I. Introduction

Consumers laud commercial weight loss programs for their convenience, ease of use, and expansive support networks.\(^1\) Weight loss programs have facilitated countless personal transformations and are even more accessible to consumers now that they are available as smartphone applications.\(^2\) People who are unable to attend in-person meetings or purchase special foods and cookbooks can now join the consumer weight loss movement without spending time or money in the process.\(^3\) Perhaps more significantly, those who are too uncomfortable or ashamed to publicly seek help with weight loss can do so anonymously behind a screen.\(^4\) However, as with other spheres

\(\)
of the internet, the shield of anonymity attracts unintended users of the programs—particularly people who are at healthy or below-average weights.\(^5\) Currently, most mobile weight loss applications lack user verification mechanisms, so people can falsely report their weights in order to receive a more strenuous weight loss program than they would be recommended based on their actual weights.

The internet and mobile phone applications are havens for people who wish to misrepresent their identities and access platforms that are not intended for them; there is even a term in the dictionary for the practice of using social media profiles to deceive others—catfishing.\(^6\) While many websites take precautions against user misrepresentation such as requiring users to provide a form of photo identification to verify their identities, most websites and mobile applications have no barriers to use and trust users’ self-identifications.\(^7\) Users who put themselves at risk or others at risk can easily take advantage of the anonymity and the honor system that most websites rely on.\(^8\) Mobile Weight loss applications often accept users’

\(^5\) See Elizabeth V. Eikey et al., Desire to be Underweight: Exploratory Study on a Weight Loss App Community and User Perceptions of the Impact on Disordered Eating Behaviors, 5 J. M. D. Internet Res. 1, 1 (Oct. 12, 2017) [hereinafter Desire to be Underweight] (finding that “6.78 percent of the community” of weight loss application users want to be underweight).

\(^6\) See Lauren Reichart Smith et al., Follow Me, What’s the Harm? Considerations of Catfishing and Utilizing Fake Online Personas on Social Media, 27 J. Legal Aspects of Sport 32, 33 (2017) (describing the practice of people creating false identities to deceive others using social media websites). Anyone can create an online profile using false information, such as an inaccurate age, geographical location, educational information, and even photographs of other people. Id.; see also Catfish, MERRIAM-WEBSTER (11th ed. 2014) (defining catfishing as “to deceive [someone] by creating a false personal profile online”).

\(^7\) See What types of ID does Facebook accept?, FACEBOOK (Oct. 20, 2018), archived at https://perma.cc/UH2C-WSS3 (listing different forms of identification that Facebook accepts from users to confirm their names or regain access to their accounts such as passports, driver’s licenses, and voter identification cards); see also Aatif Sulleyman, PAEDOPHILES CAN TARGET CHILDREN THROUGH ‘TINDER FOR TEENS’ APP, WARN POLICE, INDEPENDENT (Apr. 12, 2017), archived at https://perma.cc/6Z6K-UXFE (describing a dating app aimed at teenagers and how adults can access the app and pose as teenagers).

\(^8\) See Sulleyman, supra note 7 (explaining how easy it is for adults to create deceptive profiles on social media platforms intended for use by children); see also Srini Pillay, The Dangers of Self Diagnosis, PSYCHOLOGY TODAY (May 3, 2010), archived at https://perma.cc/J792-WLT3 (warning laypeople of the harmful consequences of
self-reported weights and do not require evidence to authenticate them, which allows individuals of healthy or below-average weights to use the applications to facilitate unhealthy weight loss and encourage other people of healthy or below-average weights to do the same.\footnote{See Alice Gregory, \textit{Hunger Games}, \textit{The New Republic} (Dec. 18, 2013), archived at https://perma.cc/7Q47-9WFR (detailing the acceleration of one woman’s eating disorder through her use of a mobile weight loss application to count and log the number of calories she consumed each day); see also Amy Iverson, \textit{Some people are using apps to promote eating disorders}, \textit{Herald Mail Media} (Nov. 7, 2018), archived at http://perma.cc/QMY7-BTWC (evaluating how people with eating disorders use weight loss applications to facilitate disordered eating behavior and to support each other in their such behaviors).} Mobile weight loss application developers can most easily gain users if they have loose regulations and therefore low accountability for people who use or want to use their websites.

This note will argue that FDA needs to hold mobile weight loss application developers to a higher standard. Instead of merely suggesting healthy goals and allowing users to input their starting weights and goal weights, application developers need to require evidence that verifies users’ starting weights and prevent the use of their applications to facilitate disordered eating. The Food and Drug Administration (“FDA”) regulates weight loss supplements and technology.\footnote{See What We Do, U.S. Food & Drug Admin. (Mar. 28, 2018), archived at https://perma.cc/C3FW-NTJX (stating that the FDA “is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices”).} This note explains why FDA should do the same for using the internet for self-diagnoses of medical conditions); see also Tom Pettifor, \textit{Facebook sex crimes soar: Offences via social networks more than quadruple in the last four years}, \textit{Mirror} (Apr. 1, 2013), archived at https://perma.cc/R2CX-SBT4 (citing a study that found the number of sex offenses in which social media played a role more than quadrupled between 2009 and 2013). Social media allows sexual predators to disguise themselves in order to gain the trust of their victims before they meet in person. \textit{See Sulleyman, supra note 7; see also Bonnie Rochman, \textit{For Teens Who Cut, Going Online Can Sometimes Help}, \textit{TIME} (Feb. 23, 2011), archived at https://perma.cc/N9LW-KTZ7 (expounding the practice of posting photos and tutorials of self-harm on websites and social media platforms that minors can easily access). A quick online search can reveal hundreds of ways for one to harm himself, and some of these websites are even designed to elude regulation from internet providers. See Rochman, supra.}
mobile weight loss applications by implementing standards for authentication of users’ self-reported weights. The FDA’s selective enforcement of its mobile application regulations only harms the American people, particularly in light of the prevalence of both eating disorders and obesity in the United States. Preventing self-destructive use of mobile weight loss applications will protect people who are vulnerable to disordered eating while maintaining the integrity of weight loss programs and their utility for their intended users.

II. History

A. The United States Food and Drug Administration

The United States Food and Drug Administration (hereinafter FDA) has existed and evolved since the late nineteenth century, despite undergoing several name changes.\(^\text{11}\) In 1862, the United States Department of Agriculture was created.\(^\text{12}\) It became the Department of Chemistry in 1890 and was later re-named the Bureau of Chemistry.\(^\text{13}\) Harvey Washington Wiley, the chief chemist at the

\(^{11}\) See History of FDA’s Internal Organization, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), archived at https://perma.cc/NNN2-8DKQ (chronicling the evolution of the FDA from 1837, when Patent Commissioner Henry L. Ellsworth called for an agency to regulate agriculture to its time as the Department of Agriculture, the Bureau of Chemistry, and ultimately the United States Food and Drug Administration); see also WALLACE F. JANSSEN, THE STORY OF THE LAWS BEHIND THE LABELS, U.S. FOOD & DRUG ADMIN. CONSUMER MAG. 1, 1 (June 1981) (explaining how the FDA evolved over time to reflect changing agricultural practices, food science, and public concerns).

\(^{12}\) See JANSSEN, supra note 11 (detailing the origin of the Department of Agriculture to encourage and to regulate agricultural development). The Department of Agriculture’s first project was a study of wine-making processes and the quality of the wine that each process creates. Id. The Department of Agriculture went on to study soil grades, food conditions, and agricultural practices. Id.

\(^{13}\) See History of the FDA’s Internal Organization, supra note 11 (outlining the transition from the Department of Agriculture to the Department of Chemistry and finally the Bureau of Chemistry); see also Early Work of the Bureau of Chemistry Drug Lab, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), archived at https://perma.cc/D8BW-Q387 (explaining that the Bureau of Chemistry enforced the 1906 Pure Food and Drug Act, particularly by inspecting drugs and synthetic products). The Bureau of Chemistry consisted of four laboratories: the Drug Inspection Laboratory, the Synthetic Products Laboratory, the Essential Oils
Bureau of Chemistry, promoted federal public health protection and advocated for the passage of the 1906 Pure Food and Drug Act (also known as the Wiley Act). The Act aimed to prevent “the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” The Bureau of Chemistry became the United States Food, Drug, and Insecticide Administration in 1927 and then finally the United States Food and Drug Administration in 1930, which it is still known as today.

In its early years, the FDA regulated agricultural practices, food safety, and drug purity. The passage of the Federal Food, Drug, and Cosmetic Act in 1938 brought the approval of new drugs and medical devices into the purview of the FDA. The FDA reviews Laboratory, and the Pharmacological Laboratory. See Early Work of the Bureau of Chemistry Drug Lab, supra.

14 See When and why was FDA formed?, U.S. FOOD & DRUG ADMIN. (Aug. 22, 2018), archived at https://perma.cc/8QX3-PTAU (highlighting Wiley’s involvement in the transition from the Bureau of Chemistry to a federal consumer protection agency that eventually became the FDA). Wiley and the Bureau of Chemistry were galvanized by infamously insanitary conditions in Chicago stockyards. Id.

15 See Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (describing the goals of the Pure Food and Drugs Act, which were primarily to regulate adulterated or misbranded foods, drugs, and alcoholic beverages in the United States and imported and exported to and from the United States).

16 See JANSSEN, supra note 11 (providing a history of how the FDA evolved over time to meet the needs of the American people and to regulate public health issues as they arose). The FDA first focused on the quality and quantity of agricultural output, then food preservation, drug purity, the pure food movement, and eventually medical technology. Id.

17 See JANSSEN, supra note 11 (reciting the FDA’s major acts and priorities from its inception to the 1870s).

18 See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(b) (1938) (barring adulterated or misbranded food, drugs, devices, and cosmetics from interstate commerce and requiring FDA pre-market approval for all new drugs and medical devices). See also Is The Product A Medical Device?, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), archived at https://perma.cc/AP42-TQZR (distinguishing which medical devices the FDA can regulate). The FDA defines medical devices as follows:
these items to ensure that they are safe for the public and they provide features that are more beneficial than detrimental to consumers. For

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar and related to this article, including a component part, or accessory which is:
1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. Intended for use in the diagnosis of disease or treatment of other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. Intended to affect the structure or function of the body of man or other animals, and
   which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id.

19 See Development & Approval Process (Drugs), U.S. FOOD & DRUG ADMIN. (June 13, 2018), archived at https://perma.cc/7TYD-85C9 (outlining the FDA’s approval process for and standards for new drugs). See also Device Approvals, Denials, and Clearances, U.S. FOOD & DRUG ADMIN. (Mar. 26, 2018), archived at https://perma.cc/Q8D3-LH4X (summarizing the FDA’s standards for approving medical devices and its four methods for medical devices to obtain FDA approval). The FDA’s 510(k) device clearance process relies on a device’s safety, efficacy, and being substantially equivalent to a legally marketed device. Id. Premarket approval is predicated on a determination that the device’s safety and efficiency have been scientifically proven. Id. Although less common, the humanitarian device exemption is allocated to devices that treat or diagnose ailments that affect a small fraction of the population. Id. Finally, de novo approval is reserved for novel, low-risk devices that can be the basis for later 510(k) approvals. Id. See also FDA approves ApsireAssist obesity device, U.S. FOOD & DRUG ADMIN. (June 14, 2016), archived at https://perma.cc/D6EH-YEA6 (illustrating uses for the AspireAssist and how it works to “drain a portion of the stomach contents after every meal”). The FDA specifies that AspireAssist should be used by “patients aged 22 and older who are obese, with a body mass index of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy,” and not by patients who have eating disorders. Id.; see also Nicholas T. Bello & Bryn L. Yeomans Sachdeo, Safety of pharmacotherapy options for bulimia nervosa and binge eating disorder, 17 EXPERT OPINION ON DRUG SAFETY 17, 18–19 (2017) (explaining that the FDA approved fluoxetine for the treatment of bulimia nervosa and lisdexamfetamine for the treatment of binge eating disorder); Weight-Loss and Weight-Management Devices, U.S. FOOD & DRUG ADMIN. (July 22, 2019), archived at https://perma.cc/Y9UB-QBW3 (listing different types and examples of FDA-approved devices for the treatment of obesity).
example, FDA has approved five weight loss medications for long-
term use, each of which has been proven to help patients lose
substantial amounts of weight: bupropion-naltrexone, liraglutide,
lorcaserin, orlistat, and phentermine-topiramate. As for medical
devices, many gain FDA approval based on substantial equivalence to
other devices that are already FDA-approved, although critics fear that
the FDA takes an overly liberal approach to this approval method.

B. Mobile Health Applications

In 2007, Apple released the first iPhone, which revolutionized
the concept of the mobile phone. With its touch screen, two-
megapixel camera, and most importantly its array of mobile
applications, the iPhone was a modern marvel. Mobile applications,
 compartmentalized software programs that users can access on their
smartphones, are now available on several platforms including Apple,
Google, and Android. As smartphones have become standard fare
for consumers, mobile applications have come to influence every

20 See Prescription weight-loss drugs, MAYO CLINIC (Sept. 18, 2018), archived at
https://perma.cc/3BW8-Q68D (outlining the different FDA-approved weight loss
medications and explaining that people can only be candidates for taking weight loss
medication when their body mass indices (BMIs) are “greater than 30” or “greater
than 27 and you have a serious medical problem related to obesity, such as diabetes
or high blood pressure”).
21 See THE BLEEDING EDGE (Netflix 2018) (delving into medical histories of patients
harmed by FDA-approved medical devices and criticizing the FDA’s 510(k) device
approval process and the leeway it gives to devices that are considered substantially
equivalent to previously approved devices). Substantial evidence signifies that a new
device is at least as safe and effective as a similar device that is already FDA-
approved. Id.
22 See Apple Reinvents the Phone with the iPhone, APPLE (Jan. 9, 2007), archived at
https://perma.cc/WZ7Z-FZ7N (announcing the release of the first-ever iPhone,
which Apple created in order to transform the mobile phone industry, combine the
iPod with a cell-phone, and bring touch screens to consumers).
23 See id. (listing the most innovative features of the iPhone including visual
voicemail, a QWERTY keyboard, and a built-in iPod).
24 See Marziah Karch, A Beginner’s Guide to Apps, LIFEWIRE (June 24, 2019),
archived at https://perma.cc/J3CF-YZKD (introducing types of applications,
different forms of applications, and examples of applications).
aspect of life – from travel to hiring service professionals and grocery shopping.\textsuperscript{25} In 2010, Apple obtained a trademark for the phrase “there’s an app for that,” which they have used in marketing to underscore the universality of mobile applications and the wide range of features that applications provide on Apple’s iPhones.\textsuperscript{26} Smartphones and mobile applications are so central to users’ daily lives that scientists question whether there is a downside to them and study the negative effects of smartphone addiction, which include difficulty sleeping, separation anxiety from one’s device, and cell phone use while driving, which has led to several fatalities.\textsuperscript{27}

As early as 2010, consumers used their mobile phones to seek guidance for health issues.\textsuperscript{28} By 2012, over half of smartphone users sought health information on their cell phones and nineteen percent (19\%) of smartphone owners had at least one mobile health application on their phones.\textsuperscript{29} As of 2018, there were more than 300,000 mobile health applications available to consumers.\textsuperscript{30} These applications take

\textsuperscript{25} See There’s an app for that, THE ECONOMIST (Dec. 30, 2014), archived at https://perma.cc/RH74-44M8 (evaluating the pervasiveness of mobile applications and their effect on the service industry).

\textsuperscript{26} See Doug Gross, Apple trademarks ‘There’s an app for that’, CNN (Oct. 12, 2010), archived at https://perma.cc/K4ZG-VVU4 (addressing the United States Patent and Trademark Office’s granting of Apple’s trademark for the phrase “there’s an app for that”).

\textsuperscript{27} See Sandee LaMotte, Smartphone addiction could be changing your brain, CNN (Dec. 1, 2017), archived at https://perma.cc/SPZ2-ENA3 (warning smartphone users of the dangerous effects of smartphone addiction, ranging from neck pains due to looking at one’s cell phone for too long to melatonin imbalances); see also Claire Pearson & Zaheer Hussain, Smartphone Use, Addiction, Narcissism, and Personality: A Mixed Methods Investigation, 5 INT’L J. OF CYBER BEHAV., PSYCHOL. & LEARNING 17, 27 (2015) (analyzing the roles of different personality traits such as narcissism as predictors of smartphone addiction and finding that some social media websites can be addicting).

\textsuperscript{28} See Susannah Fox & Maeve Duggan, Mobile Health 2012, PEW RES. CTR. (Nov. 8, 2012), archived at https://perma.cc/F5WQ-7A8G (reporting on the usage of cell phones for medical purposes such as searching for information and monitoring health conditions).

\textsuperscript{29} See id. (stating that 52\% of smartphone users gather health information on their phones and 19\% of smartphone owners have at least one health-related app on their phones).

\textsuperscript{30} See Dr. Kevin Hwang, Dangers of Defective Mobile Health Apps and Devices, VERYWELL HEALTH (Feb. 15, 2018), archived at https://perma.cc/3ZFG-94ZX (cautioning users of the dangers and limitations of mobile medical applications and pointing out that many of these applications have not been medically vetted).
many different forms, from medical terminology dictionaries, to portals for communication between patients and healthcare providers, and even diagnostic tools that can analyze lab tests.\textsuperscript{31}

Healthcare providers use mobile applications in practice to manage patient information, access diagnostic tools, update medical records, and communicate with patients.\textsuperscript{32} Nonetheless, as with most technology, mobile health applications are certainly flawed; application-based diagnoses can delay medical care, allowing medical conditions to escalate while patients are unaware of them.\textsuperscript{33} Conversely, mobile health applications have had massively positive effects on areas of healthcare such as doctor-patient communication, patient knowledge of symptomology, and the cost of care to patients.\textsuperscript{34} Patients express a preference for healthcare options that utilize mobile health applications because they can use them to access care anytime and anywhere.\textsuperscript{35} Mobile health applications most often treat diabetes, are mobile health applications that remind users to take their medication, contain basic information about different medical conditions, and facilitate communication with healthcare providers. \textit{Id.}


\textsuperscript{32} See C. Lee Ventola, \textit{Mobile Devices and Apps for Health Care Professionals: Uses and Benefits}, 39 PHARMACY & THERAPEUTICS 356, 359 (May 2014) (exploring different ways that healthcare professionals use mobile applications in their practices).

\textsuperscript{33} See McInerney, \textit{supra} note 31, at 1079 (observing the tendency of melanoma diagnosis applications to incorrectly classify melanomas as “unconcerning” and how such classifications delay medical care and considering the damages that result from reliance on faulty medical applications).


obesity, and depression, which are also some of the most prevalent health issues worldwide. Among mobile health applications for weight management, most center on physical activity, diet, or recording caloric intake and physical activity. Fitness applications often track users’ steps and exercise, heart rate, and sleep, sometimes with the aid of wearable technology such as smart watches and sometimes using only the smartphone to track these metrics.

Recently, the FDA recognized the need to monitor devices that can wirelessly transmit medical information and even released a guidance document on how it plans to regulate mobile medical and wellness applications. In its guidance document about mobile medical applications, the FDA declares its intent to all regulate mobile health applications.

36 See id. (listing the conditions that mobile health applications most commonly treat, analyzing the mobile health application market, and predicting the future of mobile health application features, launch costs, monetization, and appreciating the progress of the mobile health application market thus far).
37 See C. K. Nikolaou & M. E. J. Lean, Mobile Applications for Obesity and Weight Management: Current Market Characteristics, 41 INT’L. J. OF OBESITY 200, 202 (2017) (stating that thirty-four percent (34%) of weight management applications focus on physical activity, thirty-one percent (31%) on diet, and twenty-three percent (23%) on monitoring exercise, calorie intake and body weight).
38 See Brad Millington, A brief history (and look into the future) of fitness technology, THE CONVERSATION (Jan. 11, 2018), archived at https://perma.cc/4Q5Q-VFA8 (recalling the history of fitness technology and predicting future trends in fitness technology).
39 See 21st Century Cures Act, Pub. L. No. 114, § 3051, 130 Stat. 1033 (2016) (funding medical research, innovations, and programs that have become relevant in the 21st century); see also Public Workshop, U.S. Food & Drug Admin., Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Jan. 29, 2019) (representing the FDA’s position on how the medical technology industry should secure its wireless and internet-based healthcare technology); see also U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6–8 (Feb. 9, 2015) [hereinafter MOBILE MEDICAL APPLICATIONS] (acknowledging the progress of medical mobile applications and expounding upon how the FDA plans to regulate mobile medical applications). The FDA states that mobile medical applications are those which fit its definition of medical devices (which includes applications intended to be used to diagnose medical conditions, cure, mitigate, treat, or prevent disease, or affect the structure or function of the body) and are intended to be used as an accessory to a medical device or to transform a mobile platform into a regulated mobile device. MOBILE MEDICAL APPLICATIONS, supra. The FDA originally released this guidance document in 2013, when mobile medical applications first became a pervasive concern and amended it in 2015. Id. at 1.
medical applications that could risk patients’ health and safety if they malfunction.\textsuperscript{40} The FDA plans to apply its medical device classifications and approval processes to mobile health applications, except for those that help patients access information about their care or automate processes for healthcare providers.\textsuperscript{41} Applications with those functions circumvent FDA regulation, as the FDA considers them to have low potential to harm patients.\textsuperscript{42}

The FDA requires mobile medical applications to meet its Quality System Regulation (“QSR”) and Mobile Device Reporting (“MDR”) requirements.\textsuperscript{43} These requirements mandate that device

\textsuperscript{40} See MOBILE MEDICAL APPLICATIONS, supra note 39, at 4 (explaining that the FDA is responsible for any medical innovation that poses risks to patients and that mobile medical applications are part of that category). The FDA recommends that mobile applications abide by its quality systems regulations, including current good manufacturing practices. \textit{Id.} \textit{See also Quality System (QS) Regulation/Medical Device Good Manufacturing Practices}, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), archived at https://perma.cc/CHS7-WTKG (describing quality systems regulations as a system by which manufacturers exercise their own judgment as to which regulations apply to their devices and meet the relevant standards).

\textsuperscript{41} See MOBILE MEDICAL APPLICATIONS, supra note 39, at 13–18 (stating that the FDA intends to regulate mobile medical applications that serve as medical devices, extensions of medical devices, operate diagnostic or patient analysis software, or produce treatment recommendations).

\textsuperscript{42} See id. at 15–18 (indicating that applications that only organize, display, calculate, log, or convey information will not be subject to FDA regulation because they do not pose a serious risk of harm to patients).

\textsuperscript{43} See 21 C.F.R. § 803.1 (2014) (requiring medical device manufacturers to report “deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports”); \textit{see also} U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (Nov. 8, 2016) [hereinafter MEDICAL DEVICE REPORTING] (explaining that MDR regulations aim to “detect and correct problems in a timely manner”). MDR instructs mobile device manufacturers to create and enforce procedures for identifying medical device reportable events. MEDICAL DEVICE REPORTING, supra. Medical device reportable events are events that indicate that a particular medical device has or is likely to cause a death or serious injury or otherwise malfunction. \textit{Id.} at 2–3; MOBILE MEDICAL APPLICATIONS, supra note 39, at 34 (specifying how quality systems regulations must be applied to mobile medical applications).
and application manufacturers use current good manufacturing practices ("CGMP") to create their products and report any deaths or serious injuries to which their products may have contributed.44 Mobile medical application manufacturers are also subject to requests to correct their products from the FDA and are expected to regularly and voluntarily search their own products for any defects and correct any issues they find with their products.45

C. Commercial Weight Loss Programs

Commercial weight loss programs help participants limit their daily calorie intakes in order to lose weight.46 Sometimes, membership in these programs includes specific meal plans and prepackaged food, including liquid meal replacements.47 Weight Watchers, one of the most popular weight loss programs, began in the early 1960s when an overweight suburban housewife began hosting weekly meetings for her friends to discuss weight loss issues.48 In the age of diet pills, Weight Watchers offered a more natural way to lose weight.49 Weight Watchers prescribed a healthy diet, a modest daily

44 See 21 C.F.R. § 820.1(a)(1) (2015) (codifying current good manufacturing practice requirements, which govern the methods, facilities, and controls used for “the design, manufacturing, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use”); see also MOBILE MEDICAL APPLICATIONS, supra note 39, at 35 (stating that mobile medical applications must follow medical device reporting regulations, which involve implementing procedures to determine whether an event needs to be reported, investigating such events, and reporting them to the FDA when necessary).
45 See MOBILE MEDICAL APPLICATIONS, supra note 39, at 36 (detailing the responsibility of mobile medical application manufacturers to inspect, correct, and update their software on a regular basis and the FDA’s right to request for them to do so).
47 See id. (outlining some of the most common features included in commercial weight loss programs).
48 See Robert D. McFadden, Jean Nidetch, a Founder of Weight Watchers, Dies at 91, N.Y. TIMES (Apr. 29, 2015), archived at https://perma.cc/ZXX6-TCRM (articulating Jean Nidetch’s history and the history of Weight Watchers).
49 See Cohen et al., The Return of Rainbow Diet Pills, 102 AM. J. PUB. HEALTH 1676, 1680 (Sept. 2012) (documenting the history of rainbow diet pills and the FDA’s regulation of them); see also Frank Whittemore, The History of Diet Pills,
caloric intake, and weekly weigh-in meetings for members. Weight Watchers became a massive success, went public in 1968, and is still ranked as the top weight loss diet today.

Modern Weight Watchers (now WW) users choose between mobile application memberships, in-person memberships, or a combination of the two where users can log their food intake and their weight loss journeys and connect with other users. The WW mobile application assigns each user a specific amount of daily “smartpoints” to consume based on each user’s self-reported weight and weight loss goals. Users look up and record the foods they eat to find out the

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50 See McFadden, supra note 48 (citing the ideology of the Weight Watchers program, which includes group meetings for participants, community support, and a healthy and well-documented diet); see also Julie Davis Canter, Can the Weight Watchers Diet Actually Help You Lose Weight and Keep It Off?, EVERYDAY HEALTH (Jan. 2, 2018), archived at https://perma.cc/BMS4-4ARX (explaining how Weight Watchers uses a point system to value foods at different amounts, gives each person a daily point goal based on their weight and weight goals, and allows users to still eat their favorite foods).

51 See Katie Kindelan, Keto, Whole30 diets rank last on the best diets of 2018 list, ABC NEWS (Jan. 3, 2018), archived at https://perma.cc/95PE-6G76 (ranking several different diets and designating Weight Watchers as the best commercial diet).

52 See Homepage, WEIGHT WATCHERS (Jan. 12, 2019), archived at https://perma.cc/C3YS-5L9L (highlighting the features and different program options that Weight Watchers offers). See also Paul R. La Monica, Weight Watchers is changing its name to WW, CNN (Sept. 24, 2018), archived at https://perma.cc/K6U8-JPYL (describing Weight Watchers’s 2019 re-naming as aimed at refocusing its image on wellness, rather than weight loss); Sarah McCay, Weight Watchers Can Change Its Name—But for This Reformed Dieter, It Still Says “Thinner is Better,” VOGUE (Sept. 27, 2018), archived at https://perma.cc/CLD3-K9FD (noting that WW retained Weight Watchers’s focus on calorie counting and restriction).

53 See How SmartPoints Work, WEIGHT WATCHERS (Feb. 24, 2019), archived at https://perma.cc/6T8Y-L7H6 (explaining how WW delineates SmartPoints to different foods based on their nutritional values and how users can use the WW system to stay within their daily SmartPoint allocation).
point values of different foods. Once a user exhausts her daily point allocation, she may draw from a set of weekly points, exercise to offset the points she has consumed, or simply acquiesce to her “failure” to stay within the daily parameters that the application set for her. Other popular mobile weight loss applications include Lose it!, DietBet, MyFitnessPal, and Fitbit. These applications help users track their calorie consumption, progress toward weight goals, and exercise and give users calorie and exercise goals to meet to achieve their weight loss goals.

There are several ways for consumers to track their daily step count and log the food they eat throughout the day: some smartphones include these features, as do wearable fitness tracking devices. For instance, the Fitbit, a wearable fitness tracker, tracks physical activity and connects to its own mobile application that allows users to track their activity and progress over time and log weight, water intake, and food consumption. Fitbit and its competitors each offer several different models and allows users to connect with each other on mobile applications and challenge others to see who can get the most exercise.

51 See How to Track on the WW app, WEIGHT WATCHERS (Feb. 24, 2019), archived at https://perma.cc/SL3T-3ZFW (providing an overview of how WW application users can log the foods they eat in the application).
52 See How SmartPoints Work, supra note 53 (describing daily and weekly SmartPoints and how weekly SmartPoints can be used to supplement daily SmartPoints once a user has exceeded his point goal in a given day).
54 See How it works, supra note 56 (describing the features of popular weight loss applications, such as financial rewards for meeting goals, support communities, and tracking caloric intake and exercise).
55 See James Stables, Best fitness tracker guide 2018: Fitbit, Xiaomi, Garmin, and more, WAREABLE (Oct. 1, 2018), archived at https://perma.cc/PK99-SM63 (comparing different wearable fitness devices and their unique features); see also Chris Hoffman, How to Track Your Steps With Just an iPhone or Android Phone, HOW-TO GEEK (Jan. 15, 2016), archived at https://perma.cc/S6BM-5WPZ (explaining how to use an iPhone or android phone to track steps without an additional device).
56 See Why Fitbit?, FITBIT (Feb. 23, 2019), archived at https://perma.cc/4GU4-G8DF (expounding upon the merits and features of Fitbit’s wearable devices and mobile application).
or the highest step count in a given time period. Life insurance companies even give policy holders discounts for providing fitness tracker data to prove that they are healthy. There are even applications devoted to helping users record and share how long they fast as a weight loss tactic. While many of these devices and applications are subject to FDA regulation, the FDA could easily monitor the applications that correspond with these devices and weight loss programs and implement methods to verify users’ purported weights as to prevent them from using the technology to achieve unhealthy weight loss goals.

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60 See id. (delineating the features of FitBits, which include monitoring activity, exercise, and sleep); see also Stables, supra note 58 (listing different wearable fitness trackers and which functions each of their features best perform).

61 See Christopher Ingraham, An insurance company wants you to hand over your Fitbit data so it can make more money. Should you?, WASHINGTON POST (Sept. 25, 2018), archived at https://perma.cc/2DL7-BE5A (detailing John Hancock Insurance’s program why which it provides discounts to its policy holders who grant it access to their fitness trackers’ data).

62 See Iverson, supra note 9 (reviewing applications that are used to promote and track fasting, such as Vora and zero). These applications were designed to help people who practice intermittent fasting find a supportive community, but they are used by a large population of people with eating disorders to encourage multi-day fasts. Id. Fasting applications present a clear danger, particularly because there are no restrictions to who can access them. Id.; see also Lauren Sharkey, ‘A Twisted Comparison Game’: How Fitness Apps Exacerbate Eating Disorders, VICE (Feb. 23, 2018), archived at https://perma.cc/HM2L-Z3EN (describing the advent of fasting applications and how individuals with eating disorders use those and other weight loss applications such as MyFitnessPal and Apple’s Health application to foster their eating disorders). Patients with eating disorders and psychologists agree that tracking and posting calorie intake can exacerbate the obsessive-compulsive and social comparison aspects of eating disorders. See Sharkey, supra. Dr. Stacey Rosenfeld finds that diet and fitness applications promote social comparison by allowing people with eating disorders to compare themselves to others in vastly different situations to their own. Id. Nutritionist David Wiss points to the gamification of calorie counting and how it can intensify food issues. Id.

63 See Is The Product A Medical Device?, supra note 18 (explaining how the FDA could monitor applications that qualify as a medical device).
III. Facts

A. Online Eating Disorder Culture

The advent of mobile weight loss applications and wearable fitness tracking devices has invigorated weight loss culture in the United States.\(^6^4\) As with most popular health movements, the weight loss movement is susceptible to unhealthy and harmful uses by people who either misunderstand it or use it to reach unhealthy goals.\(^6^5\) People with eating disorders sometimes use weight loss technology to support their disordered eating and that of others by setting unhealthy weight loss goals, meticulously counting and restricting their caloric intake, and fixating on their weight, exercise, and food consumption.\(^6^6\)


\(^{6^5}\) See It’s Definitely Been a Journey, supra note 64 (discussing how weight loss applications “[n]egatively impact body satisfaction and contribute to eating disorders”); see also Elizabeth V. Eiskey & Kayla M. Booth, Recovery and Maintenance: How Women with Eating Disorders Use Instagram (iConference March 2017), archived at https://perma.cc/L54M-GWFU (studying the use of social media by people with eating disorders to foster disordered eating for themselves and others); see also Desire to be Underweight, supra note 5, at 7 (finding that 6.78% of mobile weight loss application users have unhealthy weight loss goals).

\(^{6^6}\) See It’s Definitely Been a Journey, supra note 64 (describing several unhealthy behaviors that people with eating disorders foster by using mobile weight loss applications and calling for weight loss application developers to redesign the applications with an awareness of the potential for “unintentionally encouraging negative habits”). People with eating disorders use weight loss applications to obsessively log their food intake, feel an overwhelming need to be exact in logging their food consumption, be overly aware of numbers related to weight loss (such as weight and caloric intake), restrict their eating, support compensatory behaviors, and manipulate the applications to use them to lose weight. Id. Though they are not the intended users of these applications, people who have eating disorders have unbridled access to these applications and can easily manipulate them by imputing false weights and using the applications for recommendations on how to lose weight, by overstating the amount of food they consume or understating the amount of exercise they do. Id. See also Courtney C. Simpson & Suzanne E. Mazzeo, Calorie Counting and Fitness Tracking Technology: Associations with Eating Disorder Symptomatology, 26 Eating Behav. 89, 91 (2017) (finding that a study of several
They utilize the weight loss advice, instructions, and support communities accessible on mobile weight loss applications to invigorate their body dysmorphia and unhealthy behaviors.67

The widespread availability of mobile weight loss applications and wearable fitness trackers benefits people who use that technology to obtain or maintain a healthy lifestyle.68 It is also detrimental and even dangerous to people who use it to support harmful practices.69 This danger is more prevalent with mobile applications than in-person weight loss programs because mobile weight loss applications do not screen users effectively to ensure that they are eligible to utilize the applications.70 In this way, the modern obsession with technology poses health risks to people with eating disorders because it serves as an avenue for disordered behaviors such as obsessive calorie counting, rewards for restricting their eating, and proves weight loss assistance.71

hundred college students revealed an association between fitness tracking and calorie counting and disordered eating). Eating disorder symptomatology such as eating concern and dietary restraint are linked to calorie tracking; fitness tracking can be an indicator of eating disorder symptomatology. Id.

67 See It’S DEFINITELY BEEN A JOURNEY, supra note 64, at 4–7 (stating that people with eating disorders use weight loss applications to obsessively log their food intake, feel an overwhelming need to be exact in logging their food consumption, be overly aware of numbers related to weight loss (such as weight and caloric intake), restrict their eating, support compensatory behaviors, and manipulate the applications to use them to lose weight).

68 See Ventola, supra note 32, at 360–62 (listing several benefits that mobile health applications have to users and describing how they facilitate weight loss and maintenance).

69 See It’S DEFINITELY BEEN A JOURNEY, supra note 64, at 5 (explaining that people with eating disorders can suffer great harm by using mobile weight loss applications to exacerbate the symptoms of their conditions); see also Desire to be Underweight, supra note 5, at 2 (reviewing harmful uses of mobile weight loss applications by people with eating disorders).

70 See Desire to be Underweight, supra note 5, at 6 (recognizing the use of websites and mobile applications to foster eating disorders because of the autonomy they allow users).

71 See Gregory, supra note 9 (relaying the story of a teenage girl who used MyFitnessPal in an attempt to adopt healthy eating practices, but actually used it to perpetuate disordered eating behaviors). See also Sirena Bergman, How ’healthy’ food tracking apps could actually be leading to an increase in disordered eating, METRO (Mar. 2, 2018), archived at https://perma.cc/3BLZ-4J9P (contending that
An online movement dubbed “thinspiration,” a combination of the words “thin” and “inspiration,” encourages people with eating disorders to be underweight by sharing photos of emaciated people and quotes meant to inspire disordered eating. Thinspiration promotes unhealthy means of weight loss such as distractions from hunger and teaches people to conceal their disordered eating. People can easily use mobile applications designed for other purposes to encourage themselves and others to work toward unhealthy weight goals. This practice became so severe that in 2012, Instagram banned accounts, images, and hashtags that promote self-harm, particularly eating disorders and related behaviors. Mobile weight loss applications that showcase “before and after” photo comparisons and “non-scale victories,” such as fitting into certain clothing sizes, encourage people online weight loss platforms bring health, fitness, and nutrition to the forefront of public consciousness. Dr. Christine Buske, a behavioral neuroscientist, has found that weight loss applications “normalize” disordered eating by gamifying related behaviors. See Annika K. Martin, “Stick a Toothbrush Down Your Throat:” An Analysis of the Potential Liability of Pro-Eating Disorder Websites, 14 TEX. J. WOMEN & L. 151, 155–56 (2005) (defining “thinspiration” as sharing photos of thin people in an effort to motivate one’s self or others to participate in disordered eating). These websites do not regard disordered eating as unhealthy and sometimes encourage people who do not have eating disorders to engage in disordered eating behaviors. Id. See id. at 155 (summarizing the features and content of pro-eating disorder websites and providing examples of unhealthy behaviors being encouraged on these platforms). See Eikey & Booth, supra note 65, at 1 (analyzing the use of “general-purpose” websites and applications such as Instagram by people with eating disorders to advance disordered eating and body dysmorphia). See Maura Judkis, Instagram bans ‘Thinspiration,’ pro-eating disorder images, THE WASH. POST (Apr. 24, 2012), archived at https://perma.cc/4VCZ-FTKK (announcing Instagram’s ban of thinspiration and related, pro-eating disorder content).
to celebrate weight loss benchmarks, and have become the next frontier of the thinspiration movement.\textsuperscript{76}

B. FDA Mobile Application Regulation

The FDA categorizes a mobile medical application as a medical device if it is intended “for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or if it is intended to affect the structure or any function of the body . . .”.\textsuperscript{77} It sorts mobile medical applications into three classes based on the level of risk that they pose to public health.\textsuperscript{78} Every mobile medical application must meet the particular requirements ascribed to its class of applications.\textsuperscript{79} This system is modeled after the FDA’s system of classifying medical devices.\textsuperscript{80} The FDA “strongly recommends” that all mobile medical application developers abide by its rules, but only enforces these standards upon certain types of mobile medical applications.\textsuperscript{81} Mobile medical application manufacturers are required

\textsuperscript{76} See IT’S DEFINITELY BEEN A JOURNEY, supra note 64 (noting that weight loss applications intentionally foster communities of people who can support each other in their weight loss journeys, provide weight loss tips, and congratulate others on weight loss successes). These communities are intended for people who are working toward reaching or maintaining healthy weight loss goals but can easily be used by people with eating disorders striving to be underweight. Id.

\textsuperscript{77} See MOBILE MEDICAL APPLICATIONS, supra note 43, at 8 (discussing which features distinguish a mobile application as a medical device and focusing on applications that are marketed to function like traditional medical devices or to facilitate clinical or treatment-related tasks).

\textsuperscript{78} See id. at 19 (separating mobile medical applications into Class I, II, and III, for which the level of risk associated with the application rises with its class number).

\textsuperscript{79} See id. (laying out the different requirements for each class of medical applications).

\textsuperscript{80} See id. (explaining that its mobile medical application classifications are designed to reflect its medical device classifications).

\textsuperscript{81} See id. at 13 (requesting that all mobile medical application developers comply with its quality system regulations); see also Examples of Mobile Apps For Which the FDA Will Exercise Enforcement Discretion, U.S. FOOD & DRUG ADMIN. (Aug. 1, 2016) [hereinafter Examples of Mobile Apps], archived at https://perma.cc/33J4-TBK6 (professing that the FDA will exercise enforcement discretion with respect to weight loss applications).
to submit a premarket notification of the FDA unless they are 510(k) exempt, a status also afforded to medical devices and that parallels 510(k) exemptions for medical drugs.\textsuperscript{82} Manufacturers must register the location where they create the application annually, avail the application to a clinical study, and comply with FDA labeling requirements and QSR requirements.\textsuperscript{83} They are also required to periodically make any necessary improvements to their applications and check them for software deficiencies.\textsuperscript{84}

Although deleting all mobile weight loss applications would be unfair for those who rely on them for healthy weight loss, the encouragement of disordered eating behaviors on mobile weight loss applications is critically dangerous to people who are vulnerable to disordered eating. The FDA’s recent guidance document explains that its goal in regulating mobile medical applications is to reduce the health risks these innovations pose to their users.\textsuperscript{85} The FDA declares that it will practice enforcement discrimination in regard to mobile weight loss applications because they pose a “lower risk to the public” than applications the FDA does regulate.\textsuperscript{86} As studies have established

\textsuperscript{82} See Mobile Medical Applications, supra note 39, at 30–32 (providing examples of medical devices that have been approved via 510(k) submissions).
\textsuperscript{83} See id. at 33–34 (summarizing the FDA’s establishment registration, medical device listing, and investigational device exemption requirements).
\textsuperscript{84} See id. at 36 (acknowledging that medical application manufacturers must regularly inspect, repair, and upgrade their devices and may also make any voluntary adjustments as they see fit).
\textsuperscript{85} See id. at 6–7 (explaining the FDA’s rationale that mobile medical applications are software that can pose potential risks to public health and thus the FDA should regulate them). The FDA classifies mobile applications as medical applications if they are designed to execute some form of medical treatment, such as diagnosis, treatment, cure, or prevention. Id. at 8. The FDA will only regulate mobile medical applications that pose significant risks to public health. Id. at 6.
\textsuperscript{86} See Examples of Mobile Apps, supra note 81 (clarifying that the FDA intends to regulate mobile medical applications that “pose lower risk to the general public” less harshly than others). Such applications include weight loss applications, applications that send emergency notifications to first responders, and applications that present reminders or activity trackers to help patients manage gum disease. Id. The FDA describes this genre of applications, in relation to eating disorders, as:

Mobile apps that are intended for individuals to log, record, track, evaluate, or make
decisions or behavioral suggestions related to the developing or maintaining
general
fitness, health or wellness, such as those that:
that a class of mobile weight loss application users aspire to be underweight and use the applications to facilitate that goal, it is clear that mobile weight loss applications are medical applications that can be and are used to harm consumers.\textsuperscript{87} Instituting procedures to verify the self-reported weights of mobile weight loss application users would benefit both the intended audience of mobile weight loss applications and those who suffer from eating disorders and use them for self-harm.

IV. Analysis

As the agency responsible for protecting public health and governing any substances that may affect public health\textsuperscript{88}, the FDA should issue specific guidelines to regulate mobile weight loss applications so no one who engages in disordered eating behaviors can use the applications to harm themselves. The FDA regulates weight loss devices and drugs as well as mobile medical applications, so mobile weight loss applications fit squarely within its purview.\textsuperscript{89}

- Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Actively monitor and trend exercise activity;
- Use social gaming to encourage healthy lifestyle habits; and
- Calculate calories burned in a workout.

\textit{Id.}

\textsuperscript{87} See \textit{Desire to be Underweight}, supra note 5, at 4 (finding that 6.78\% of mobile weight loss application users want to have body mass index (BMI) scores that qualify as unhealthy and that most of these users are at healthy weights or even underweight when they start using the applications).

\textsuperscript{88} See 21 U.S.C. § 331 (1938) (outlining various actions which are prohibited).

\textsuperscript{89} See \textit{Prescription weight-loss drugs}, supra note 20 (delineating each of the FDA-approved weight loss medications); see also \textit{FDA approves AspireAssist}, supra note 19 (providing a description of one of several FDA-approved weight loss devices);
Moreover, the FDA’s mission is to prevent food, drugs, and medical devices from harming the public. Mobile weight loss applications are designed to address health issues such as obesity, but there is staggering evidence that the applications have also been used to facilitate disordered eating and related behaviors. Although the FDA requires weight loss medications and devices to meet certain specifications and considers mobile weight loss applications to be mobile devices, the FDA exercises enforcement discretion with regard to mobile weight loss applications. Eating disorders are uniquely dangerous because they cause people to actively pursue self-harming behaviors, and mobile weight loss applications are so widely available as to be a common mechanism for this abuse. The FDA’s duty to protect the public from harm due to medical devices includes oversight of mobile weight loss applications, and in deciding to practice enforcement discrimination with regard to these applications, it allows people with serious illnesses to use that technology for self-harm.

A. Lack of Distinction from FDA-Regulated Weight Loss Devices

see also Bello & Yeomans, supra note 19, at 18 (citing the FDA’s approval of medications to treat bulimia nervosa and binge eating disorder).

90 See What We Do, supra note 10 (expounding on the FDA’s goal and responsibility to protect and advance public health).

91 See Nikolau & Lean, supra note 37 (considering the advent of mobile weight loss applications and how they treat and prevent obesity); see also Eikey et al., supra note 5 (indicating that many weight loss application users aspire to be underweight); see also Iverson, supra note 9 (pointing out how people use mobile applications intended to track intermittent fasting to track dangerous long-term fasts and encourage others to do the same); see also Sharkey, supra note 62 (evaluating how people with preexisting eating disorders have used a variety of weight loss applications to further their eating disorder behaviors); see also It’s DEFINITELY BEEN A JOURNEY, supra note 64 (disclosing how weight loss applications escalate eating disorders).

92 See Development & Approval Process (Drugs), supra note 19 (outlining the FDA’s approval process and standards for new drugs); see also Device Approvals, Denials, and Clearances, supra note 19 (reviewing the FDA’s requirement for medical device approval); see also MOBILE MEDICAL APPLICATIONS, supra note 39, at 19 (concluding that the FDA will not submit mobile weight loss applications to the same scrutiny as other medical applications).

93 See It’s DEFINITELY BEEN A JOURNEY, supra note 64 (pointing out how people who have eating disorders constantly seek ways to monitor their food consumption and how mobile weight loss applications provide a convenient and very accessible platform for doing so).
The FDA considers obesity “a major public health concern in the United States” and has approved several drugs and medical devices designed to combat obesity.\textsuperscript{94} It has clarified that for its purposes, certain mobile medical applications are considered medical devices.\textsuperscript{95} Mobile weight loss applications are designed to mitigate, treat, and prevent obesity.\textsuperscript{96} They affect the structure of the body by teaching people how to eat and exercise in a way that will reduce the sizes of their bodies.\textsuperscript{97} Furthermore, the FDA explicitly mentions mobile weight loss applications in its list of applications that may meet the definition of a medical device.\textsuperscript{98} According to the FDA, it will not regulate mobile weight loss applications as it will other mobile medical applications because mobile weight loss applications “pose a lower risk to the public.”\textsuperscript{99}

The FDA would benefit from re-evaluating its risk analysis. Intended use aside, studies have confirmed the correlation between eating disorder symptomology and the use of fitness tracking

\textsuperscript{94} See Weight-Loss and Weight-Management Devices, supra note 19 (offering a definition of obesity and a list of treatments for obesity such as lap bands, gastric balloon systems, and gastric emptying systems); see also Prescription weight-loss drugs, supra note 20 (documenting the FDA’s approval of five weight loss medications).

\textsuperscript{95} See MOBILE MEDICAL APPLICATIONS, supra note 39, at 4 (specifying that the FDA will only regulate mobile medical applications that fit its definition of a medical device and pose a significant risk to the public); see also Is The Product A Medical Device?, supra note 18 (explaining the FDA’s definition of a medical device).

\textsuperscript{96} See Nikolaou & Lean, supra note 37 (articulating how mobile weight loss applications treat obesity).

\textsuperscript{97} See id. (finding that the mobile weight loss application market consists primarily of exercise and dieting applications, which help users lose weight and tone their muscles).

\textsuperscript{98} See MOBILE MEDICAL APPLICATIONS, supra note 39, at 25 (listing types of applications that may be considered medical devices, including “[m]obile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness”).

\textsuperscript{99} See id. at 19 (stating that although mobile weight loss applications may be considered medical devices, the FDA will not regulate them as stringently as other medical devices).
applications. Eating disorders such as anorexia nervosa can be fatal; symptoms include muscle atrophy, irregular heartbeat, liver damage, infertility, osteoporosis, anemia, and malnutrition. Eating disorders are linked with the highest fatality rate out of all mental illnesses and affect and at least thirty (30) million people in the United States. Eating disorders are also marked by compulsive tracking of exercise and caloric intake, which can be exacerbated by technology that facilitates such tracking and gives users constant access to that information. Eating disorder experts assert that mobile weight loss applications can aggravate disordered eating behaviors by way of social comparison via “friend” features and newsfeeds of other peoples’ accomplishments, gamification of eating and exercise with point systems, and fostering fixation on tracking exercise or food consumption by rewarding consistent entries. If mobile weight loss application developers restrict people with low BMI values from using

100 See IT’S DEFINITELY BEEN A JOURNEY, supra note 64 (affirming that weight loss applications foster disordered use through obsessive food logging, restricting eating, and manipulating the applications to allow them to reach unhealthy weights); see also Levinson et al., supra note 71 (verifying that MyFitnessPal use contributes to eating disorders); see also Simpson & Mazzeo supra note 66, at 18 (establishing that fitness tracking is related to eating disorder symptomatology).

101 See Martin, supra note 72, at 154 (describing the symptoms of anorexia nervosa and bulimia nervosa); see also Eating Disorder Statistics, supra note 71 (highlighting the fact that every 62 minutes, at least one person dies as a direct result of an eating disorder).

102 See Eating Disorder Statistics, supra note 71 (revealing that eating there are at least thirty million people with eating disorders in the United States and that “[e]ating disorders have the highest mortality rate of any mental illness”).

103 See IT’S DEFINITELY BEEN A JOURNEY, supra note 64 (demonstrating how people with eating disorders identify compulsive tracking as a pillar of their disorders and explaining how weight loss applications feed into that tendency). Weight loss applications enable unhealthy fixation on dietary and exercise information, which compounds eating disorders. Id. See also Martin, supra note 72, at 153–54 (articulating that the need to obsessively control one’s diet is a symptom of eating disorders).

104 See Sharkey, supra note 62 (quoting psychologists and a nutritionist about how social comparison on weight loss applications tends to cause people with eating disorders to restrict their eating more stringently than they usually do); see also Bergman, supra note 71 (focusing on the game-like nature of weight loss applications and clarifying how that can make eating disorder behaviors seem more normal); see also Simpson & Mazzeo, supra note 66 (declaring that fitness tracking can expose a person’s disordered eating tendencies).
these features, they will prevent the exacerbation of eating disorder symptoms.\textsuperscript{105}

The FDA regulates medications and devices created to help people lose weight and medications designed for the treatment of eating disorders.\textsuperscript{106} The FDA admits that mobile weight loss applications may be considered mobile medical applications for its purposes.\textsuperscript{107} Mobile weight loss applications have the same goals as some of the weight loss medications and devices that the FDA chooses to regulate.\textsuperscript{108} In fact, mobile weight loss applications are available to a far wider audience than other devices or medications because many of them are available free of charge and do not require a prescription.\textsuperscript{109} The FDA advises that patients should be evaluated and treated for eating disorders as a prerequisite for using obesity treatment

\textsuperscript{105} See Simpson & Mazzeo, supra note 66 (articulating that those people who have a lower BMI from using the apps will exacerbate their symptoms).

\textsuperscript{106} See Prescription weight-loss drugs, supra note 20 (illustrating the chemical composition and risks associated with each FDA-approved weight loss medication); see also Weight-Loss and Weight-Management Devices, supra note 19 (introducing the FDA-approved weight loss devices as obesity treatment and listing factors to consider before using a weight loss device); see also Bello & Yeomans, supra note 19 (citing the FDA’s approval of medications to treat eating disorders).

\textsuperscript{107} See MOBILE MEDICAL APPLICATIONS, supra note 39, at 4 (explaining that mobile weight loss applications may be considered medical applications for the purpose of FDA regulation when they serve the same purpose as ordinary medical devices or are accessories to medical devices and could pose a risk to a patient’s safety if they malfunction).

\textsuperscript{108} See Levinson et al., supra note 71 (portraying MyFitnessPal as an application that tries to help users lose weight and develop a healthy relationship with food and with eating); see also Prescription weight-loss drugs, supra note 20 (specifying that weight loss medications are to be used for overweight or obese individuals); see also Weight-Loss and Weight-Management Devices, supra note 19 (stating that weight loss devices are a treatment for obesity).

\textsuperscript{109} See Iverson, supra note 9 (observing the wide accessibility of the mobile weight loss application market to consumers, including children); see also Gregory, supra note 9 (considering the thousands of “Health & Fitness” applications in the Apple iTunes store, the most common wearable fitness trackers, and the ease of access to these tools); see also Hwang, supra note 30 (finding that the “explosive proliferation” of mobile health application in combination with the inadequacy of pre-market testing of these applications puts patients who use the applications at risk).
devices, so it is incomprehensible that it would not require the same for mobile applications that function as obesity treatments, particularly as the general public has far greater access to mobile applications than it does lap-band and gastric bypass devices.  

110 Being that the FDA finds devices and medications related to weight loss and eating disorders to be subject to its regulations, the natural step is for it to govern mobile weight loss applications in a similar fashion.

B. Public Health Interest

The purpose of the FDA is to protect the American people from health risks.  

111 According to the National Association of Anorexia Nervosa and Associated Disorders, at least thirty (30) million people in the United States suffer from eating disorders.  

112 Out of all mental illnesses, eating disorders have the highest mortality rate; this indicates how significant of a health risk eating disorders are to the American population.  

113 The FDA purportedly supervises any products and mobile applications that could endanger the health of the American people, yet it applies a lower level of scrutiny to mobile weight loss applications, which pose a serious health risk to people with eating disorders.

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110 See Weight-Loss and Weight-Management Devices, supra note 19 (establishing that obesity treatment devices are for people who are obese, which is characterized by having a body mass index (BMI) of “30 kg/m² or more”). Body mass index is calculated based on a person’s weight-to-height ratio. Id. The FDA tells the public that eating disorders are an important factor to consider when deciding whether an obesity treatment device is appropriate for a particular patient. Id.

111 See What We Do, supra note 10, at 1 (underscoring the FDA’s objective to protect public health and oversee the production of health-related items).


113 See id. (warning of the dangers and the prevalence of eating disorders in the United States); see also Martin, supra note 72, at 154 (noting that eating disorders have the highest mortality rate of all mental illnesses).

114 See 21 U.S.C. § 331 (codifying the FDA’s right to control food, drugs, devices, tobacco products, mob, and cosmetics); see also MOBILE MEDICAL APPLICATIONS, supra note 39 (dismissing weight loss applications from the class of mobile medical applications that the FDA will regulate); see also Levinson et al., supra note 71, at 3 (discovering a positive correlation between reported use of MyFitnessPal and the severity of eating disorder symptomology among people with eating disorders); see also Simpson & Mazzeo, supra note 66, at 8 (substantiating reports that calorie intake tracking can enhance “rigidity and anxiety regarding calorie intake”).
The FDA’s justification for this deficiency is that mobile weight loss applications pose a “lower risk of harm” to the general public than other medical applications.\textsuperscript{115} It is true that most mobile weight loss applications track and coach low-risk activities, such as recording the amount of calories that one consumes and counting the steps that one takes in a day.\textsuperscript{116} Unfortunately, it is also easy to manipulate these applications to help people attain unhealthy weight loss goals.\textsuperscript{117} The FDA should oversee mobile weight loss applications to protect people from using them for self-harm, in alignment with the FDA’s goal to regulate all medications and medical devices in the United States and to protect the public from harmful medical inventions.\textsuperscript{118}

In addition to concerns about people with eating disorders, the FDA should regulate mobile weight loss applications because of the risks they pose to their intended users. Even when using a mobile weight loss application as its creators anticipated, one can engage in unhealthy behavior and find social support for doing so.\textsuperscript{119} The

\textsuperscript{115} See Examples of Mobile Apps, supra note 81 (declaring that the FDA considers weight loss applications to present a lower risk of danger to the public than other mobile medical applications).
\textsuperscript{116} See Sharkey, supra note 62 (acknowledging that many mobile weight loss applications record calorie intake and exercise in an effort to help users stay healthy).
\textsuperscript{117} See Gregory, supra note 9 (telling the story of a how a teenage girl used MyFitnessPal to support her disordered eating behaviors); see also It’s DEFINITELY BEEN A JOURNEY, supra note 64 (sharing the stories of study participants with eating disorders who manipulated weight loss applications to allow them to lose weight). It is very easy to manipulate weight loss applications as to facilitate unhealthy weight loss. See It’s DEFINITELY BEEN A JOURNEY, supra note 64. People do so by imputing a higher weight so that the application gives a more intensive diet plan, failing to log exercise so the application will limit calories more strictly, and purging the food they entered into the application. Id.
\textsuperscript{118} See 21 U.S.C. §§ 301–399i (setting forth the different items that the FDA has jurisdiction over); see also Ekey & Booth, supra note 65 (exposing the ways that people with eating disorders use social media websites and mobile applications to teach others ways to harm themselves).
\textsuperscript{119} See Iverson, supra note 9 (citing different applications designed to time and record fasting and explaining that many of these applications allow users to interact by seeing each other’s fasting records and encouraging each other to fast for longer amounts of time); see also Sharkey, supra note 62 (showcasing examples of social
saturation of the mobile weight loss application market brings many types of applications with many different functions to consumers; without the FDA regulating these applications as it does other weight loss products, consumers have no protection from unsavory and unhealthy weight loss plans.\(^{120}\) When diet pills were the pre-eminent weight loss trend in the 1960s and 1970s, the FDA monitored them and informed the public of any medications it considered dangerous.\(^{121}\) Once the FDA began regulating diet pills, it was able to monitor the diet pill market and reduce consumers’ access to dangerous weight loss drugs, thereby mitigating harm to the American people.\(^{122}\) Now, mobile weight loss applications are the leading weight loss trend, so the FDA needs to monitor them as it did (and continues to do) with diet pills.\(^{123}\) Unfortunately, the FDA does not regulate the mobile weight loss application market as it does the weight loss medication market, so the American people are not afforded the same protection from harm by today’s most recent and universal weight loss instruments.

Furthermore, the FDA has a strong interest in protecting those who cannot protect themselves. People with eating disorders, who are at risk of harm from mobile weight loss applications often welcome the harm that the applications can cause because their eating disorders

\(^{120}\) See Elliott, supra note 56 (listing some of the many weight loss applications available in the Apple app store); see also Nikolau & Lean, supra note 37 (outlining the mobile weight loss application market and the describing some of the different types of mobile weight loss applications).

\(^{121}\) See Cohen et al., supra note 49, at 2 (recounting the diet pill trend of the 1960s and the FDA’s subsequent regulation of many diet medications).

\(^{122}\) See id. at 10 (describing the FDA’s approaches to regulating different diet pills over time and how it was able to investigate and seize diet pills that had significant harmful consequences to patients who consumed them).

\(^{123}\) See Sharkey, supra note 62 (describing the trend of weight loss applications and stating that “for every new fad diet that appears, there’s an app”); see also Millington, supra note 38 (discussing the integration of fitness technology into American society).
predispose them to do so. At some level, they are aware that they are using the applications to damage their bodies, but that does not make them stop using the applications. Eating disorders are mental illnesses that stem from the need to control one’s body and diet, so many patients either aren’t self-aware of the gravity of their destructive behaviors or want the dangerous results that mobile weight loss applications garner. People with eating disorders self-regulate in an unhealthy way, so realizing that these applications can help them lose weight will only make them more eager to use these applications.

The FDA is a body of experts that researches and moderates items that threaten public health in the United States. As such, the American people rely on its expertise. The FDA’s “enforcement discretion” with regard to mobile weight loss applications discounts the real safety hazards that these applications present as people who have eating disorders are known for seeking out ways to harm themselves and need to be protected from the damage they perpetuate upon themselves.

C. How to Regulate Mobile Weight Loss Applications

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124 See It’S DEFINITELY BEEN A JOURNEY, supra note 64 (highlighting the desire that people with eating disorders have to do anything they can to feel slimmer and the actions they take to use weight loss applications to accomplish that).
125 See Desire to be Underweight, supra note 5 (finding that even when people felt that weight loss applications presented unhealthy goals, they still used the applications).
126 See Martin, supra note 72, at 153 n.3 (providing the definition of bulimia nervosa, which is characterized by a perceived lack of control); see also It’S DEFINITELY BEEN A JOURNEY, supra note 64 (quoting people with eating disorders who have varying levels of self-awareness about their conditions and want to lose weight).
127 See It’S DEFINITELY BEEN A JOURNEY, supra note 64 (pointing out eating disorder patients’ patterns of obsessive calorie and exercise tracking, awareness that these behaviors are unhealthy, and return to the same behaviors and applications to accomplish their weight loss goals).
128 See What We Do, supra note 10 (defining what the FDA is and what it does to uphold its goal of preserving public health in the United States).
129 See JANSSEN, supra note 11 (describing the work of the FDA and how American people rely on the FDA to protect their health and quality of life).
Mobile weight loss applications should face the same scrutiny and be held to the same standards as other mobile medical applications. If people who have eating disorders can manipulate an application to teach them how to lose weight, then clinical studies—which the FDA requires for other medical devices—would reveal that flaw.\(^\text{130}\) If applied to these applications, MDR would hold mobile application developers accountable for deaths and serious injuries resulting from the use of their applications, or for having practices that could foreseeably cause death or serious harm to users.\(^\text{131}\) This would empower anyone to report defects in the applications and beseech application developers to react to their concerns.\(^\text{132}\) QSR would enforce requirements for monitoring the applications, which could include verifying users’ self-reported weights.\(^\text{133}\) Since the FDA already imposes these standards on the mobile medical applications that it does regulate, it would only have to apply those existing requirements to mobile weight loss applications.\(^\text{134}\)

If mobile weight loss applications verify a user’s starting weight by requiring photos of the individual on a scale, like DietBet does, it will be a lot more difficult for underweight people to abuse the applications.\(^\text{135}\) DietBet’s employees moderate the weight verification.

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\(^\text{130}\) See Gregory, supra note 9 (telling the story of a teenage girl who used a weight loss application to teach herself how to lose weight and to help her track her calorie intake to her detriment). Some people look to weight loss applications as a way to save themselves from unhealthy and dangerous eating behaviors, but these applications very often cause fixation on exercise and food intake, which can be very dangerous. Id.; see also H.R. 114 § 2051 (2016) (discussing the modifications to the clinical trial requirements for medical devices).

\(^\text{131}\) See MEDICAL DEVICE REPORTING, supra note 43, at 2 (indicating that MDR helps medical device manufacturers keep track of deficiencies of their devices). The penalties for failing to follow MDR requirements include criminal prosecution, civil financial penalties, and injunction. Id.

\(^\text{132}\) See id. at 4 (stating that medical device manufacturers must report all medical device reportable events that they become aware of from any source).

\(^\text{133}\) See MOBILE MEDICAL APPLICATIONS, supra note 39, at 34 (announcing that QSR institutes a framework for mobile medical application manufacturers to “ensure safe distribution, installation, and operation” of their products).

\(^\text{134}\) See id. (recounting how mobile medical application developers should apply QSR).

\(^\text{135}\) See How it works, supra note 56 (explaining that in order to participate, users must submit one photo of them standing on a scale and another photo of the weight listed on the scale with a codeword provided by the application). DietBet specifies
photos that users submit. DietBet has algorithms to detect suspicious weight inputs and requires extra weight verification for users whom its algorithms demarcate for having questionable weight inputs. Similarly, one symptom of several eating disorders is compulsively collecting data about one’s caloric intake and exercise. Currently mobile weight loss applications are a useful tool for people who obsessively gather and review this data, but they might not be if there was a limit on how long each user could view their information in the application. Once there is a successful model of weight verification and a system that cannot be used to exacerbate eating disorders, other applications with the same safeguards will be able to apply for 510(k) approval.

V. Conclusion

The FDA should regulate mobile weight loss applications just as stringently as it regulates other mobile medical applications. The purpose of the FDA is to address all major public health concerns. People with eating disorders use mobile weight loss applications to harm themselves by exacerbating their eating disorder symptoms and the FDA needs to protect these people by making it more difficult to manipulate mobile weight loss applications into helping people who do not need them. Eating disorders are mental illnesses and people who suffer from them are not able to stop themselves from engaging in self-harming eating practices and even seek out means of recording

that users must wear lightweight clothing in the photos they submit and not wear any accessories, as not to artificially inflate the readout on the scale. Id.  

136 See How it works, supra note 56 (noting that DietBet employees assess the validity of each photo that users submit to ensure that they do not falsify their weights).  

137 See How it works, supra note 56 (describing DietBet’s weight verification systems and methods for examining potential user misrepresentation, which include requiring users to submit videos of them weighing themselves in order to prove their self-reported weights).  

138 See Martin, supra note 72, at 154 (reiterating the most common symptoms of eating disorders and how the symptoms often manifest themselves through obsessive monitoring of one’s food and exercise).  

139 See Sharkey, supra note 62 (listing several different ways that people can use eating disorders to foster an unhealthy fixation on their diet and exercise).
their caloric intake in order to restrict it and to shame themselves for it. The FDA has a duty of care to all Americans, and the prevalence and gravity of eating disorders merits the FDA’s protection of people who suffer from eating disorders.

Just as the FDA removes unhealthy medications and dangerous medical devices from the marketplace, it should either remove mobile applications that can easily be used to foster eating disorders or enforce regulations on mobile weight loss applications so that they cannot be used for disordered eating. Mobile applications such as DietBet provide thorough and effective models for verifying users’ weights and moderating mobile weight loss applications as not to allow people to use them to achieve unhealthy weight goals. Requiring mobile weight loss applications to have similar features would only benefit public health and protect those who are most vulnerable to being harmed by these applications. The FDA needs to recognize the gravity of the effect that mobile weight loss applications have on people who have eating disorders and regulate mobile weight loss applications as it does with the other mobile applications that it has classified as mobile devices.