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FDA Approved?: Examining the FDA’s Approach to Mobile Medical Apps and its Sufficiency

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Is there an app for that? Yes! Apps are flooding the market and many of them utilize mobile health (“mhealth”) technologies. Mhealth “is the use of portable devices such as smartphones and tablets for medical purposes, including diagnosis, treatment, or support of general health and well-being.”¹ Take for example, Airstrip OB, an app permitting physicians to remotely monitor data from a pregnant woman and fetus, such data includes heart rates and contraction patterns.² Another app permits patients to record electrocardiograms on their smartphone, using a single lead that snaps onto the phone.³ The patient must hold the phone against his or her chest to record cardiac events and the app transmits the results to his or her cardiologist.⁴ A number of other apps act as health and wellbeing managers, they provide medication reminders, check symptoms and still others perform billing and scheduling functions.⁵ See Appendix A of this note for visuals of MMAs.

Despite growth in the industry and creation of such apps, the federal agency tasked with regulation of Mobile Medical Apps (MMAs), the Food and Drug Administration (FDA), is still working to catch-up. In 2013, the Food and Drug Administration promulgated *Guidance to Industry and Food and Drug Administration Staff on Mobile Medical Applications*.⁶ The FDA

¹ Nathan G. Cortez, *FDA Regulation of Mobile Health Technologies*, 371 NEW ENG. J. MED. 372 (2014).

² Alex Krouse, *Ipads, Iphones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 753 (2012).

³ Cortez, *FDA Regulation*, *supra* note 1, at 372.

⁴ *Id.*

⁵ *Id.*

⁶ FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF—MOBILE MEDICAL APPLICATIONS (September 25, 2013), *available at*

articulated three areas within the MMA context: non-medical devices, low-risk MMAs subject to enforcement discretion, and MMAs with increased risk that are subject to regulation as medical devices. The FDA has determined that many mobile apps are not medical devices under the Food, Drug and Cosmetics Act (FDCA). Given the influx of mobile apps, the FDA announced that it intends to exercise regulatory discretion, a federal agency's unreviewable decision to not take enforcement action, in the case of low-risk MMAs. MMAs whose functionality could pose a risk to a patient's safety will be regulated according to the existing regulatory approach for regulated medical devices. The majority of mobile apps on the market at this time fit into the first two areas, non-medical devices and low-risk MMAs subject to enforcement discretion.⁷ See Appendix B of this note for a visual of the FDA's approach to MMAs.

The sheer volume and variety of MMAs is presenting the FDA with the challenge of creating an effective classification system and currently fueling the uncertainty many MMA manufacturers are experiencing. The FDA has stated that manufacturers developing a MMA with an entirely new intended use should contact the FDA to discuss what regulatory requirements may apply.⁸ However, the lack of clarity in the FDA's guidance document makes even the threshold consideration difficult to determine. How might a manufacturer determine whether he or she has created a device with an entirely new intended use or simply an analogue to an existing medical device without a comprehensive guidance document? Given the foregoing, the FDA will likely receive requests for individual app guidance and advisory opinions from many manufacturers. Manufacturers that voluntarily submit their app for review will have to bare

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm> [hereinafter FDA, GUIDANCE ON MOBILE MEDICAL APPS].

⁷ *Id* at 4.

⁸ *Id* at 12.

delay and expense as a result the FDA will become inundated by submissions. Additionally, this means that innovation may be stifled as it is costly to create an app for which there may be regulatory uncertainty.⁹ Consumers will likely bare the burden of delayed innovation that could have been utilized earlier and have costs shifted to them. These challenges raise the issue of whether the vast number of new MMAs hitting the market simultaneously justifies the lack of regulatory oversight and the exercise of enforcement discretion currently exercised by the FDA. This note argues that the volume and variety of MMAs is extensive and defies strict taxonomy;¹⁰ consequently not all MMAs fit squarely within the FDA's framework as a result of the limitations of the statute. The FDA guidance is evidence of the incongruence between the stated approach to MMAs and the challenge of appropriately categorizing the plethora of MMAs. Furthermore, the FDA's wide reliance on the substantially equivalent concept to clear and ensure the safety and efficiency of MMAs is insufficient and will allow latent risks to remain unresolved and potentially harm patients and consumers.

Part I of this note examines the FDA's statutory and regulatory approach to medical devices. Part II addresses specifically the FDA's approach to MMAs and explores *Guidance to Industry and Food and Drug Administration staff on Mobile Medical Applications* promulgated by the FDA,¹¹ including detailed examples of devices subject to regulation and those subject to enforcement discretion. Part III argues that enforcement discretion in the MMA context is problematic because low-risk does not mean no risk and low-risk devices may have unforeseen potential for harm. Part IV recommends that the FDA implement regulation, a MMA

⁹ Jenny Gold, *FDA Regulators Face Daunting Task as Health Apps Multiply*, USA TODAY (June 27, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-06-22/health-apps-regulation/55766260/1>.

¹⁰ Cortez, *supra* note 1, at 372.

¹¹ FDA, *supra* note 6.

certification process, and recall and assessment program for MMAs that requires MMAs with reported adverse events be subject to the most rigorous scrutiny before a subsequent release into the market.

I: FDA's Existing Approach to Oversight of Medical Devices

There are three levels of authority from which the Food and Drug Administration (FDA) oversees the regulation of medical devices: statutory, regulatory and agency guidance. Congress enacted the Food, Drug, and Cosmetics Act (FDCA) that provided the FDA with authority over medical devices. The FDA has subsequently promulgated regulations to further pair down the scope of medical devices. The FDA has recently released nonbinding recommendations through guidance documents to address MMAs. Guidance documents do not establish legally enforceable responsibilities,¹² however, courts of law may give deference to the policies set forth by federal agencies in guidance documents, despite their intended use as recommendations or suggestions. The FDA has relied extensively on its authority to promulgate guidance documents as a key mechanism in regulating MMAs.

The Congressional statute, the FDCA, defines a “device” as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory,or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its

¹² *Id.* at 5.

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.¹³

While the definition is quite broad Congress does include some key provisions for narrowing the scope of what constitutes a medical device.

First, the statute begins by drawing distinctions and highlighting comparisons between devices and drugs. Use of the phrase “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, or any supplement”¹⁴ signals that the item must be mechanical as opposed to the definition of a drug¹⁵ which seems to be more amorphous. Second, the statute seeks to specify that a medical device or drug must have medicinal purposes and thus has to be “intended for use” or “intended to affect” health of the human or animal body. “Intended use” and “Intended effect” suggest that the FDA oversees those devices that are intended to have a curative, remedial, ameliorative or restorative effect on the body. “Intended use” is the critical factor in determining whether a device constitutes a medical device under the FDCA and the

¹³ 21 U.S.C. § 321(h) (2009).

¹⁴ *Id.*

¹⁵ “The term “drug” means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.” 21 U.S.C. § 321 (h).

concept is discussed below. Third, Congress further separated devices from drugs stating that a device “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.”¹⁶ Thus, the key distinction between devices and drugs is that devices do not utilize chemical action and are not metabolized.

Whether a device is of the type that the FDA is charged with overseeing depends on the intended use of the device; functionality is key.¹⁷ The FDA has promulgated regulations to further delineate what constitutes a medical device. The accompanying regulations focus on defining intended as a key factor in defining and subsequently classifying devices.¹⁸ The regulations state that the words “intended use” refer to the manufacturer’s objective intent.¹⁹ The intent is determined by the manufacturer’s declarations or circumstances surrounding distribution.²⁰ The FDA, through its regulation, states that labeling, advertisement or oral and written assertions by the manufacturer can represent a devices intended use. ²¹ Further, upon distribution, additional uses for which the device is not labeled or advertised may become apparent.²²

The regulations caution that intended use is not static, but can change after being introduced into the market. When the intended use is altered it is the responsibility of the distributor or manufacturer (whichever is or should be aware of the new intended use), to provide

¹⁶ *Id.*

¹⁷ 21 C.F.R. §801.4 (2013).

¹⁸ Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV.1201 (2014).

¹⁹ 21 C.F.R. § 801.4.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

adequate labeling and explanation of the new intended use.²³ A device is considered misbranded if a manufacturer or distributor does not update the labeling and advertisement for a device upon becoming aware of new intended uses. Generally, a device is considered misbranded when labeling is false or misleading, packaging does not include information concerning the name and place of business of the manufacturer, packer, or distributor, an accurate statement regarding the contents of the package is not affixed, the information is not prominently displayed, or use or warning information is inadequate.²⁴

Thus, the intended use centers both on the functionality of the device and the representations of the manufacturer. The functionality as perceived by the manufacturer informs its labeling and advertisement of a device. Thus, the FDCA gives the FDA the power to regulate devices that do not utilize chemical action or metabolize to achieve its primary intended use of preventing, diagnosing, or curing the human or animal body.

Upon meeting the FDCA's definition of a device and determining the intended use of the device, the intended use is subsequently used to categorize devices. Under the FDCA, Congress has created three categories of devices for human use based on the degree of risk: class I (low risk), class II (moderate risk), and class III (high risk).²⁵ The FDA must classify all devices intended for human use according to the framework articulated and mandated by Congress.²⁶ Class I encompasses devices "for which insufficient information exists to determine that ...reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but these devices are not purported or represented to be for a

²³ *Id.*

²⁴ 21 U.S.C. § 352 (2013).

²⁵ 21 U.S.C. § 360c (2012).

²⁶ *Id.*

use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury.”²⁷ Class I devices are subject to general controls.²⁸ General controls include: registration and device listing; premarket notification, although most class I devices are exempt from this control, prohibitions against adulteration and misbranding, records and reports; and good manufacturing practices.²⁹

Class II includes devices with increased risk. Class II devices encompass devices “which cannot be classified under Class I because the general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance.”³⁰ Class II devices are subject to premarket notification through the 510(k) process.³¹ The concept of substantial equivalence (SE) is at the heart of the 510(k) premarket notification process.³² The statutory standard for substantial equivalence:

The term “substantially equivalent” or “substantial equivalence” means, with respect to a device being compared to a predicate device, that the device has the

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ 21 U.S.C. § 360 (k) (2012).

³² *Id.*

same intended use as the predicate device and that the Secretary by order has found that the device--

(i) has the same technological characteristics as the predicate device, or
(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.³³

The 510(k) process allows manufacturers to market devices that are determined to be the SE to devices already on the market.³⁴ When the FDA determines that a new device is the SE of a legally marketed predicate device, the new device is classified the same as the predicate device.³⁵

A finding that a new device is not substantially equivalent (NSE) to a predicate device results in

³³ 21 U.S.C. § 360c.

³⁴ James M. Flaherty, Jr., *Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process*, 63 FOOD & DRUG L. J. 907 (2008).

³⁵ FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF—THE 510 (K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)], 3, (JULY 28, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf> [hereinafter FDA, GUIDANCE ON 510 (K) PROGRAM].

the new device having to undergo premarket approval (PMA).³⁶ Thus, the 510(k) process is the mechanism a manufacturer uses to garner marketing approval and the mechanism the FDA uses to clear class II devices.³⁷ Further, the 510(k) classification process is the means through which the FDA examines issues of safety and effectiveness presented by new devices and determines whether controls are robust enough to counteract safety concerns.³⁸

Thus a new device may be found to be the substantial equivalent of a predicate device when they share a common intended use and technological characteristics.³⁹ In the case that the new and predicate device have different technological characteristics, a device may nonetheless be found to be the substantial equivalent of a predicate device, if (1) a demonstration that the device is as safe and effective as the predicate device and (2) the new device does not raise concerns of safety and effectiveness that differ from the predicate device.⁴⁰ Therefore, having a common intended use is necessary factor in determining substantial equivalence. From the FDA's perspective, having an equivalent intended use provides assurance that the device is safe and effective.

Class III devices carry the highest risk; Class III devices are those that cannot be classified as a class I or class II devices because insufficient information exists to determine the applicability of general or special controls, and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or

³⁶ *Id.* at 3.

³⁷ *Id.*

³⁸ *Id.* at 3-4.

³⁹ *Id.*

⁴⁰ *Id.*

injury.⁴¹ Between 1976 and 1990, more than 98% of new devices were cleared through the 510(k) process,⁴² including some class III devices.⁴³ Some Class III devices may qualify for review under the 510(k) process if it can be demonstrated that the device is the SE of a legally marketed class III predicate device.⁴⁴ When a new class III is NSE to any predicate device, it is subject to the PMA process. The PMA process requires an independent showing of safety and effectiveness of a device through clinical trial prior to market approval.⁴⁵ The safety and effectiveness of a device is determined according to the following:

- (A) with respect to the persons for whose use the device is represented or intended,
- (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and
- (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.⁴⁶

A manufacturer of a new class III device must provide supporting data suggesting that the device is safe and effective.⁴⁷ A clinical trial conducted by experts is needed to evaluate and confirm the effectiveness of the device and purports that the device will have the effect it promised.⁴⁸

The 510 (k) process standard of review differs from that of the PMA process in that the 510 (k) process is comparative and the PMA standard requires an independent showing of the safety and effectiveness of a device.⁴⁹ The PMA process is more stringent than the 510(k) process.⁵⁰

⁴¹ 21 U.S.C. § 360c.

⁴² PETER HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 991 (2007).

⁴³ Cortez, *FDA Regulation*, *supra* note 1, at 374.

⁴⁴ 21 C.F.R. § 807.87 (2007).

⁴⁵ 21 U.S.C. § 360c.

⁴⁶ *Id.*

⁴⁷ 21 C.F.R. § 807.87.

⁴⁸ 21 U.S.C. § 360c.

⁴⁹ FDA, Guidance on 510(k) program, *supra* note 35, at 6.

⁵⁰ Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 *FOOD & DRUG L.J.* 245, 248 (2004).

Essentially, Class I devices are subject to general controls, but do not undergo any premarket review. Class II devices are cleared as safe and effective, and effectively bypass premarket review, if they have a counterpart device that has already been cleared by showing SE. Many class III devices can bypass premarket review in the same way that Class II devices do through a showing of SE. However, those class III devices found NSE to any predicate will be subjected to the PMA process and require independent showing of safety and effectiveness of a device through clinical trial prior to market approval. The FDA utilizes this same system of classification in overseeing MMAs.

II: FDA's Oversight Approach to Mobile Medical Apps

In a guidance document entitled, *Guidance to Industry and Food and Drug Administration staff on Mobile Medical Applications*,⁵¹ rather than regulation, the FDA has set forth its oversight approach to MMAs. The FDA website states: "Guidance documents represent FDA'S current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."⁵² It should be noted that regulations are binding and legally enforceable. Contrarily, guidance documents are inherently tentative and simply detail the agency's current thinking on MMAs. The guidance document provides nonbinding recommendations and suggestions for manufacturers; they do not constitute law and have no binding legal authority. However, courts give deference to the

⁵¹ FDA, GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 6.

⁵² FOOD & DRUG ADMIN., ABOUT FDA GUIDANCE DOCUMENTS, <http://www.fda.gov/regulatoryinformation/guidances/default.htm#about> (last visited Dec. 6, 2014).

recommendations and suggestions promulgated in guidance documents and these “policies” in the form of recommendations and suggestions often have de facto force of law.

As a threshold-matter, a mobile medical app must meet the statutory definition of a device under the FDCA. Additionally, to constitute a MMA the device must be intended for used as an accessory to a regulated medical device, or to transform a mobile platform into a regulated medical device.⁵³ For the purposes of MMAs, an accessory is an extension of one or more medical devices that connect to the device to control the device or display, store, analyze, or transmit patient-specific data.⁵⁴ A mobile platform is a commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity that is handheld, such as a smartphone, tablet computer, or other portable computer.⁵⁵ A mobile platform becomes transformed into a regulated medical device though the use of attachments, display screens, sensors or other similar components.⁵⁶

The Guidance document states that the FDA will focus its attention on manufacturers of mobile apps, those who ‘create, design, label, or initiate specifications for a mobile medical app.’⁵⁷ The FDA only plans to apply its existing regulatory oversight to those mobile apps that constitute medical devices under the statute and whose intended use could pose a risk to a patient’s safety if the mobile app were to malfunction.⁵⁸ Furthermore, the FDA must classify mobile medical apps according to the three-tier approach (classes I-III) as mandated by

⁵³ FDA, GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 6, at 7.

⁵⁴ *Id.* at 14.

⁵⁵ *Id.* at 7.

⁵⁶ *Id.* at 14-5.

⁵⁷ *Id.* at 9.

⁵⁸ *Id.* at 13.

Congress.⁵⁹ The FDA does not intend to regulate those devices that do not meet the definition of a medical device as it does not have the authority to do so.⁶⁰ Lastly, the FDA will exercise enforcement discretion to apps that meet the definition of a medical device, but pose a low-risk, perhaps even negligible risk, to the public.⁶¹

A. Non-medical devices

These are mobile apps that do not meet the definition of a device under the FDCA. The FDA does not regulate these devices. For more examples of mobile apps that are not medical devices see *Appendix A: Examples of mobile Apps that are Not Medical Devices*

B. Subset of mobile medical apps subject to FDA regulatory oversight

The following are mobile apps the FDA considers to be MMAs subject to the FDA's regulatory oversight: (1) apps that are an extension of one or more medical devices for purposes of controlling the device or displaying, storing, analyzing, or transforming patient-specific medical device data; (2) apps that transform a mobile platform into a conventional medical device through use of attachments, display screens, sensors or by including functionalities similar to regulated medical devices; and (3) apps that perform patient-specific analysis and provide a patient-specific diagnosis or treatment recommendations.⁶²

i. MMAs: "Extensions"

"Extensions" are "mobile apps that are an extension of one or more medical devices for purposes of controlling the device(s) or displaying, storing, analyzing, or transforming patient-

⁵⁹ 21 U.S.C. 360c.

⁶⁰ FDA, GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 6, at 4.

⁶¹ *Id.* at 14.

⁶² *Id.* at 14-5.

specific medical device data.”⁶³ An example of an “extension” that displays patient-specific medical device data is a “remote display of data from bedside monitors, display of previously stored electroencephalogram waveforms and display of medical images directly from a picture archiving and communication system.”⁶⁴ Mobile apps that display data to perform active patient monitoring are subject to regulation correlated with such medical devices.⁶⁵

An example of an “extension” that controls medical devices includes apps that “control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pump from the mobile platform.”⁶⁶ The FDA regards such MMAs as an appendage of the connected device and as such it must comply with the regulations applicable to the connected device.⁶⁷ Furthermore, the FDA “considers such mobile medical apps to extend the intended use and functionality of the connected medical device.”⁶⁸

An example of an “extension” that displays, stores, or transfers medical data in its original format include: “apps that are intended to display to store medical device data, without controlling or altering the functions of a connected medical device and constitute a Medical Device Data System (MDDS)...”⁶⁹ These devices are subject to class I requirements and general controls, including “adequate design controls, registration, device listing, adverse event reporting and corrections and removals.”⁷⁰ The FDA states that such general controls are adequate

⁶³ *Id.* at 14.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

safeguards for mobile medical apps that are used as an ancillary display because the app is not intended to provide diagnosis or treatment.⁷¹

Extensions are considered to simply extend the intended use of the connected medical device⁷² as such an “extension” is subject to the same regulations and requirements as the device it is enhancing.⁷³ Thus, the FDA will apply the same oversight to the extension as it does to the connected device. This is similar to the concept of substantial equivalence, where a medical device that is has an analogous intended use as a predicate device will be considered substantially equivalent and cleared based on that designation.

ii. MMA: “ Transformations”

“Transformations” are “mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.”⁷⁴ MMA that use attachments, display screens or sensors to transform mobile platform into a regulated medical device are subject to the same device classification designation (class I-III) that the transformed platform is subject to, in addition to applicable regulations.⁷⁵ The Guidance document provides the following examples:

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

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 15.

- a mobile app that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function is considered to transform the mobile platform into an electronic stethoscope.⁷⁶

The FDA has cleared many mobile medical devices with attachments.⁷⁷ An MMA that functions as an attachment to a medical device will be classified identically to its connected medical device and be subject to the same requirements.

iii. MMAAs: “Software”

MMAAs constituting “software” include “ mobile apps that become a regulated medical device (software) by performing patient –specific analysis and providing patient –specific diagnosis, or treatment recommendations.”⁷⁸ Additionally, these MMAAs are similar to or perform the same function as those types of software devices that have been previously cleared or approved.⁷⁹ Applications that perform sophisticated analysis or interpret data from another medical device include: “apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; computer aided detection software (CAD); image processing software; and radiation therapy treatment planning software.”⁸⁰

The FDA notes that “software” presents the same level of risk regardless of the platform used.⁸¹ Furthermore, the FDA suggests that manufacturers of “software” MMAAs that perform patient-specific analysis contact the FDA to discuss what regulations may be applicable.⁸² Thus, the FDA seems to want to take a case-by-case approach to software MMAAs. Furthermore, the

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 16.

FDA seems to suggest that performing patient-specific analysis is a particular concern and should be addressed directly.

The MMAs subject to enforcement either enhance a connected medical device by enabling the display, storage, or transmission of patient specific data; transform a mobile platform into a medical device through the use of attachments display screens, or sensors; or become software that performs patient-specific analysis. The FDA will categorize each MMA the same as the device it is enhancing, transforming or enabling for consistency and predictability. However in the case of “software” the FDA makes a request that manufacturers of these sorts of MMAs reach out for particular guidance in complying with regulations. Thus, suggesting that the performing patient-specific analysis may require addition safeguarding to ensure safety and efficiency of these MMAs. For more examples of MMAs subject to enforcement see *Appendix C: Examples of mobile Apps that are focus of the FDA’s regulatory oversight (mobile medical apps)*.

C. Mobile Medical Apps subject to enforcement discretion

The FDA will exercise enforcement discretion as to those devices that meet the definition of a medical device, but pose a low risk to the public.⁸³ These are devices, for which the FDA believes there is such a low risk of harm that it is inappropriate to classify them and place them into classes I-III. The FDA intends to exercise enforcement discretion as to these low risk devices, meaning that the FDA does not intend to enforce requirements under the FDCA⁸⁴ The FDA intends to exercise enforcement discretion for the following general category of MMAs:

- (1) Help patients (i.e., users) self- manage their disease or conditions without providing specific treatment or treatment suggestions;

⁸³ *Id.*

⁸⁴ *Id.* at 16.

- (2) Provide patients with simple tools to organize and track their health information;
 - (3) Provide easy access to information related to patients' health conditions or treatments;
 - (4) Help patients document, show, or communicate potential medical conditions to healthcare providers;
 - (5) Automate simple tasks for health care providers [perform simple calculations routinely used in clinical practice]; or
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.⁸⁵

The bullet pointed descriptions above are the general categories of MMAs subject to enforcement discretion. In addition to the above, the guidance document provides 6 specific examples that generally correlate with the bullet pointed descriptions. MMAs that are subject to enforcement discretion include: (1)“mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.”⁸⁶ This primarily targets apps that encourage or facilitate behavioral change.⁸⁷ The FDA provides that this would include apps that coach patients and promote strategies for maintaining health such as “healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules.”⁸⁸ The *Appendix B: Examples of mobile Apps for which FDA intends to exercise enforcement discretion* provides a salient example: “ Mobile apps that help patients with diagnosed psychiatric conditions (e.g. post-traumatic stress disorder (PTSD), depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a ‘Skill of the day’ behavioral technique or audio message that the user can access when experiencing anxiety.”⁸⁹ These sorts of apps provide guidance on making behavior changes, do not are voluntary, do not require patient-

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* at 23.

specific information for utilization and generally are intended to help patients build or cultivate tools or coping techniques rather than preventive, restorative, or curative the human body.

Additionally, enforcement discretion applies to apps that (2) “provide patients with simple tools to organize, and track health information.”⁹⁰ These are apps that are designed to provide simple mechanisms for organizing and tracking health information without recommending alterations to prescribed treatment.⁹¹ This covers MMAs with simple means of logging, tracking or trending events or measurements to provide to a patient’s health care provider.⁹² The type of events and measurements these simple tools are supposed to track and trend include blood pressure measurements, drug intake times, diet, and daily routine or emotional state.⁹³ While the FDA does not give specific examples of “simple tools” likely a food and exercise log as well as a medication log that includes dosage, drug intake times,⁹⁴ and reactions would be the type of app illustrated by this example.

MMAs that are subject to enforcement discretion also include: (3)“mobile apps that provide easy access to information related to patients’ health conditions or treatments (beyond providing an electronic ‘copy’ of a medical reference).”⁹⁵ These apps match patient-specific information with reference information to facilitate a user’s assessment of a particular patient.⁹⁶ These apps provide contextually relevant information.⁹⁷ Generally a practice guide would

⁹⁰ *Id.* at 17.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

constitute an MMA that provides contextual information beyond reference information.⁹⁸ The FDA guidance provides the following examples: “apps that use a patient’s diagnosis to provide a clinician with best practice treatment guidelines for common illnesses or conditions such as influenza; and apps that are drug-drug interaction or drug-allergy look-up tools.”⁹⁹ These apps allow a physician to access to best practices, techniques and alternative treatments, but do not perform patient-specific analysis.

Further MMAs that are subject to enforcement discretion comprise: (4) “mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions.”¹⁰⁰ These are apps that are not specifically labeled or promoted for medical uses, but because of the circumstances of distribution which is a key component in determining or updating a medical devices’ intended use, may meet the definition of a medical device.¹⁰¹ The Guidance provides “these products either pose little or not risk, or are the sole responsibility of the health care providers who have used them in medical applications.”¹⁰² The FDA includes MMAs that could be used to facilitate videoconferencing portals between patients, healthcare providers and caregivers.¹⁰³ Additionally, apps that utilizes a mobile device’s built-in or connected camera for the purpose of documenting or transmitting images (in place of a verbal description) to be used in consultation between healthcare providers and patients.¹⁰⁴

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

The FDA’s enforcement discretion encompasses the following MMAs: (5) “mobile apps that perform simple calculations routinely used in clinical practice.”¹⁰⁵ These apps are intended for medical use, but have the functional simplicity of ‘paper charts, spreadsheets, timers and generic mathematical calculations.’¹⁰⁶ These apps include medical calculators such as: “Body Mass Index (BMI); Total Body Water / Urea Volume of Distribution; Mean arterial pressure; Glasgow Coma Scale score; APGAR score; NIH Stroke Scale; and Delivery date estimator.”¹⁰⁷ These are not only simple calculations that act as test, but are common and can be useful to know despite the patient’s condition. These calculations provide general indications of health and wellness.

Enforcement discretion applies to: (6) “mobile apps that enable individuals to interact with personal health record (PHR) systems and electronic health record (EHR) systems.”¹⁰⁸ These MMAs enable patients and providers to gain mobile or electronic access to health record systems or health information stored in PHR or EHR systems.¹⁰⁹ *Appendix B* provides the following example: “Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g. body temperature, heart rate, blood pressure, or respiratory rate).”¹¹⁰

MMAs subject to enforcement discretion are those that generally pose a low risk to consumers. Generally, these apps facilitate healthy lifestyles, ensure provide tools to organize

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 18.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 24.

health information and enable patients to access their own health information, but not have the intended use of diagnosing, preventing, restoring, curing, nor are they purported to supporting or sustaining life. Thus, they generally have low risk of impairing health. Likely if followed properly have a negligible or positive effect on health; these apps are likely a zero sum game. For more examples of MMAs subject to enforcement discretion see *Appendix B: Examples of mobile Apps for which FDA intends to exercise enforcement discretion*.

III: Classification and Clearance Overhaul

This note argues that the classification system as well as the clearance and approval processes utilized by the FDA is outdated and insufficient to ensure the safety and efficiency of all MMAs. The volume and variety of MMAs is extensive and defies strict taxonomy;¹¹¹ consequently not all MMAs fit squarely within the FDA's framework. The FDA guidance is evidence of the incongruence between the FDA's approach to MMAs and the challenge of appropriately categorizing the plethora of MMAs. Furthermore, the FDA's clearance and approval processes for MMAs is inadequate as its wide reliance on the substantially equivalent concept to clear and ensure the safety and efficacy of MMAs is insufficient. The extensive reliance on the 510(k) process to clear MMAs is inherently flawed. Furthermore, the 510 (k) and embodies that FDA stance to consumer protection and sends the message that MMAs have a caveat emptor warning attached, but lacks real controls to ensure consumer safety.

The FDA has reasonably insisted on applying its existing framework for medical devices to MMAs as it is mandated by Congress and has provided a carve-out for MMAs with negligible risk. While this approach is reasonable, it is not feasible as this approach is not flexible or fluid

¹¹¹ Cortez, *FDA Regulation*, *supra* note 1, at 372.

enough to accommodate all MMAs. Technology informs a device's intended use and in turn intended use informs a device's classification. The technology and intended uses of MMAs are too voluminous and varied to fit neatly into four classifications: subject to enforcement (class I- low-risk; class II- moderate-risk; and class III- high-risk) and subject to enforcement discretion (negligible risk). Not all MMAs fit neatly into the risk-based three-class system mandated by Congress. The Medical Device Amendment, enacted in 1976, charged the FDA with issuing regulations that classify all devices already in commercial distribution into one of three regulatory categories (classes I-III).¹¹² Technology has changed so much since 1976 and changes rapidly from year to year. Even recent amendments are unlikely to anticipate the technologies used by MMAs and prospectively determine that the three-tier system would remain an appropriate form of taxonomy. Thus, it is illogical to clear an MMA because of its seeming similarity with a device that was released to market before 1976, particularly when a self-interested manufacturer's assertions about the device are a decisive component, intended use, in determining SE. MMAs have outgrown the three-tier system and while a case-by-case approach is inefficient, another approach is necessary to account for MMAs and the rapid growth in technology. Additionally, the guidance document conveniently fails to address and categorize multifunctional MMAs that may have more than one intended use, resulting in multiple classifications (combinations of classes I-III, i.e. classes II and III).

Fitting a ball into a square, accurately describes the process of attempting to contain all MMAs within the four categories enumerated above. Because the FDA has adopted such an inappropriate approach, it has created confusion rather than bright line rules. In particular, the line between low risk devices subject to enforcement discretion and class I devices subject to

¹¹² Medical Device Amendment of 1976, PL 94-295 (S 510), PL 94-295, 90 Stat 539 (1976).

enforcement is unclear. A class I device “is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury”¹¹³ This definition of a class I device could easily encompass the mobile apps for which the FDA intends to exercise enforcement discretion. This questions the need for a category of devices subject to enforcement discretion, thus, making it an inappropriate catchall. There is seemingly no difference between class I devices and MMAs subject to enforcement discretion, except for the fact that MMAs are accessories to regulated medical devices or transform a mobile platform into a regulated medical device unlike tongue depressors and thermometers. However, these slight definitional differences do not amount to actual difference.

The following is an example of the blurred lines between classes I devices and MMAs subject to enforcement. The FDA states that it will apply enforcement discretion to “mobile apps that provide easy access to information related to patients’ health conditions or treatments (*beyond* providing an electronic ‘copy’ of a medical reference).” (emphasis added)¹¹⁴ Conversely, the guidance states that “mobile apps that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations” are subject to enforcement.¹¹⁵ However, for example, WebMD’s symptom checker could easily fit into both categories- subject to enforcement and subject to enforcement discretion. WebMD, an app that provides valuable health information, tools for managing your health, and support to those who seek information, “applies accumulated medical knowledge to

¹¹³ 21 U.S.C. § 360c.

¹¹⁴ FDA, GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 6, at 17.

¹¹⁵ *Id.* at 14.

patient-specific inputs, generating more granular diagnosis and treatments.”¹¹⁶ The app uses patient-specific information to provide a user with easy access to information related to patients’ health conditions or treatments. When initializing the app and utilizing symptom checker, it requires a patient to enter age, zip code, and gender and then it requires a patient to pinpoint the affected by pointing to the region of the body on a model. Then the patient must pick from a list of symptoms, refine those symptoms by picking from an additional list, and build a profile of symptoms before being provided with a list of possible diagnoses. The Guidance document does not mention apps like WebMD’s symptom checker and this is an app that straddles the line.

Furthermore, the WebMD app and apps like it are seemingly harmless, but provide a level of customization that may mislead an unwary patient. These apps do more than simply provide information and reference materials. Part of the app, the symptom checker, gathers personal health information (PHI), albeit general, and provides a narrowed and personalized menu of potential conditions that a patient may have and even gives an indication of the likelihood of each condition. Furthermore, the app provides information on treatment, self-care, and when to see the doctor. These apps are intended for use by the general public which makes them even more concerning. The average person may not consult a medical professional to confirm the condition, treatments, and advice of the WebMD app. This is particularly concerning for patients with preexisting conditions that might require more nuanced treatment in order to avoid adverse reactions. While these apps have a role in empowering patients with information and knowledge and even saving resources such as clinics, nurses and physicians’ time and expense of addressing simple conditions for which self-care is appropriate, these apps in their current unregulated and unrecognized state are problematic. While WebMD likely has

¹¹⁶ Cortez, *The Mobile Health Revolution?*, *supra* note 18, at 1204.

disclaimers and other warnings for to alert consumers to the fact the app is to be used for general knowledge (although when I downloaded and utilized the app as research for my note, I was not asked to agree to any terms or acknowledge my understand of any disclaimers prior to use), it is easily foreseeable that a patient may delay or forgo seeking medical attention because the app suggests simple home or over-the-counter remedies. Without regulation and even mention of such apps in the FDA guidance, these apps present too much uncertainty for manufacturers and potential harm to consumers. The onerous is placed on patients to ensure the safety of an MMA rather than the FDA as consumer reports of adverse events are likely the mechanism through which the FDA will address issues with WebMD like apps. The Guidance clearly states that it is a guide to industry persons such as manufacturers of apps and FDA staff, but this is problematic as the guidance has little direct focus on consumer protection. It is as if the FDA has adopted a caveat emptor “buyer beware” stance.¹¹⁷ Guidance and potential regulation in this area needs to be more robust to anticipate the chance of harm from apps with seemingly negligible potential for harm.

Furthermore, the FDA’s use of the substantially equivalent concept to clear new devices that have a legally marketed predicate is insufficient to ensure the safety and efficacy of MMAs. Nathan Cortez, Professor of Law at the Southern Methodist University, Dedman School of Law, writes that many MMAs are being cleared by the FDA as “substantially equivalent” to analogous predicate devices that have been previously cleared under the 510(k) process.¹¹⁸ Further, he argues that many mhealth products utilizing emerging technologies should be subject to more

¹¹⁷ Samuel J. Dayton, *Rethinking Health App Regulation: The Case for Centralized FDA Voluntary Certification of Unregulated Non-Device Mobile Health Apps*, 11 IND. HEALTH L. REV. 713, 726 (2014).

¹¹⁸ Cortez, *FDA Regulation*, *supra* note 1, at 375.

rigorous premarket approval, but most apps have been subject to premarket notification under the 510 (k) process and cleared as being substantially equivalent to a predicate device, despite the fact that many predicate devices have different technological characteristics from new apps as many predicate devices were developed before smartphone and mobile technology existed.¹¹⁹ This suggests that this system of clearance may be outdated and that a new means to ensure that new devices and predicates are analogous and truly constitute the substantial equivalence of one another is needed to ensure safety and efficiency of MMAs hitting the market now.

Lastly, while enforcement discretion is an established agency power, it is problematic in the context of MMAs because it is reactionary rather than proactive. Once MMAs, like other mhealth products, are placed on the market the FDA reviews reported adverse events to make determinations concerning withdrawal of a device or changes to the labeling and advertisement of a device,¹²⁰ but this is a less than functional approach to ensuring the safety and effectiveness of MMAs. This approach waits for MMAs subject to enforcement discretion to malfunction before seeking to implement safeguards. Again, low risk does not mean no risk and as discussed above some apps with seemingly negligible levels of risk can be harmful without proper safeguards.

IV: Regulation, Revision, and Recall

The FDA needs to enact regulation specifically addressing MMAs to give manufacturers clearer guidelines and encourage high-quality innovation.¹²¹ Proposed regulation should be submitted for full notice and comment rule-making in order for the public and manufacturers of MMAs to weigh-in and give the FDA a clearer picture of the variety of MMAs in existence and

¹¹⁹ *Id.* at 374-5. *See* Medical Device Amendment, *supra* note 112.

¹²⁰ Cortez, *FDA Regulation*, *supra* note 1, at 374.

¹²¹ *Id.* at 376.

technologies utilized. This will put the FDA on notice of challenges manufacturers have experienced thus far. New FDA promulgated regulation must be coupled with Congressional updates to the FDA's authority so that the FDA may appropriately address MMAs and preserve the FDA's discretion to manage emerging risks.¹²² It is hoped that the FDA's final regulations will be more prospective than the guidance document, provide clarity, and furnish manufacturers with clearly delineated guidelines, certainty, and bright line rules where possible. Regulation rather than recommendations and suggestions presented through guidance documentation is needed as regulations would be legally binding upon manufacturers and provide a more concrete set of guidelines for manufacturer as well as better encourage compliance. Proposed regulations should be robust and provide a far more comprehensive appendix of examples based on a more encompassing survey of MMAs and incorporation of the notes and comments provide by industry persons.

MMAs should be subjected to a rigorous clearance process to ensure the safety and efficiency.¹²³ Premarket notification clearance through the 510(k) process with unreasonable reliance on SE is insufficient to ensure the safety and efficiency of MMAs. Additionally, MMAs subject to enforcement discretion are currently not subjected to any premarket clearance or approval process; they are simply monitored for adverse events subsequent to market release. Because MMAs have emerging technology that may be vastly different than predicate devices the 510(k) process is inappropriate for MMAs and another clearance procedure should be implemented. Congressional creation of a unique clearance and approval process for MMAs is

¹²² *Id.*

¹²³ Dayton, *supra* note 117, at 727.

the answer.¹²⁴ The FDA should work with Congress to determine criteria that would ensure safety and efficacy of MMAs as well as create premarket screening procedures that would sift out problematic MMAs. One approach to determining the appropriate clearance criteria may be to revise the classes (I-III), implement specific controls for each new class, and use the controls as a checklist for safety and efficiency. With the potentially thousands of emerging MMAs, the FDA will be unable to enforce new regulation and more rigorous clearance without additional resources and manpower. Thus, the FDA should certify industry review boards as experts on MMAs as well as the unique MMA-centered clearance and approval pathway. This will allow the FDA to outsource the task of screening MMAs, but retain control over the process. Thus, the FDA should form review boards that consist of MMA manufacturers, physicians, scientists, medical device producers as well as distributors. The FDA can educate these review boards, provide them with a voice in the process and task them with the job of clearing MMAs. Nathan Cortez, a prominent legal scholar, suggests that the FDA should charge manufacturers a clearance fee to fund the additional enforcement resources, i.e., industry review boards.¹²⁵

Currently, MMAs subject to enforcement discretion do not undergo any premarket approval, these MMAs are only subject to post-market monitoring. If the above recommendations cannot be implemented, then at very least a more robust recall and assessment process for MMAs should be implemented. Recall is an effective method of removing or correcting mhealth products that may be in violation of FDA laws.¹²⁶ Recall is voluntary; recall is a duty of manufacturers and distributors to facilitate protection of the public health and well

¹²⁴ Cortez, *FDA Regulation*, *supra* note 1, at 376-7.

¹²⁵ *Id.* at 377.

¹²⁶ 21 C.F.R. § 7.40 (2010).

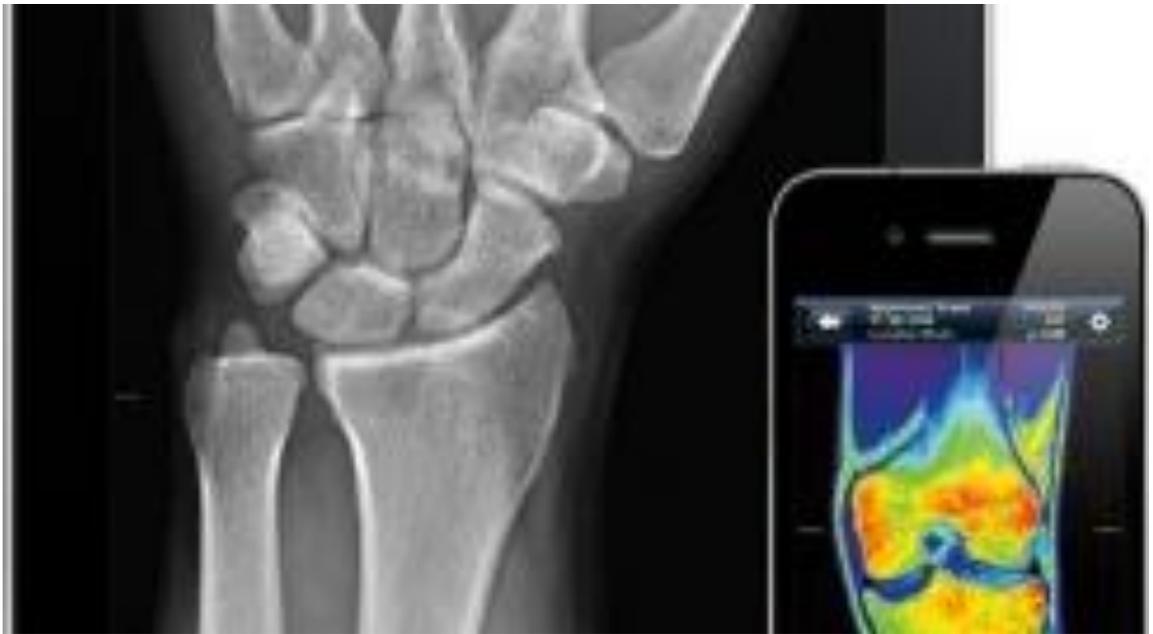
being from injury and deception due to product malfunction.¹²⁷ However, it should be noted that clear laws and regulation are needed in order to apprise manufacturers of when they are in violation of the law. Further, if an MMA has had the opportunity to harm a consumer or has become the subject of a reported malfunction, it should subsequently be subjected to the most heightened scrutiny. Prior to a second release to market the particular MMA should be subjected to the PMA process. The PMA's requirement of clinical trials and an accompanying research report attesting to a device's continued safety and efficiency should be sufficient to correct the issue. Implementation of the PMA process during recall and assessment will not solve the problem of the FDA's tendency to be reactionary rather than proactive, but it will ensure that problematic MMAs are cured of applicable defects.

Conclusion

As MMAs with new and varied technology emerge and multiple, adoption of regulation, a unique clearance and approval pathway for MMAs as well as a rigorous recall and assessment program recommended in this note is necessary. Implementing the above recommendations will provide MMA manufacturers with clarity and predictability as well as support the FDA implementing change needed to appropriately control MMAs, set up enforcement, and ensure public safety.

¹²⁷ *Id.*

Appendix A





Wound Measurement and Documentation System



Medco Pharmacy Mobile App



Appendix B

FDA's approach to MMAs

