

An mHealth Regulatory Coalition White Paper: Consumer Medical Devices Used To Manage Health

The mHealth Regulatory Coalition urges FDA to develop and issue a new guidance document explaining the difference between disease-related claims that the agency regulates under its medical device authorities, and wellness related claims that the agency does not regulate. This paper is intended to provide our proposed framework for such a guidance.

Background: What is the issue?

In the old days, we lived under the fiction that taking care of health was dichotomous:

1. Doctors managed the diagnosis and treatment of disease and they did so largely in doctors' offices or hospitals.
2. Consumers generally understood that certain things like a well-rounded diet and exercise were good for us, and we managed that in our home by ourselves.

In that scenario FDA's responsibilities were relatively clear. FDA focused on the tools used by doctors in a healthcare setting to manage disease. According to the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (section 201(h)), medical devices include those products "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." The central thrust of that definition is that the product is used in connection with disease or other conditions, the word conditions being added to address such things as pregnancy. Thus, in the early days of the 1976 amendments, the definition was relatively clear in that it referred to products used in the domain of healthcare institutions to diagnose or treat disease or such conditions as pregnancy.

Today those activities are not so neatly separated. We have a much more sophisticated understanding with regard to how daily activities influence the likelihood of disease or other adverse health conditions. So consumers are taking proactive steps in their homes to better manage their health and ward off disease. Based on newly available genetic information, for example, consumers have a better understanding of where they may be at risk for disease, which in turn allows them to manage much more carefully the elements of their daily lives that constitute risk factors for that disease.

Old approach: assessing disease

The broad category of diagnostics was broken down into three subcategories.

Subcategory	Defining Characteristics Of The Subcategory
Screening	This is when a testing product is used on an asymptomatic individual. At the same time, these products might be used on individuals who are in some manner deemed higher risk of a disease, for example testing for hepatitis among individuals

	struggling with substance abuse. If a screening test produces a positive result, the individual is often referred for diagnosis.
Diagnosis	This is when a testing product is used on a symptomatic individual to assess and confirm a diagnosis. So these products might be used, for example, when an adult presents an emergency room with shortness of breath, dizziness and nausea to assess for a myocardial infarction. If an individual is diagnosed with a certain disease or condition, depending on the disease, the physician may need to monitor that individual's health status relative to the disease.
Monitoring	This is when a testing product is used on a patient who has a confirmed diagnosis, for the purpose of assessing health status in order to manage treatment over time. A common monitoring system is a blood glucose test strip and reader used to measure blood glucose levels in a patient with diabetes. One of the differences between this category and the other two is that this category of testing is done as a part of therapy management, where the other two are done as a part of determining whether therapy is needed.

New approach: managing wellness

To that list of subcategories we propose to add the following 4th subcategory.

Managing wellness	<p>This new category combines elements of screening and monitoring.</p> <ul style="list-style-type: none"> • Like screening, these testing products would be used on asymptomatic individuals where there may be some indication that the individual is at risk for a particular disease, for example because of family history, genetic makeup and other risk factors. • But like monitoring, these tests would involve tracking information over time as an aid to long-term health management. For example, regular use of a weight scale when dieting.
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Emerging clinical evidence

There is a growing body of clinical evidence around preventive health and a consumer's ability to effectively ward off disease by better general health management based on information collected over time. That research focuses on areas such as the following:

Use case 1. Reducing the risk of diabetes.

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- Target consumer example: A person at risk of diabetes because of family history and weight. But presently the person does not have the symptoms of diabetes.
- The CDC observes that people with prediabetes who lose 5%–7% of body weight and get at least 150 minutes a week of moderate physical activity can reduce the risk of developing type 2 diabetes by 58%.
- Product – an app that helps them manage their calorie intake, exercise level, and other factors known to reduce the risk of diabetes.

Use case 2. Reducing the risk of heart disease.

- Target consumer example: A person at risk of heart disease because of family history, sedentary lifestyle, smoking and poor eating habits. But presently the person does not have the symptoms of heart disease.
- The American Heart Association recommends a diet low in fat, particularly saturated and trans fats, enriched in fruits, vegetables, whole grains, and fish, and low in added sugar and salt. The AHA also recommends against smoking. Smoking cessation may have beneficial effects on the lipid profile by increasing HDL-C (mean, 4 mg/dL). Exercise, physical activity, and weight loss may also increase HDL-C and lower triglyceride levels. The AHA recommends 30 minutes of moderate-intensity aerobic exercise on most days of the week.
- Product: an app designed specifically to track the elements of dietary intake related to the risk of heart disease, particularly fat and cholesterol levels. The app could also help implement elements of a smoking cessation program, and track physical activity, for example, by connecting to a pedometer.

The bottom line is that we as a society need to be encouraging use of products that help people live healthier lives. The further bottom line is that these apps do not engender any material risk, and therefore do not merit FDA regulation even though they mention disease.

Scope: What are the defining characteristics of products in this category?

In each of the three categories below, we are focusing solely on products used by consumers outside of a healthcare institution to measure information about their bodies. These categories include any specialized software or hardware, or combination of the two, that serve these purposes.

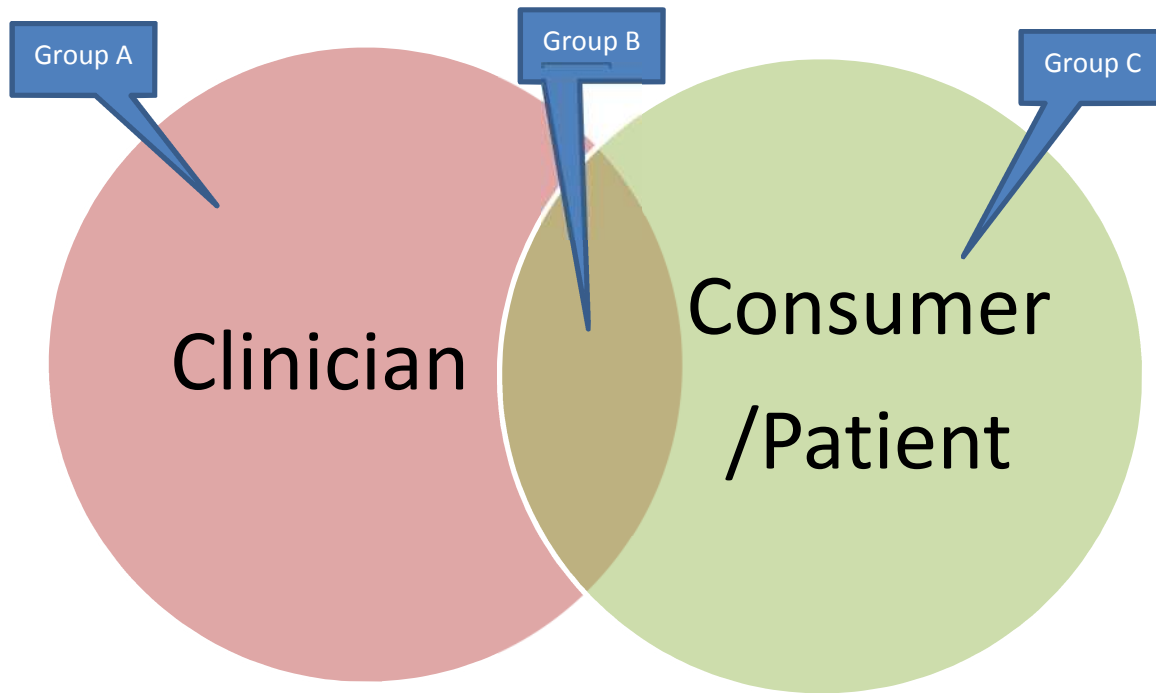
From a big picture perspective, we divide these products into three different groups based on the roles of the doctors and patients/consumers. We explained more below, but at a high level:

1. Group A includes those products that produce information that is really only meaningful to the doctor or other caregiver, because interpreting the information requires specialized expertise. Think about interpreting an EKG.

2. Group B includes those products that produce information that is meaningful to both the doctor and the patient. While this may be result of training that the doctor gives to the patient, nonetheless the information is meaningful to the patient. Think about a blood glucose meter that people with diabetes use to manage their diabetes and report the results to the doctor. Products in this category really rely on collaboration between caregiver and care receiver.
3. Group C includes those products that produce information that is used by consumers alone without a doctor's oversight. Think about weight scales and mobile apps that allow the consumer to track and trend his or her weight to avoid future health problems.

Visually, the groups can be viewed through the following Venn diagram:

Responsibility for Interpreting the Information



Group A – Doctor- Directed Disease Assessment Devices

The essence of this category is devices/SaMD designed to produce information that doctors are trained to interpret and understand, and consumers are not, but that are destined for consumer hands with the goal of feeding the information back to the doctor on some periodic basis. Devices in this category are easy to spot because there are existing FDA device classifications for the associated functionality, such as urine analysis for occult blood and so forth. The common thread that runs through all of these measuring devices is higher-risk disease states or conditions, with an imperative need for accuracy in either diagnosis of the disease or monitoring in the case of a chronic disease. Further, the devices will

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be available through prescription because it will be necessary to involve a doctor in the interpretation of the information.

Obviously if devices are intended for use by doctors on patients, they too will be in this category.

FDA regulates this category. While many devices in this category will be in class II, some devices will be regulated as class I devices (or class II exempt from premarket notification) because the technology is so well characterized that FDA premarket review is not necessary.

Group B –Disease Assessment Devices used Collaboratively by Doctor and Patient

The defining characteristic of devices in this category is that consumers are fully capable of interpreting the information produced by these devices, but at the same time a health professional should be involved. It's important to understand that there can be a natural evolution of disease assessment tests from physician-directed (Group A) to consumer-directed (Group B) as companies innovate with new ways to make the information more meaningful to people without a medical background. So long as the information is truly understandable by consumers without special medical training, assessing disease can include:

1. Screening
2. Diagnosis
3. Monitoring of a serious disease that requires reporting to a healthcare professional

As already explained, products in this group are also characterized by the need for the patient to collaborate with his or her physician. The disease or condition is serious enough, and the measurements important enough, for the doctor to be kept at least generally informed in the case of monitoring, or consulted in the case of screening or diagnosis.

There are two different roles these products might play:

1. Devices that measure

FDA regulates the tools used for measuring in this category, and any associated accessories (see separate policy position on the scope of accessory classification). Most of these devices should be in class I, not subject to FDA review, except those new technologies that are not well enough characterized to produce reliable results, where inaccurate results could substantially jeopardize the safety of the consumer. This latter category should be in class II.

2. Devices that do not measure

If a product is not a tool used for measuring, nor an accessory of such a product, the product does not fall within FDA regulation. Examples of this would include mobile apps and other software that are merely intended to record and analyze health data for consumers.

Group C –Health and Wellness Managing Devices

The defining characteristics of devices in this category are:

1. Intended for use by consumers who
 - a. Are well--
 - i. Experiencing no meaningful symptoms of the disease at issue
 - ii. But may or may not have risk factors of concern, including family history or genetic makeup; or
 - b. Have been or may still be sick, (i.e. has been diagnosed and treated), but--
 - i. live outside of a healthcare facility,
 - ii. without a healthcare professional monitoring the disease or condition, just the consumer himself and/or perhaps his family members to ensure he is following instructions;
2. Repeated use over time for the purpose of tracking and trending health information;
3. For the purpose of influencing lifestyle decisions to reduce the future risk of disease or other conditions, or managing health issues without active health professional oversight; and
4. Are not invasive.

The essence of this category is disease avoidance and/or health maintenance. So long as those four conditions are met, it is permissible for the labeling for these products to mention the diseases the products are intended to help the consumer avoid or manage without triggering FDA regulation.

A couple of examples may make this more concrete.

- A fitness/wellness app that uses body sensors to detect the user's bio signals for purposes such as measuring body fat to support general conditioning.
- Also to support a consumer's general fitness and wellness goals, an app that uses sophisticated analytics to review and analyze data generated from unregulated products that detect such things as heart rate or body fat.

Those products should remain unregulated even if the manufacturer chooses to educate consumers regarding general risk factors for specific diseases, and encourages the consumers to use these products to track and trend information over time so that the consumer can live a healthier life and avoid those diseases or other conditions.

FDA should not regulate this category. All of the devices in this category either are not medical devices or if they technically meet the definition of medical device, are so low risk they should be subject to enforcement discretion.¹

¹ This conclusion lines up with the FDA's statement in its Mobile Medical Application Guidance on certain types of applications, including wellness management applications: "Some mobile apps in the above categories and listed below may be considered mobile medical apps, and others might not. For those mobile apps listed below that are

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To further explain the three groupings, we are including as attachment one a list of some of the available mobile apps that fit into these groupings.

A footnote on off label use

As with all FDA regulation of medical devices, these categories are based on the manufacturer's intended use for the product. And as with all medical devices, there is a chance that purchasers will use the product in a way different than was intended. That is unavoidable. But at the same time, FDA should not permit a sham intended use. An intended use will not be deemed a sham if there is in fact a substantial market for use of the product precisely as the manufacturer has intended.

devices, FDA intends to exercise enforcement discretion because they pose a low risk to patients." (FDA Mobile Medical Application Guidance, MMA-1741, Page 16, September 25, 2013)

Attachment 1

Examples of Apps That Fall Into These Groups

Each of the following examples is presently on the market, without any apparent compliance with FDA requirements. We urge FDA to issue a guidance document to clarify the dichotomy between regulated disease claims (Group A and Group B) and unregulated health and wellness claims (Group C) so that the marketplace can come into compliance more effectively. The text that describes each app is taken from the official description of the app in iTunes and/or the company website.

Proposed Grouping	Existing App Available In The United States
Group A	<p>Sleep Aid By Remote Analysis Description “As a long-time iPhone user I was enthusiastic to be the medical advisor for the team to develop this application. Sleep apnea is a common sleep disorder and our aim was to create a tool that enables anyone easily detect the need for a further sleep study. Sleep Aid does not substitute a diagnosis made by your doctor but may give an alarm that one should see a doctor to find out how to sleep better. Remember that snoring may compromise the quality of your sleep. Consult your ENT-specialist to get treatment for your snoring.”</p> <p>Miikka Peltomaa, MD, PhD Otolaryngology, Head and Neck Surgery ENT Center Aino Jarvenpaa, Finland</p> <p>“Sleep Aid is a smart application for anyone who suspects s/he may suffer from a sleep disorder. Especially sleep apnea is a severe and insidious disease that – if not treated – may cause a number of other conditions and can in the worst case lead to death. If you find signs of sleep apnea in your recording, always consult your doctor.”</p> <p>Heikki Lehti, MD, PhD Pulmonology Kerava, Finland</p> <p>SLEEP APNEA</p> <p>Sleep apnea is characterized by recurrent episodes of airway obstructions and corresponding cessations of airflow and breathing. A cessation in breathing is called an apnea.</p> <p>The most common reason for an apnea is a physical block to airflow when the tissues in the throat prevent normal breathing. This is especially common among overweight people but individuals with normal weight may suffer from it as well.</p>

Proposed Grouping	Existing App Available In The United States
	<p>Sleep Aid makes it easy for you to determine whether you suffer from sleep apnea and should consult a doctor. The application records eventual snoring sounds and creates an easy-to-read graph. By examining the graph, you can find out your snoring. You can also listen to your breathing and snoring pattern.</p> <p>SLEEP AID</p> <p>Sleep Aid includes samples of typical snoring and sleep apnea events. You can compare your own recording with the provided samples to determine whether there are symptoms or signs of sleep apnea. Remember, however, that only a doctor can make the diagnosis. Always consult a physician when you think you may suffer from a medical condition.</p> <p>FEATURES</p> <ul style="list-style-type: none"> • Recording your snoring sounds • Easy-to-read graph of your snoring • Listening to your snoring • Snore and sleep apnea samples • Useful information about sleep apnea
Group A	<p>MaculaTester By Sabina Technology, LLP Description The MaculaTester® - A New Way to Monitor Visual Function!</p> <p>Diseases that affect the macula (the center of the retina) including macular degeneration and diabetic retinopathy are the main causes of blindness worldwide. The best defense against these macular diseases is early detection.</p> <p>This simple test of your vision can alert you to early changes that may indicate a problem with your macula caused by diabetes or macular degeneration.</p> <p>The MaculaTester (Pat. No. 8,047,652), is an INTERACTIVE version of the Amsler Grid - the standard test used by eye doctors to test macular function for over 50 years.</p> <p>Image distortion is often the first visual change that patients notice when the condition is starting or advancing. Since the distortion can be subtle and difficult to notice at first, the Amsler Grid is used to help detect it as early as possible - while it is still treatable.</p> <p>Most doctors give their patients a card with an Amsler Grid to test themselves at home between eye exams. Unfortunately, many patients loose it or forget to use it.</p> <p>The MaculaTester performs the same function as the Amsler Grid but with several distinct advantages:</p> <p>1) It is interactive - allowing you to record the area of distortion by touching the screen.</p>

Proposed Grouping	Existing App Available In The United States
	<p>The recorded image is saved with date and time so you can show it to your doctor, as well as compare to previous images to look for any changes.</p> <p>2) It resides on your iPhone/iPod Touch - so you won't lose it.</p> <p>3) Our free "push notification" feature reminds you to perform the test at regular intervals - so you won't forget to use it.</p> <p>-CHECK OUT THE VIDEO DEMONSTRATION ON OUR WEBSITE - www.maculatester.com.</p> <p>- This app is intended for use only as an early screening test for macular dysfunction. It is not designed or intended to be used as a tool to diagnose macular degeneration, diabetic retinopathy or any other disease process. This test is not a substitute for an examination by a qualified eye care professional.</p>
Group B	<p>Cardiograph: Heart Rate Pulse Measurement using your iPhone & iPad Camera - Track the Cardio Fitness of your Friends and Family By MacroPinch Ltd.</p> <p>Description Cardiograph is an application which measures your heart rate. You can save your results for future reference, keep track of multiple people with individual profiles, add notes and locations, and even print out your measurements for sharing or safe keeping.</p> <p>Cardiograph uses your device's built-in camera to take pictures of your fingertip and calculate your heart's rhythm - the same approach used by professional medical equipment!</p> <p>"I know you have the disclaimer on the screen but I don't care, Cardiograph saved my life. Your app was key to understanding what was going on and help the doctors understand too." Bob Spadafora - *****</p> <p>"After having two heart valve replacements and a by-pass, I feel it is not only smart - but also necessary - to have such a reliable heart rate monitor with me everywhere I go." Dantv – *****</p> <p>"I am an EMT and it helps me actually see what is going on. It is by no means definitive like a monitor but it is a great indicator of problems I would not see otherwise." Granniem – ****</p> <p>"I had a pulse oximeter on one hand, medical quality, and my iPhone app in the other and the app was dead-on accurate." Like it but hate it – *****</p>
Group C	<p>Stress Check is the most innovative tool available for quantifying your level of psychological or physical stress. By measuring your heart rate through the camera and light features on your iPhone, Stress Check can estimate your level of stress in real time.</p>

Proposed Grouping	Existing App Available In The United States
	<p>Using Stress Check by Azumio you will be able to:</p> <ul style="list-style-type: none"> • Quantify your level of stress • Determine the effects of different stressors • Control stress and observe progress • Reduce chances of certain chronic diseases known to be correlated with stress <p>Everyone has experienced changes in heart rate before taking an exam, giving a public speech, or when exercising. In fact, not only does your heart rate increase, but the time variations between consecutive heart beats become more random and scattered as well. By analyzing this factor of heart rate variability (HRV), it is possible to estimate your level of stress wherever you are, with no additional hardware.</p> <p>Analysis of HRV requires heart pulse data to be measured continuously for a certain period of time. The more you use Stress Check, the better the app gets to know you and your heart.</p> <p>Algorithms used to analyze HRV follow recommendations of European Society of Cardiology (ESC) and the North American Society of Pacing and Electrophysiology (NASPE).</p>
Group C	<p>HeartWise Blood Pressure Tracker By SwEng L.L.C.</p> <p>Description</p> <p>There is a reason our software is one of the highest-rated Apps on the App Store - with more than 1,000 ratings and reviews, our customers have been quite clear: HeartWise is the easiest-to-use application for quickly recording and keeping track of your blood pressure, resting heart rate, and weight. Our trend-setting visualization quickly shows you trends, detailed analysis, statistics that tell you how your blood pressure fluctuates on a daily basis and over time. Our powerful statistics and charts are unmatched and give you unprecedented visualization.</p> <p>HeartWise features:</p> <ul style="list-style-type: none"> - An elegant data entry screen that is seamlessly intuitive.

Proposed Grouping	Existing App Available In The United States
	<ul style="list-style-type: none"> - Tracks systolic and diastolic blood pressure, resting heart rate (Pulse), and weight. - Automatically calculates mean arterial pressure, pulse pressure, and body mass index. - Export your data by email as a fully formatted report, in spreadsheet format, or as plain text. - Easily import existing records or data from other applications. - Configure Reminders to alert you when it's time to take a measurement or your medication. - News and Announcements - Detailed statistics reporting shows how your blood pressure and other measurements change over time. - Support for weight in Imperial units (pounds) or metric (kilograms). - Clear, crisp charts with a quick "camera" feature to save high-resolution copies to your photo library! <p>HeartWise has a simple, streamlined interface that lets you input data in seconds. The touch of a button gives you detailed charts and statistical reports that show trends visually and how your blood pressure - and your health - changes over time.</p> <p>HeartWise has a fully capable export feature that allows you to send your data as a fully formatted report, as a spreadsheet, or as plain text directly from your phone. You can send your blood pressure, pulse, and weight history to yourself - or even your doctor. Similarly, existing data or measurements from other applications can be easily opened and imported into HeartWise.</p>
Group C	<p>Nutrition Menu - Calorie, Exercise, Weight & Water Tracking By Shroomies</p> <p>Advance your diet by having nutritional information for over 100,000 food items right at your fingertips! Whether you go out to eat or cook at home, Nutrition Menu takes the guesswork out of choosing healthy meals and even includes a calculator to compute your Food Score. Have the peace of mind knowing that your meal fits within your dietary allowance. You can then track from meal to meal insuring a higher weight loss by</p>

Proposed Grouping	Existing App Available In The United States
	<p>keeping a journal of what you have consumed. Whether you are counting carbs, watching calories, or have diabetes, Nutrition Menu makes it easy for anyone who needs to track what they eat.</p> <p>"The mother of all iPhone calorie counters" - Fitness Magazine</p> <p>FOOD FEATURES:</p> <ul style="list-style-type: none"> ✓ Over 49,000 restaurant menu items of 360 USA and some Canadian restaurants (see website for list) ✓ Over 51,000 entries for common foods like apples, meat, frozen meals, etc ✓ Shows Points Plus and Points Classic numbers ✓ No Internet communication means fast access to information ✓ Nutrition info includes calories, fat, carbs, fiber, serving size, protein, cholesterol, sodium, and sugars ✓ Add your own custom foods ✓ Put your popular foods in the Favorites ✓ Search feature ✓ Updates nutritional values when you change quantity <p>EXERCISE FEATURES:</p> <ul style="list-style-type: none"> ✓ 149 built-in exercises ✓ Add your own custom exercises ✓ Activity Score Calculator ✓ Put your custom exercises in the Favorites ✓ Calculate calories burned by exercising based on your weight

Proposed Grouping	Existing App Available In The United States
	<p>JOURNAL FEATURES:</p> <ul style="list-style-type: none"> ✓ Shows daily summary with progress bars ✓ Breaks down calories in a pie chart ✓ Shows all foods and exercises for a day ✓ Supports extra Food Scores for the week ✓ Write daily notes ✓ Email the Journal and import into a spreadsheet ✓ App icon on the Home Screen shows today's total Food Score <p>WEIGHT TRACKING FEATURES:</p> <ul style="list-style-type: none"> ✓ Weight tracking with graph ✓ Use pounds or kg ✓ Change time range of weight graph <p>WATER FEATURES:</p> <ul style="list-style-type: none"> ✓ Use cups, oz, or mL ✓ Set your personal goal