focused much on anti-competition or unfairness issues thus far in the mHealth app space, but that might change in the near future<sup>82</sup> — especially when one considers the data practices that have been outside the scope of this general overview of consumer protections.<sup>83</sup>

# B. Relevant Guidance and Tools for App Developers, Reports, and Hearings

In an effort to promote business and innovation and best practices in the marketplace, the FTC has collaborated with agencies with overlapping and adjacent subject matter jurisdictions (including the Federal Communications Commission or FCC)<sup>84</sup> to develop guidance and tools for mHealth app developers. For example, in 2016 the FTC created an interactive tool for mHealth app developers in collaboration with the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the FDA. The tool walks app developers through a series of 10 questions to help identify which laws might apply to an app and also provides hyperlinks to tips for protecting consumers' privacy and data security.85 Also in 2016, the FTC published "Best Practices" on its website, enumerating eight specific practices that can help mHealth app developers with privacy and security design issues: (1) "Minimize data;" (2) "Limit access and permissions;" (3) "Keep authentication in mind;" (4) "Consider the mobile ecosystem;" (5) "Implement security by design;" (6) "Don't reinvent the wheel;" (7) "Innovate how you communicate with users;" and (8) "Don't forget about other applicable laws."86

Several recent FTC reports are useful to businesses and consumers of mHealth apps and related technologies,<sup>87</sup> including "Mobile Privacy Disclosures: Building Trust Through Transparency" issued in 2013; "Data Brokers: A Call for Transparency and Accountability" issued in 2014; "Careful Connections: Building Security in the Internet of Things" issued in 2015, "Big Data: A tool for inclusion or exclusion? Understanding the issues" issued in 2016, and "The Sharing Economy: Issues Facing Platforms, Participants & Regulators" issued in 2016.

In addition to the relevant guidance, tools, and reports, the FTC has held a series of 14 public hearings on "Competition and Consumer Protection in the 21st Century.<sup>88</sup> Through these hearings, the FTC demonstrated a serious commitment to learning from experts on issues that will undoubtedly inform the approach the FTC takes to advance competition and consumer protection in mHealth technologies. **IV. Conclusions and Policy Recommendations** The FTC is an extraordinary agency with broad powers that enable it to be adaptive, proactive, and rapidly responsive (if it so chooses). This is in stark contrast to most administrative agencies, which must carry out their policy missions within rigid, fixed boundaries. The FTC embodies the "flexibility and practicality" needed by Congress for implementing policies to ensure fairness in emerging technologies and markets<sup>89</sup> and necessarily must consider new practices "as

The few enforcement actions taken against app developers have focused on deceptive practices; however, a shift in focus toward anti-competitive business methods and unfair practices is needed. Few technology platforms (such as Google and Apple) dominate the market, shaping opportunity for both consumers and businesses. The FTC should look not only at the app developers but upstream to the technology platforms when searching for effective means with which to promote fairness and competition for mHealth apps.

they arise in the light of the circumstances in which they are employed."<sup>90</sup> As FTC Commissioners Rohit Chopra and Rebecca Slaughter have observed, "It was no accident that, over one hundred years ago... Congress wanted an expert administrative agency with broad and flexible authority to 'hit at every trade practice, then existing or thereafter contrived, which restrained competition or might lead to such restraint if not stopped in its incipient stages."<sup>91</sup>

There are, however, challenges on the horizon for the FTC. Despite all of the activities that the FTC has done in the past decade to promote competition and ensure consumer protections in mHealth apps, the position<sup>92</sup> of FTC Chief Technologist has been vacant since April 2018, and it remains unclear as to whether the current FTC Chairman Joseph J. Simons will fill that vacancy or pivot the FTC in a different direction.<sup>93</sup> The Office of Technology Research and Investigation (OTech), created in 2015, has gone silent on its webpage and Tech@FTC blog,<sup>94</sup> and the FTC reportedly only employs five full-time technologists.<sup>95</sup> Additionally, Congress appears interested in tweaking the FTC's authority,<sup>96</sup> but it is not yet clear whether the result will augment or limit the FTC's efforts relevant to mHealth technologies: changes to the FTCA to make it easier for the FTC's oversight to reach non-profit entities (e.g., to challenge anti-competitive price-fixing within the health care industry) and common carriers (e.g., to regulate technology platforms more effectively in coordination with the FCC) and to impose civil penalties (e.g., for data privacy violations) would be welcomed, but other proposed changes could

inhibit the FTC's agility that goes to the core of its mission.97 Furthermore, while many recognize that the FTC has scant resources with which to fulfill its tremendous responsibilities and acknowledge the FTC was in deregulatory crosshairs in decades past,<sup>98</sup> new calls for an expansion of the FTC's powers - as opposed to clarifying them delicately and with specificity - just might invite the Supreme Court's revival of the nondelegation doctrine,99 which could jeopardize the FTC's very existence. Complementary consumer protections are available among the states and enforced by state Attorneys General,100 but a weakened or dismantled FTC could have catastrophic effects for consumers and businesses in mHealth. Champions of the FTC and its work might be wise to exercise restraint in their requests of Congress at this time.

As highlighted in Part III, much of the FTC's activities taken thus far regarding mHealth apps have focused on providing reports and tools to educate consumers and app developers on important priorities (e.g., privacy by design and anti-discrimination by design). The few enforcement actions taken against app developers have focused on deceptive practices; however, a shift in focus toward anti-competitive business methods and unfair practices is needed. Few technology platforms (such as Google and Apple) dominate the market, shaping opportunity for both consumers and businesses. The FTC should look not only at the app developers but upstream to the technology platforms when searching for effective means with which to promote fairness and competition for mHealth apps. Whether consumers and businesses would be better off if these technology giants were broken up, or, alternatively, if it would be more effective for the FTC to leverage the app stores (wielding considerable control over which apps are made readily available to consumers) to spread best practices is yet unclear. Technology platforms dominating the electronic health record market through health care sys-

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tem partnerships (such as Epic) are also ripe for FTC anti-competitive scrutiny. By focusing efforts on the technology platforms, the FTC might help consumers and businesses while avoiding supervisory burdens that would accompany settlement agreements and consent decrees with individual mHealth app developers. The unfairness doctrine also holds considerable potential to help prevent the proliferation of Big Data-driven discrimination facilitated by data generated by mHealth apps and subsequent processing by data brokers.

Ultimately, a pro-science, pro-consumer, pro-business, and pro-innovation future for mHealth apps is possible, but we need the FTC to realize it.

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#### References

- Pew Research Center, "Mobile Fact Sheet," February 5, 2018, available at <a href="https://www.pewinternet.org/fact-sheet/mobile/">https://www.pewinternet.org/fact-sheet/mobile/</a>> (last visited February 26, 2020).
- A. Edwards, "mHealth: Healthcare Mobile App Trends in 2019," Ortholive Blog, February 2, 2019, available at <a href="https://www.ortholive.com/blog/mhealth-healthcare-mobile-app-trends-in-2019">https://www.ortholive.com/blog/mhealth-healthcare-mobile-app-trends-in-2019</a>> (last visited February 26, 2020).
- M. Pohl, "325,000 Mobile Health Apps Available in 2017 -Android Now the Leading mHealth Platform," Research 2 Guidance, 2017, available at <a href="https://research2guidance.com/325000-mobile-health-apps-available-in-2017/">https://research2guidance. com/325000-mobile-health-apps-available-in-2017/> (last visited February 26, 2020).
- Zion Market Research, "Global mHealth Apps Market Will Reach USD 111.1 Billion by 2025: Zion Market Research," *Globe Newswire*, January 24, 2019, available at <a href="https://www.globenewswire.com/news-release/2019/01/24/1704860/0/en/Global-mHealth-Apps-Market-Will-Reach-USD-111-1-Billion-By-2025-Zion-Market-Research.html">https://www.globenewswire.com/news-release/2019/01/24/1704860/0/en/Global-mHealth-Apps-Market-Will-Reach-USD-111-1-Billion-By-2025-Zion-Market-Research.html</a> (last visited February 26, 2020).
- E.g., V. J. Roth, "The mHealth Conundrum: Smartphones & Mobile Medical Apps-How Much FDA Medical Device Regulation Is Required," North Carolina Journal of Law & Technology 15 (2014): 359-424, at 364-65.
- 6. Apple, "Apple Introduces ResearchKit, Giving Medical Researchers the Tools to Revolutionize Medical Studies," (Press

release), March 9, 2015, available at <a href="https://www.apple.com/newsroom/2015/03/09Apple-Introduces-ResearchKit-Giving-Medical-Researchers-the-Tools-to-Revolutionize-Medical-Studies/">https://www.apple.com/newsroom/2015/03/09Apple-Introduces-ResearchKit-Giving-Medical-Researchers-the-Tools-to-Revolutionize-Medical-Studies/</a> (last visited February 26, 2020). E. Wicklund, "ResearchStack Goes Live, Opening mHealth

- E. Wicklund, "ResearchStack Goes Live, Opening mHealth Studies to the Android Ecosystem," *mHealth Intelligence*, October 7, 2016, *available at* <a href="https://mhealthintelligence">https://mhealthintelligence</a>, ocm/news/researchstack-goes-live-opening-mhealth-studiesto-the-android-ecosystem> (last visited February 26, 2020).
- E.g., B. Fung, "The FTC Was Built 100 Years Ago to Fight Monopolists. Now, It's Washington's Most Powerful Technology Cop," Washington Post, September 25, 2014, available at <a href="https://www.ashingtonpost.com/news/the-switch/wp/2014/09/25/the-ftc-was-built-100-years-ago-to-fightmonopolists-now-its-washingtons-most-powerful-technology-cop/> (last visited February 26, 2020); O. Tene, "With Ramirez, FTC became the Federal Technology Commission," January 18, 2017, available at <a href="https://iapp.org/news/a/withramirez-ftc-became-the-federal-technology-commission/>">https://iapp.org/news/a/withramirez-ftc-became-the-federal-technology-commission/> (last visited February 26, 2020).</a>
- For a comprehensive review of the FTC, see C. Hoofnagle, Federal Trade Commission Privacy Law and Policy (New York, NY: Cambridge University Press, 2016).

- Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) codified at 15 U.S.C. §§41-58.
- 12. E.g., Federal Trade Commission, "Our History," *available at* <<u>https://www.ftc.gov/about-ftc/our-history></u> (last visited February 26, 2020).
- Federal Trade Commission, "Bureau of Competition," available at <https://www.ftc.gov/about-ftc/bureaus-offices/bureaucompetition> (last visited February 26, 2020); Federal Trade Commission, "Bureau of Consumer Protection," available at <https://www.ftc.gov/about-ftc/bureaus-offices/bureauconsumer-protection> (last visited February 26, 2020); and Federal Trade Commission, "Bureau of Economics," available at <https://www.ftc.gov/about-ftc/bureaus-offices/bureaueconomics (last visited February 26, 2020).
   E.g., E. Ramirez, "The FTC: A Framework for Promoting
- 14. E.g., E. Ramirez, "The FTC: A Framework for Promoting Competition and Protecting Consumers," *George Washington Law Review* 83 (2015): 2049-2063; and Hoofnagle, *supra* note 9, at 83-96.
- 15. See Hoofnagle, supra note 9, at xvi.
- 16. See Hoofnagle, *supra* note 9, at 70 (footnote 18), citing Judge Learned Hand, "An Unseen Reversal," The New Republic, January 9, 1915 at 7-8. For a summary of the FTC's authority, see also, Federal Trade Commission, "A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority," April 2019, *available at <a href="https://www.ftc.gov/about-ftc/what-we-do/enforcement-authoritys">https://www.ftc.gov/about-ftc/what-we-do/enforcement-authoritys</a> (last visited February 26, 2020).*
- See, e.g., Presidential Commission for the Study of Bioethical Issues, "Privacy and Progress in Whole Genome Sequencing," October 2012, available at <a href="https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\_1.pdf">https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\_1.pdf</a> (last visited February 26, 2020) (Figure 2: U.S. Federal Privacy Laws at 61); H. Zimmerman, "The Data of You: Regulating Private Industry's Collection of Biometric Information," University of Kansas Law Review 66 (2018): 637-671, at 643 and 645.
- 18. California Consumer Privacy Act of 2018, AB-375 signed into law on June 28, 2018 as amended by SB-822 signed into law on September 30, 2018; See also J. Stephens, "California Consumer Privacy Act," ABA Business and Corporate Litigation Committee Newsletter, July 2, 2019, available at <htps:// www.americanbar.org/groups/business\_law/publications/ committee\_newsletters/bcl/2019/201902/fa\_9/> (last visited February 26, 2020).
- Office of the Attorney General, "Guidance on Vermont's Act 171 of 2018, Data Broker Registration, V.S.A. §§ 2430, 2433, 2436, and 2437," December 11, 2018, available at <a href="https://www.sec.state.vt.us/media/914592/2018-12-11-vt-data-bro-">https://www.sec.state.vt.us/media/914592/2018-12-11-vt-data-bro-</a>

<sup>10.</sup> Id., at 26.

- 20. FTC v. Raladam Co., 283 U.S. 643, 51 S. Ct. 587 (1931).
- 21. Federal Trade Commission Act, Pub. L. No. 75-447, §3, 52 Stat. 111 (1938) (aka the Wheeler-Lea Amendments).
- 22. See Hoofnagle, supra note 9, at 37.
- FTC v. Sperry & Hutchinson, 405 U.S. 233, 92 S. Ct. 898 (1972); See also, Hoofnagle, *supra*, note 9, at 54.
- E.g., Trans-Alaska Pipeline Authorization Act, Pub. L. No. 93-153, 87 Stat. 591, §408-409 (1973); Magnuson-Moss Warranty — Federal Trade Commission Improvement Act, Pub. L. No. 93-637, 88 Stat. 2183 (1975) codified at 15 U.S.C. ch. 50 § 2301 et seq.; See also, supra, note 9, at 54-55.
- 25. E.g., Federal Trade Commission Improvements Act of 1980, Pub. L. No. 96-252, 94 Stat. 374 (1980); FTC Act Amendments of 1994, Pub. L. No. 103-312, 108 Stat. 1691 (1994) codified in relevant part at 15 U.S.C. §45(n); and J. H. Beales, "The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection," The Marketing and Public Policy Conference; Washington, DC., May 30, 2003, available at <a href="https://www.ftc.gov/public-statements/2003/05/ftcs-use-unfairness-authority-its-rise-fall-and-resurrection#N\_7> (last visited February 26, 2020).
- 26. Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (2019).
- See, e.g., Federal Food, Drug, and Cosmetic Act (FD&C Act), 27. Pub. L. No. 75-717, 52 Stat. 1040 (1938) codified as amended at 21 U.S.C. §§ 301 et seq. (2019); 21st Century Cures Act, Pub. L. No. 114-255 (2016); U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of the Center Director, Center for Biological Evaluation and Research, "Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff," February 9, 2015, available at <a href="https://">https://</a> www.fda.gov/media/80958/download> (last visited February 26, 2020); U.S. Department of Health and Human Services, Food and Drug Administration, "Software as a Medical Device (SaMD)" August 31, 2018, available at <a href="https://www.fda.gov/">https://www.fda.gov/</a> MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/ default.htm> (last visited February 26, 2020); J.K. Wagner, "Understanding FDA Regulation of DTC Genetic Tests Within the Context of Administrative Law," American Journal of Human Genetics 87 (2010):451-456; J.K. Wagner, "The Sky is Falling for Personal Genomics! Oh Nevermind. It's Just a Cease & Desist Letter from the FDA to 23andMe," Genomics Law Report, December 3, 2013, available at <a href="https://">https://</a> theprivacyreport.com/2013/12/03/the-sky-is-falling-for-personal-genomics-oh-nevermind-its-just-a-cease-desist-letterfrom-the-fda-to-23andme/> (last visited February 26, 2020); C.J. Guerrini, J.K. Wagner, S.C. Nelson, G.H. Javitt, and A.L. McGuire, "Who's on Third? Regulation of Third-Party Genetic Interpretation Services," Genetics in Medicine 22 (2020): 4-11.
- E.F. Kaye, Commissioner, "Statement of Commissioner Elliott F. Kaye Regarding a Framework of Safety for the Internet of Things," January 31, 2019, available at <a href="https://www.cpsc.gov/s3fs-public/A\_Framework\_for\_Safety\_Across\_the\_Internet\_of\_Things\_1-31-2019\_0.pdf?1KJ.t4Tn04v9OtEBr-2s0wyLAP.KsuuQ3> (last visited February 26, 2020).</a>
- N.W. Averitt and R. H. Lande, "Consumer Sovereignty: A Unified Theory of Antitrust and Consumer Protection Law," *Anti*trust Law Journal 65 (1997): 713-756, at 713-714.
- E.g., supra, note 9, at 98-117; D.J. Solove and W. Hartzog, "The FTC and the New Common Law of Privacy," Columbia Law Review, 114 (2014): 583-676, at 625; and Ramirez, supra, note 14.
- 31. E.g., *supra*, note 9, at 119-140; *supra*, note 29, at 718, 725-26, and 733; and T. Rosch, Commissioner, Deceptive and Unfair Acts and Practices Principles: Evolution and Conver-

gence, Speech at the California State Bar, (May 18, 2007), 2007 WL 2506620, available at <a href="https://www.ftc.gov/">https://www.ftc.gov/</a> sites/default/files/documents/public\_statements/deceptiveand-unfair-acts-and-practices-principles-evolution-andconvergence/070518evolutionandconvergence\_0.pdf> (last visited February 26, 2020). See also Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, United States Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (December 17, 1980), appended to International Harvester Co., 104 F.T.C. 949, 1061, (1984), available at <http://www.ftc.gov/bcp/policystmt/ad-unfair. htm> (last visited February 26, 2020); Letter from James C. Miller III, FTC Chairman, to John D. Dingell, Chairman, House Comm. On Energy and Commerce 5-6 (October 14, 1984), appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984); and Federal Trade Commission, FTC Policy Statement Regarding Advertising Substantiation (March 11, 1983), appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).

- 32. E.g., Hoofnagle, *supra*, note 9; S.L. Pardau and B. Edwards, "The FTC, the Unfairness Doctrine, and Privacy by Design: New Legal Frontiers in Cybersecurity," *Journal of Business* & *Technology Law* 12 (2017): 227-276, at 232-235; Solove and Hartzog, *supra*, note 30, at 640.
- 33. See, e.g., F. Pasquale, "Privacy, Antitrust, and Power," George Mason Law Review 20 (2013): 1009-1024, at 1023. See also, generally, F. Pasquale, The Black Box Society: The Secret Algorithms That Control Money and Information (Cambridge, MA: Harvard University Press, 2015).
- T. McSweeney and B. O'Dea, "Data, Innovation, and Potential Competition in Digital Markets — Looking Beyond Short-Term Price Effects in Merger Analysis," February 2018, available at <a href="https://www.ftc.gov/system/files/documents/public\_statements/1321373/cpi-mcsweeny-odea.pdf">https://www.ftc.gov/system/files/documents/public\_statements/1321373/cpi-mcsweeny-odea.pdf</a>> (last visited February 26, 2020).
- 35. C.f. FTC v. Wyndham Worldwide Corp., 10 F. Supp. 3d. 612 (D.N.J. 2014), aff'd 799 F.3d 236 (3rd Cir. 2015); LabMD, Inc. v. Federal Trade Commission, 894 F.3d 1221 (11 Cir. 2018), available at <a href="http://media.ca11.uscourts.gov/opinions/pub/files/201616270.pdf">http://media.ca11.uscourts.gov/opinions/pub/files/201616270.pdf</a>> (last visited February 26, 2020).
- 36. See, e.g., Beales, supra, note 25 (warning that "an unwarranted aversion" to the unfairness doctrine would cause overreliance and a perversion of the principles of deception); Rosch, supra, note 31; Solove and Hartzog, supra, note 30, (noting a "dramatic" shift by the FTC to turn the focus away from "Broken Promises" and toward "Broken Expectations," which could lead to the FTC requiring businesses to correct mistaken consumer expectations and explaining, at 640, that among the unfair trade practices that have emerged are retroactive policy changes); and R. Hirsch and J. Harrison, "Digital Health Privacy: Old Laws Meet New Technologies," Competition: The Journal of Antitrust, UCL, and Privacy Section of the California Lawyers Association 27, no. 1 (2018): 21-28.
- 37. 15 U.S.C. § 45(n) (2019).
- 38. C. Keegan and C. Schroeder, "Unpacking Unfairness: the FTC's Evolving Measures of Privacy Harms," *Journal of Law*, *Economics & Policy* 15 (2019): 19-40, at 19 and 28 (noting a "deception creep" and that the unfairness doctrine has been used in privacy cases as "an intensifier" of deceptive practices).
- Letter from James C. Miller III, FTC Chairman, to John D. Dingell, Chairman, House Comm. On Energy and Commerce 5-6 (October 14, 1984), appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984); see also, Rosch, *supra* note 31.
- 40. See Hoofnagle, *supra*, note 9, at 134-135.
- 41. POM Wonderful, LLC v. FTC, 777 F.3d 478 (D.C. Cir. 2015).
- 42. Federal Trade Commission, 'Acne Cure' Mobile App Marketers Will Drop Baseless Claims under FTC Settlements, Press Release, September 9, 2011, available at <a href="https://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobileapp-marketers-will-drop-baseless-claims-under">https://www.ftc. gov/news-events/press-releases/2011/09/acne-cure-mobileapp-marketers-will-drop-baseless-claims-under</a>> (last vis-

unregulated health research using mobile devices  $\bullet$  spring 2020

ited February 26, 2020); Federal Trade Commission, FTC Approves Final Settlement Orders Against Marketers Who Claimed Their Mobile Apps Could Cure Acne, Press Release, October 25, 2011, available at <https://www.ftc.gov/newsevents/press-releases/2011/10/ftc-approves-final-settlementorders-against-marketers-who> (last visited February 26, 2020); In the Matter of Koby Brown, individually, and d/b/a Dermapps, et al., FTC File No. 102-3205; In the Matter of Andrew N. Finkel, individually, FTC File No. 102-3206.

43. *Id.* ('Acne Cure' Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements).

44. Id.

- 45. Complaint, In the Matter of Koby Brown, individually, and d/b/a Dermapps, et al., FTC File No. 102-3205, available at <https://www.ftc.gov/sites/default/files/documents/cases/2 011/10/111021dermappsempt.pdf> (last visited February 26, 2020) and Complaint, In the Matter of Andrew N. Finkel, individually, FTC File No. 102-3206, available at <https:// www.ftc.gov/sites/default/files/documents/cases/2011/10/1110 21dermappscmpt.pdf> (last visited February 26, 2020).
- 46. Supra note 43.
- 47. Id.
- Decision and Order, In the Matter of Koby Brown, individually, and d/b/a Dermapps, et al., FTC File No. 102-3205, at 2-3, available at <a href="https://www.ftc.gov/sites/default/files/documents/cases/2011/10/111021dermappsdo.pdf">https://www.ftc.gov/sites/default/files/documents/cases/2011/10/111021dermappsdo.pdf</a>> (last visited February 26, 2020); Decision and Order, In the Matter of Andrew N. Finkel, individually, FTC File No. 102-3206, at 2 https://www.ftc.gov/sites/default/files/documents/cases/2011/10/111021acnedo.pdf
  (last visited February 26, 2020).
- 49. Complaint, In the Matter of Koby Brown, individually, and d/b/a Dermapps, et al., FTC File No. 102-3205, at 3, available at <a href="https://www.ftc.gov/sites/default/files/documents/cases/2011/10/111021dermappscmpt.pdf">https://www.ftc.gov/sites/default/files/documents/cases/2011/10/111021dermappscmpt.pdf</a>> (last visited February 26, 2020).
- 50. Federal Trade Commission, 'Melanoma Detection' App Sellers Barred from Making Deceptive Health Claims: FTC Charged Mole Detective Sellers with False Advertising Earlier This Year, Press Release, August 13, 2015, available at <https:// www.ftc.gov/news-events/press-releases/2015/08/melanomadetection-app-sellers-barred-making-deceptive-health> (last visited February 26, 2020).
- 51. Federal Trade Commission, FTC Approves Final Order Barring Misleading Claims about App's Ability to Diagnose or Assess the Risk of Melanoma, Press Release, April 13, 2015, available at <https://www.ftc.gov/news-events/press-releases/2015/04/ ftc-approves-final-order-barring-misleading-claims-aboutapps> (last visited February 26, 2020). See also Complaint, supra note 49; In the Matter of Health Discovery Corporation, FTC File No. 132-3211; and FTC v. Avrom Boris Lasarow; L Health Ltd., formerly known as Lasarow Healthcare Technologies Ltd., a private company limited by shares; Kristi Zuhlke Kimball; and New Consumer Solutions LLC, a limited liability company, FTC File No. 132-3210.
- 52. See Federal Trade Commission, supra note 50.
- 53. Id.
- 54. Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief Against Defendant Avrom Boris Lasarow, available at <a href="https://www.ftc.gov/system/files/documents/cases/150813lasarowstip.pdf">https://www.ftc.gov/system/files/documents/cases/150813lasarowstip.pdf</a>> (last visited February 26, 2020); and Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief Against Defendants Kristi Zuhlke Kimball and New Consumer Solutions, LLC, at 6, available at <a href="https://www.ftc.gov/system/files/documents/cases/new\_consumer\_solutions\_5-1-15.pdf">https://www.ftc.gov/system/files/documents/cases/new\_consumer\_solutions\_5-1-15.pdf</a>> (last visited February 26, 2020).
- 55. M.K. Olhausen, Commissioner, "Dissenting statement of Commissioner Maureen K. Olhausen In the Matter of Health Discovery Corporation, File No. 132-3211 and FTC v. Avrom Boris Lasarow, et al., File No. 132-3210," February 23, 2015, available at <a href="https://www.ftc.gov/system/files/documents/">https://www.ftc.gov/system/files/documents/</a>

public\_statements/626051/150223moledetectivemkodissstmt.pdf> (last visited February 26, 2020).

- 56. Id.
- Federal Trade Commission, FTC Charges Marketers of 'Vision Improvement' App with Deceptive Claims, Press Release, September 17, 2015, available at <a href="https://www.ftc.gov/newsevents/press-releases/2015/09/ftc-charges-marketers-visionimprovement-app-deceptive-claims">https://www.ftc.gov/newsevents/press-releases/2015/09/ftc-charges-marketers-visionimprovement-app-deceptive-claims</a>> (last visited February 26, 2020).
- 58. Federal Trade Commission, FTC Approves Final Order Prohibiting 'Ultimeyes' Manufacturer from Making Deceptive Claims that the App Can Improve Users' Vision, Press Release, February 23, 2016, available at <a href="https://www.ftc.gov/news-events/">https://www.ftc.gov/news-events/</a> press-releases/2016/02/ftc-approves-final-order-prohibitingultimeyes-manufacturer> (last visited February 26, 2020); Decision and Order, In the matter of Carrot Neurotechnology, Inc., Adam Goldberg, and Aaron Seitz, FTC File No. 142-3132, available at <a href="https://www.ftc.gov/system/files/documents/">https://www.ftc.gov/system/files/documents/</a> cases/160223carrotneurodo.pdf> (last visited February 26, 2020).
- M.K. Ohlhausen, Commissioner, "Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Carrot Neurotechnology, Inc., Matter No. 1423132," February 23, 2016, available at <a href="https://www.ftc.gov/system/files/documents/public\_statements/922213/160223carrotneurostatem">https://www.ftc.gov/system/files/documents/public\_statements/922213/160223carrotneurostatem ent.pdf> (last visited February 26, 2020).</a>
- 60. Federal Trade Commission, Lumosity to Pay \$2 Million to Settle FTC Deceptive Advertising Charges for Its "Brain Training" Program: Company Claimed Program Would Sharpen Performance in Everyday Life and Protect Against Cognitive Decline, Press Release, January 5, 2016, available at <a href="https://www.ftc.gov/news-events/press-releases/2016/01/lumositypay-2-million-settle-ftc-deceptive-advertising-charges">https://www.ftc.gov/news-events/press-releases/2016/01/lumositypay-2-million-settle-ftc-deceptive-advertising-charges</a> (last visited February 26, 2020).
- 61. FTC v. Lumos Labs, Inc., a corporation, d/b/a Lumosity, and Kunal Sarkar and Michael Scanlon, FTC File No. 132-3212.
- 62. See Federal Trade Commission, *supra* note 60; Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief, *available at* <a href="https://www.ftc.gov/system/files/documents/cases/160105lumoslabsstip.pdf">https://www.ftc.gov/system/files/documents/cases/160105lumoslabsstip.pdf</a>> (last visited February 26, 2020).
- 63. J. Brill, Commissioner, "Concurring Statement of Commissioner Julie Brill in the Matter of Lumos Lab, Inc. ("Lumosity", Kunal Sarkar, and Michael Scanlon," January 5, 2016, available at <a href="https://www.ftc.gov/public-statements/2016/01/concurring-statement-commissioner-julie-brill-matter-lumoslab-inc">https://www.ftc.gov/public-statements/2016/01/concurring-statement-commissioner-julie-brill-matter-lumoslab-inc> (last visited February 26, 2020).</a>
- 64. See Commissioners, Chairwomen and Chairmen of the Federal Trade Commission November 2018, available at <a href="https://www.ftc.gov/system/files/attachments/commissioners/commissioner\_chart\_november\_2018\_0.pdf">https://www.ftc.gov/system/files/attachments/commissioners/commissioner\_chart\_november\_2018\_0.pdf</a>> (last visited February 26, 2020).
- 65. Federal Trade Commission, Marketers of Blood-Pressure App Settle FTC Charges Regarding Accuracy of App Readings, Press Release, December 12, 2016, available at <a href="https://www.ftc.gov/news-events/press-releases/2016/12/marketers-blood-pressure-app-settle-ftc-charges-regardings">https://www.ftc.gov/news-events/press-releases/2016/12/marketers-blood-pressure-app-settle-ftc-charges-regardings</a> (last visited February 26, 2020).
- 66. Id.
- 67. Complaint for Permanent Injunction and Other Equitable Relief, Federal Trade Commission v. Aura Labs, Inc., a corporation, also d/b/a AuraLife and AuraWare, and Ryan Archdeacon, individually and as an officer of Aura Labs, Inc., FTC File No. 152-3150, available at <a href="https://www.ftc.gov/system/files/documents/cases/161212\_aura\_labs\_complaint.pdf">https://www.ftc.gov/system/files/documents/cases/161212\_aura\_labs\_complaint.pdf</a> (last visited February 26, 2020).
- 68. Order for Permanent Injunction and Monetary Judgment, Federal Trade Commission v. Aura Labs, Inc., a corporation, also d/b/a AuraLife and AuraWare, and Ryan Archdeacon, individually and as an officer of Aura Labs, Inc., FTC File No. 152-3150, available at <a href="https://www.ftc.gov/system/files/doc-">https://www.ftc.gov/system/files/doc-</a>

uments/cases/161212\_aura\_labs\_final\_order.pdf> (last visited February 26, 2020).

- 69. Federal Trade Commission, 'Breathometer' Marketers Settle FTC Charges of Misrepresenting Ability to Accurately Measure Users' Blood Alcohol Content: Pitched on TV's "Shark Tank," the App-Supported Smartphone Devices Targeted Consumers Who Wanted to Make Smart Driving Decisions after Drinking, Press Release, January 23, 2017, available at <a href="https://www.ftc.gov/news-events/press-releases/2017/01/breathometer-marketers-settle-ftc-charges-misrepresenting-ability">https:// www.ftc.gov/news-events/press-releases/2017/01/breathometer-marketers-settle-ftc-charges-misrepresenting-ability> (last visited February 26, 2020).
- 70. Id.
- 71. Id.
- 72. Id.
- 73. Stipulated Final Order for Permanent Injunction and Other Equitable Relief, FTC v. Breathometer, Inc. and Charles Michael Yim, individually and as Chief Executive Officer of Breathometer, Inc., FTC File No. 162-3057, available at <a href="https://www.ftc.gov/system/files/documents/cases/170123breathometer\_dkt.\_4-1\_-\_stipulated\_order.pdf">https://www.ftc.gov/system/files/documents/cases/170123breathometer\_ dkt.\_4-1\_-\_stipulated\_order.pdf</a>> (last visited February 26, 2020).
- M.K. Ohlhausen, Commissioner, "Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Breathometer, Inc., Matter No. 1623057," January 18, 2017, available at <a href="https://www.ftc.gov/system/files/documents/public\_statements/1054953/170123breathometerohlhausenstate">https://www.ftc.gov/system/files/documents/public\_statements/1054953/170123breathometerohlhausenstate</a> ment.pdf> (last visited February 26, 2020).
- 75. See Commissioners, Chairwomen and Chairmen of the Federal Trade Commission November 2018, available at <https://www.ftc.gov/system/files/attachments/commissioners/commissioner\_chart\_november\_2018\_0.pdf> (last visited February 26, 2020); and Federal Trade Commission, Mobile App Settles FTC Allegations That It Failed to Deliver Promised Cash Rewards for Meeting Exercise and Diet Goals: Operators of Pact App to Pay More Than \$940,000 in Settlement, Press Release, September 21, 2017, available at <https://www.ftc.gov/news-events/press-releases/2017/09/mobile-app-settlesftc-allegations-it-failed-deliver-promised> (last visited February 26, 2020).
- Federal Trade Commission v. Pact, Inc.; Yifan Zhang, individually and as an officer of Pact, Inc.; and Geoffrey Oberhofer, Individually and as an Officer of Pact, Inc., FTC File No. 152-3010, (September 21, 2017).
- 77. See Federal Trade Commission, Press Release, *supra*, note 75. 78. *Id*.
- 79. Complaint for Permanent Injunction and Other Equitable Relief, FTC v. Pact Inc., Yifan Zhang, individually and as an officer of Pact Inc., and Geoffrey Oberhofer, individually and as an officer of Pact, Inc., FTC File No. 152-3010, available at <a href="https://www.ftc.gov/system/files/documents/cases/1523010pactcomplaint.pdf">https://www.ftc.gov/system/files/documents/cases/ 1523010pactcomplaint.pdf</a>> (last visited February 26, 2020).
- Stipulation and Proposed Order for Permanent Injunction and Monetary Judgment, FTC v. Pact Inc., Yifan Zhang, Individually and as an Officer of Pact Inc., and Geoffrey Oberhofer, Individually and as an Officer of Pact, Inc., FTC File No. 152-3010, available at <a href="https://www.ftc.gov/system/files/documents/cases/1523010pactstiporderjudgment.pdf">https://www.ftc.gov/system/files/documents/cases/1523010pactstiporderjudgment.pdf</a>> (last visited February 26, 2020).
- See, e.g., Federal Trade Commission, "Office of Technology Research and Investigation: Related Enforcement," *available at* <a href="https://www.ftc.gov/node/799871">https://www.ftc.gov/node/799871</a> (last visited February 26, 2020).
- 82. C. Kang, "The Man Deciding Facebook's Fate," New York Times, March 8, 2019, available at <htps://www.nytimes. com/2019/03/08/technology/ftc-facebook-joseph-simons. html/> (last visited February 26, 2020) (quoting Chairman Simons as saying, "In antitrust, you want to focus on areas where there is likely to be market power or monopology power...So it is not unreasonable to look at big digital platforms and say, well, that might be an ripe area to look at.").
- 83. See supra note 35. See also, Federal Trade Commission, FTC Releases Staff Perspective Examining Informational Injuries,

Press Release, October 19, 2018, available at <a href="https://www.">https://www.</a> ftc.gov/news-events/press-releases/2018/10/ftc-releases-staffperspective-examining-informational-injuries> (last visited February 26, 2020); L. Andrews, "A New Privacy Paradigm in the Age of Apps," Wake Forest Law Review (2018): 421-477 (finding "egregious practices" regarding diabetes and psychiatry mHealth apps that at the very least would garner FTC's attention for misrepresentations if there are inconsistencies between data sharing and privacy policies, at 447-449); N.P. Terry, "Appification, AI, and Healthcare's New Iron Triangle," Journal of Health Care Law and Policy 20 (2018): 117-180 (underscoring, "Big data brokers have been voracious consumers of healthcare data", at 156). For general signs that anti-trust activities are possibly on the horizon, see, e.g., Federal Trade Commission, FTC Charges Surescripts with Illegal Monopolization of E-Prescription Markets, Press Release, April 24, 2019, available at <a href="https://www.ftc.gov/news-events/press-">https://www.ftc.gov/news-events/press-</a> releases/2019/04/ftc-charges-surescripts-illegal-monopolization-e-prescription> (last visited February 26, 2020); J.D. McKinnon and J.V. Grimaldi, "Justice Department, FTC Skirmish Over Antitrust Turf," Wall Street Journal, August 5, 2019, available at <https://www.wsj.com/articles/justice-department-ftc-skirmish-over-antitrust-turf-11564997402> (last visited February 26, 2020); T. Syrett, "The FTC's Qualcamm Case Reveals Concerning Divide with DOJ on Patent Hold-Up," June 28, 2019, IP Watchdog, available at <a href="https://www.">https://www.</a> ipwatchdog.com/2019/06/28/ftcs-qualcomm-case-revealsconcerning-divide-doj-patent-hold/id=110764/> (last visited February 26, 2020); M. Isaac and N. Singer, "Facebook Antitrust Inquiry Shows Big Tech's Freewheeling Era Is Past," New York Times, July 24, 2019, available at <a href="https://www.nytimes">https://www.nytimes</a>. com/2019/07/24/technology/facebook-ftc-antitrust-investigation.html> (last visited February 26, 2020); A. Durkee, "Huge Group of States Considering Antitrust Probe of Facebook, Google, Amazon, and Apple," *Vanity Fair*, August 20, 2019, available at <https://www.vanityfair.com/news/2019/08/ tech-antitrust-investigation-state-attorney-general> (last visited February 26, 2020); and D. Wakabayashi, K. Benner, and S. Lohr, "Justice Department Opens Antitrust Review of Big Tech Companies," New York Times, July 23, 2019, available at <https://www.nytimes.com/2019/07/23/technology/justicedepartment-tech-antitrust.html?module=inline> (last visited February 26, 2020).

- See, e.g., J.A. Eisenach and I. Knable Gotts, "Looking Ahead: The FTC's Role in Information Technology Markets," George Washington Law Review 83 (2015): 1876-1901 (explaining how the FCC's authority converges with the FTC's in the "internet ecosystem" and warning of an expanded FCC role in net neutrality and information technology markets as potentially limiting the FTC); and L. Fair, "FTC-FDA warning letters: Influential to influencers and marketers," FTC Business Blog, June 7, 2019, available at <a href="https://www.ftc.gov/news-">https://www.ftc.gov/news-</a> events/blogs/business-blog/2019/06/ftc-fda-warning-lettersinfluential-influencers-marketers> (last visited February 26, 2020) (reporting on the FTC and FDA jointly sending warning letters to companies regarding their endorsement-related responsibilities implicated by social media influencers of their brands). See also, generally, P. Ross and D. Vorhaus, "mHealth on the Horizon: Federal Agencies Paint Regulatory Landscape with Broad Brushstrokes," Genomics Law Report, December 5, 2012, available at <a href="https://theprivacyreport.com/2012/12/05/">https://theprivacyreport.com/2012/12/05/</a> mhealth-on-the-horizon-federal-agencies-paint-regulatorylandscape-with-broad-brushstrokes/> (last visited February 26, 2020).
- 85. Federal Trade Commission (in cooperation with the U.S. Department of Health & Human Services (HHS): the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the Food and Drug Administration (FDA), "Mobile Health Apps Interactive Tool," April 2016, available at <a href="https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool">https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool</a> (last visited February 26, 2020).

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- Federal Trade Commission, "Mobile Health App Developers: FTC Best Practices," Guidance, April 2016, available at <a href="https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices">https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices</a> (last visited February 26, 2020).
- 87. Federal Trade Commission, "Protecting Consumer Privacy in an Era of Rapid Change: A Proposed Framework for Businesses and Policymakers," Preliminary FTC Staff Report, December 2010, available at <a href="https://www.ftc.gov/reports/">https://www.ftc.gov/reports/</a> preliminary-ftc-staff-report-protecting-consumer-privacy-erarapid-change-proposed-framework> (last visited February 26, 2020); Federal Trade Commission, "Protecting Consumer Privacy in an Era of Rapid Change: Recommendations for Businesses and Policymakers," FTC Report, March 2012, available at <https://www.ftc.gov/reports/protecting-consumer-privacy-era-rapid-change-recommendations-businesses-policymakers> (last visited February 26, 2020); Federal Trade Commission, "Mobile Privacy Disclosures: Building Trust Through Transparency," FTC Staff Report, February 2013, available at <https://www.ftc.gov/reports/mobile-privacy-disclosures-building-trust-through-transparency-federal-tradecommission> (last visited February 26, 2020); Federal Trade Commission, "Data Brokers: A Call for Transparency and Accountability," FTC Report, May 2014, available at <a href="https://">https://</a> www.ftc.gov/reports/data-brokers-call-transparency-accountability-report-federal-trade-commission-may-2014> (last visited February 26, 2020); Federal Trade Commission, "Careful Connections: Building Security in the Internet of Things," Guidance, January 2015, available at <a href="https://www.ftc.gov/">https://www.ftc.gov/</a> system/files/documents/plain-language/pdf0199-carefulconnections-buildingsecurityinternetofthings.pdf> (last visited February 26, 2020); Federal Trade Commission, "Big Data: A Tool for Inclusion or Exclusion? Understanding the Issues," FTC Report, January 2016, available at <a href="https://www.ftc.gov/">https://www.ftc.gov/</a> reports/big-data-tool-inclusion-or-exclusion-understandingissues-ftc-report> (last visited February 26, 2020); and Federal Trade Commission, "The Sharing Economy: Issues Facing Platforms, Participants & Regulators," FTC Staff Report, November 2016, available at <a href="https://www.ftc.gov/reports/">https://www.ftc.gov/reports/</a> sharing-economy-issues-facing-platforms-participants-regulators-federal-trade-commission> (last visited February 26, 2020).
- Federal Trade Commission, "Hearings on Competition and Consumer Protection in the 21st Century," *available at* <a href="https://www.ftc.gov/policy/hearings-competition-consumer-protection">https://www.ftc.gov/policy/hearings-competition-consumer-protection</a>> (last visited February 26, 2020).
- See Yakus v. United States, 321 U.S. 414, 425, 64 S.Ct. 660, 668 (1944).
- 90. FTC v. R.F.Keppel & Bro., 291 U.S. 304, 314, 54 S.Ct. 423, 427 (1934); Sperry, supra, note 23.
- FTC, "FTC Chief Technologists," *available at* <a href="https://www.ftc.gov/about-ftc/biographies/ftc-chief-technologist">https://www.ftc.gov/about-ftc/biographies/ftc-chief-technologist</a>> (last visited February 26, 2020).
- 92. R. Chopra and R.K. Slaughter, Commissioners, "Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter: Federal Trade Commission Reprot on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes," June 24, 2019, available at <https://www.ftc.gov/system/ files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101\_ section\_5\_report\_dissenting\_statement\_by\_chopra\_and\_ slaughter\_6-27-19.pdf> (last visited February 26, 2020) (quoting Fed. Trade Comm'n v. Cement Inst., 333 U.S. 683, 693, (1948)).

- 93. See, e.g., M. Wood, "The FTC Has No Chief Technologist as It Weighs Big Tech Investigations," *Marketplace Tech*, April 2, 2019, *available at* <a href="https://www.marketplace.org/2019/04/02/should-we-care-ftc-doesnt-have-chief-technologist/> (last visited February 26, 2020).</a>
- 94. Office of Technology Research and Innovation, available at <https://www.ftc.gov/about-ftc/bureaus-offices/bureau-con-sumer-protection/office-technology-research-investigation> (last visited February 26, 2020), which was last updated April 25, 2018; Tech@FTC, available at <https://www.ftc.gov/ news-events/blogs/techftc> (last visited February 26, 2020), which last post was dated April 12, 2018.
- 95. House Committee on Energy and Commerce Staff, "Memorandum to the Subcommittee on Consumer Protection and Commerce Members and Staff," May 3, 2019, at 4, *available at* <a href="https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FTC%20Oversight%20">https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FTC%20Oversight%20</a> Memo%20050319.pdf> (last visited February 26, 2020).
- 96. United States Cong. House. Subcommittee on Consumer Protection and Commerce of the Committee on Energy and Commerce, Hearing on 'Oversight of the Federal Trade Commission: Strengthening Protections for Americans' Privacy and Data Security, May 8, 2019. Washington, DC, Materials are available at <a href="https://energycommerce.house.gov/committee-activity/hearings/hearing-on-oversight-of-the-federal-trade-commission-strengthenings">https://energycommerce.house.gov/committee-activity/hearings/hearing-on-oversight-of-the-federal-trade-commission-strengthenings</a> (last visited February 26, 2020).
- 97. FTC, "Prepared Statement of the Federal Trade Commission on 'Legislative Hearing on 17 FTC Bills' Before the Committee on Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade on May 24, 2016," available at <a href="https://www.ftc.gov/system/files/documents/public\_statements/9504-03/160524commtestimony-17-bills.pdf">https://www.ftc.gov/system/files/documents/public\_statements/9504-03/160524commtestimony-17-bills.pdf</a>> (Last visited February 26, 2020).
- 98. E.g., C.J. Hoofnagle, W. Hartzog, and D. Solove, "The FTC Can Rise to the Privacy Challenge, but Not without Help from Congress," *Brookings*, August 8, 2019, *available at* <a href="https://www-brookings-edu.cdn.ampproject.org/c/s/www.brookings.edu/blog/techtank/2019/08/08/the-ftc-can-rise-to-the-privacy-challenge-but-not-without-help-from-congress/amp/> (last visited February 26, 2020).
- See, e.g., M. Sohoni, "Opinion Analysis: Court Refuses to Res-99. urrect Nondelegation Doctrine," SCOTUSblog, June 20, 2019, available at <a href="https://www.scotusblog.com/2019/06/opinion-">https://www.scotusblog.com/2019/06/opinion-</a> analysis-court-refuses-to-resurrect-nondelegation-doctrine/> (last visited February 26, 2020); M.J. Stern, The Supreme Court's Conservatives are Ready to Take a Wrecking Ball to the Entire Federal Bureaucracy, Slate, June 20, 2019, available at <https://slate.com/news-and-politics/2019/06/neil-gorsuchsupreme-court-conservatives-gundy-sex-offender.html> (last visited February 26, 3030); E. Zoldan, "Gundy v. United States: A Peek into the Future of Government Regulation," The Hill, June 21, 2019, available at <a href="https://thehill.com/">https://thehill.com/</a> opinion/judiciary/449687-gundy-v-united-states-a-peek-intothe-future-of-government-regulation> (last visited February 26, 2020); K.E. Hickman, "Gundy, Nondelegation, and Never-Ending Hope," The Regulatory Review, July 8, 2019, available at <https://www.theregreview.org/2019/07/08/hickman-nondelegation/> (last visited February 26, 2020).
- 100. See, e.g., National Consumer Law Center, "Consumer Protection in the States: A 50-State Evaluation of Unfair and Deceptive Practice Laws," March 2018, *available at* <a href="http://www.nclc.org/issues/how-well-do-states-protect-consumers.html">http://www.nclc.org/issues/how-well-do-states-protect-consumers.html</a> (last visited February 26, 2020).