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Overview of FDA Regulation

(with a Medical Device Emphasis)

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- This presentation supports an oral briefing and should not be relied upon solely on its own to support any conclusion of law or fact.
- These slides are intended to provide general educational information and are not intended to convey legal advice.

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FDA Definitions

Drug

An article (other than food)

- **Recognized in USP or other compendia;**
- **Intended to diagnose, cure, mitigate, treat or prevent disease;**
- **Intended to affect structure or function of body of man; or**
- **Intended as component of these**

Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act"), which, as amended, can be found at
http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

"Biologic"

- **"... any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product ... applicable to the prevention, treatment, or cure of diseases or injuries of man..."**
  - Biologics include such vitally important products as polio and measles vaccines, diphtheria and tetanus toxoids, and skin test substances, as well as whole blood and blood components for transfusion.
  - **"True" Biotech products –** are biologics, but also may meet the definition of:
    - Drug
    - Device – particularly diagnostics

Drug vs. Biologic (in general)

Drug

- Chemical synthesis
- MW less than 500 kD
- Screen base on similarity to other chemical structures
- Characterization – well-defined
- Not extremely heat sensitive

Biologic

- Composed of or extracted from a living organism
- MW greater than 500 kD
- Complex structures – hard to characterize
- Less well-defined
- Heat sensitive
- Immunogenic

"Device" -- 201(h) of the Act

- **"an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is:**
  - recognized in the official National Formulary, or the United States Pharmacopoeia, 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 any of 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 any of its primary intended purposes."

Food – Section 201(f) of the Act

- **The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.**

Dietary Supplement – Section 201(ff) of Act

- **Dietary Supplement Health and Education Act (DSHEA) of 1994**
- **Taken by mouth that contains a "dietary ingredient" to supplement the diet.**
- **"Dietary ingredient" -- must be one or any combination of the following substances:**
  - a vitamin,
  - a mineral,
  - an herb or other botanical,
  - an amino acid,
  - a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
  - a concentrate, metabolite, constituent or extract.
- **"New dietary ingredient" -- a "dietary ingredient" not marketed in the U.S. in a dietary supplement before October 15, 1994.**
  - ***Prior market clause*** – if in an IND or approved, can not be a dietary supplement

Cosmetic – Section 201(i) of Act

- (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
- (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

Key Concept – Intended Use

- **All definitions are keyed to "intended … to/for"**
- **Change in intended use can render a product that might look like one regulated commodity (e.g., a food) into another (e.g., a drug)**
  - **Intended Use** – inferred by FDA be wide range of statements:
    - ***Labels***
    - ***Labeling*** – "accompanies" – i.e., explains – the product
    - ***Advertising*** – not defined in the Act
    - ***Internet/Social Media*** – FDA will call "Labeling" if it wants
    - ***Verbal statements*** – often used to buttress other statements
  - **Example**: Milk internet site: "Treats AIDS"

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Mission & Structure of FDA

The Mission of the FDA

The FDA promotes, protects, and enhances public health through the medical product development and evaluation process.

The FDA's mission is to:

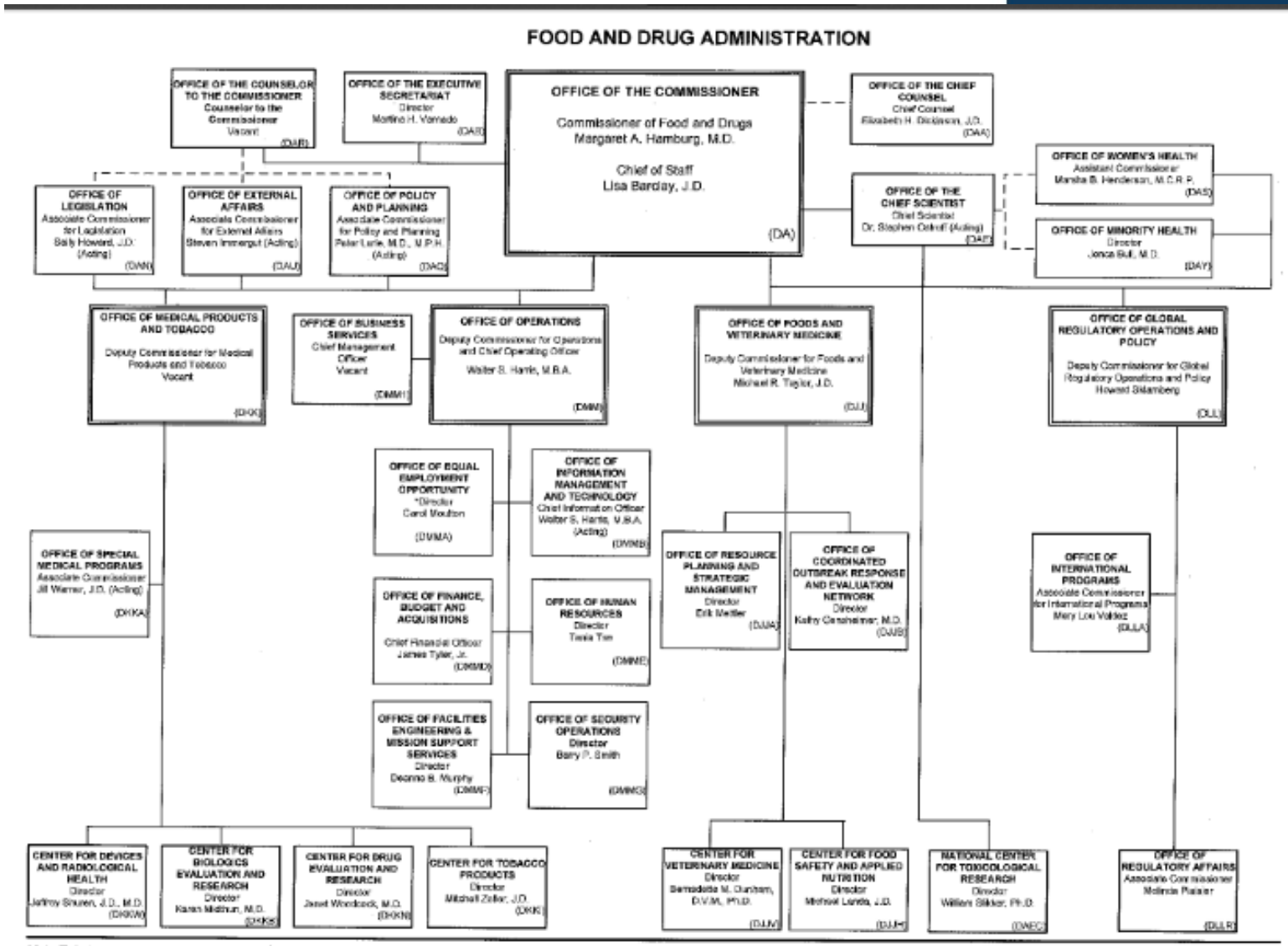
Approve products for marketing that are effective for the labeled indications, provide benefits that outweigh their risks, are of high quality, and have directions for use that are complete and honestly communicated.

Core FDA Functions

- **Gatekeeper to Marketplace – product approval/clearance**
- **Cop on the Beat – enforcement and compliance**
- **Sentinel of Health Concerns – adverse event monitoring**
  - partly in coordination with CDC and other federal, state and local health authorities

Who Regulates What at FDA?

- ***Drugs and Therapeutic Biologics***: Center for Drug Evaluation and Research (CDER)
- ***Biologics, Including Blood, Cell & Gene Therapy***: Center for Biologics Evaluation and Research (CBER)
- ***Medical Devices and Radiological Products***: Center for Devices and Radiological Health (CDRH)
- ***Foods, Dietary Supplements, and Cosmetics:*** Center for Food Safety and Applied Nutrition (CFSAN)
- ***Tobacco:*** Center for Tobacco Products (CTP)
- ***Animal Drugs*** – Center for Veterinary Medicine (CVM)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4/11/14
Approved by the FDA Reorganization Coordinator and Principal Delegation Control Officer

Who Else Regulates Medical Products ?

Regulating U.S. Medical Products involves more than just FDA

- ***Domestic*** **—** includes FDA, BATF, EPA, **FTC**, DEA, CPSC, FSIS, CDC, FCC, Commerce, Agriculture, Transportation Departments.
  - **FTC** – jurisdiction over most medical device advertising
    - But, FDA will regard many things as "labeling"
- ***International*** **—** add USTR, Agency for International Development, US Treasury (Customs), State Department

Medical Device Regulation

Device Classifications

- **Class I – General Controls --** devices that pose the least amount of risk and typically can be introduced into commerce without any prior FDA clearance as long as the company otherwise complies with all of what are known as the "General Controls" (see later slide)
- **Class II – Special Controls**
  - Originally "Performance Standards"
  - Can even be for a "supporting or sustaining human life" if FDA can identify the Special Controls that will assure that the device has "adequate assurance of safety and effectiveness"

Device Classifications …

- **Class III – Premarket Approval –**
  - If device is:
    - 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 injury,
  - ***Clinical studies*** – needed
  - ***User Fees*** – ~ $250,000 (more detail later)

General Controls

- **Registering** the device establishment at which the device is made and **listing** the device (a notice process) w/FDA
- **Quality Systems Regulation (QSR)** -- regulations that implement the Good Manufacturing Practice (GMP) requirements for medical devices
- **Medical Device Reporting (MDR)** -- system to keep FDA informed of potential defects and other problems associated with the use of the device
- **Labeling**

General Controls …

- **Other general provisions --** that apply to all medical devices regardless of their class:
  - ***Adulteration*** – Section 501
    - General
    - QSR violation – deemed adulterated
  - ***Misbranding*** – Section 502
    - General
    - Restricted device advertising – not meeting 502(q)
- **Recalls and Corrections –** reports under 21 CFR 806

A Look at a Classification Regulation

- **Sec. 880.6230 Tongue depressor.**
  - (a) ***Identification.*** A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
  - (b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.
    - [45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

To Market a Medical Device

- **Have to find the applicable device classification**
  - Some are similar
  - If can, that tells you how FDA basically regulates
- **If you do find an applicable device classification –** still may not be clear what FDA will want in the way of data
  - Guidance documents – may be issued
  - If not, may need to meet with FDA
- **If you can't, your device is "new" –** automatically placed in Class III and needs a PMA – but, see *de novo,* later in slide deck

The 510(k)

- **Must "notify" FDA 90 days before propose to begin marketing a new device or certain modified devices**
- **However, in reality, a 510(k) is much more than a "notice," and marketing cannot begin until clearance**
- **Purpose -- allow FDA to determine:**
  - if device is truly novel and requires new proof of safety and efficacy; or
  - whether device is similar enough ("***substantially equivalent***" or "SE") to a device already lawfully on the market (a "***predicate***") to permit marketing without as detailed a review as a Premarket Approval Application (PMA) required of Class III device

The 510(k) …

- **FDA -- considerable discretion to decide whether a product requires a 510(k) or a PMA, or is available for *de novo* reclassification**
- **Class I devices --** Small number (specifically called out in the regulations)
- **Most Class II devices –** a few are exempt (e.g., electric adjustable hospital bed)
- **510(k) exempt devices --** if the new device exceeds the limitations of the exemption, a 510(k) will be needed, if not a PMA depending on the extent of the deviation

The 510(k) --

- **Pre-amendment Class III devices --** (marketed post-1976) for which PMAs are not currently required; very limited
  - FDA effort ongoing to classify these products
- **Standard for clearance of a 510(k): "Substantial equivalence" to predicate device**

What is Substantial Equivalence?

- **1976 Congressional Record**

  "The term 'substantially equivalent' is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."

Criteria for Substantial Equivalence (SE)

- **The new device has the same intended use; and,**
- **The new device has the same technological characteristics --** (i.e., same materials, design, energy source, etc.);
- **Or, if it has new technological characteristics --** those new technological characteristics do not raise new questions of safety or efficacy, and
  - There are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics; **and**
  - There are data to demonstrate that the new technological features have not diminished safety or effectiveness.

Intended Use – Key Concept

- **Both as to FDA definition (e.g., cosmetic vs. drug) and in differentiating device classifications**
- **Section 513(i)(1)(E) of the Act -- generally limits the determination of the intended use of a device that is the subject of a 510(k) to the proposed labeling in the submission**
- **Off-label uses may not be considered unless**
  - There is a "reasonable likelihood" that the device will be used for an intended use other than that in the proposed labeling; **and**
  - That use could cause harm

Intended Use …

- **If FDA finds there is likely off-label use that could cause harm, must notify applicant:**
  - Sponsor can modify the device design to address the off-label use; or
  - Sponsor can request a written determination from the FDA Office Director;
  - FDA can issue a SE letter with limitations specifying appropriate limitation regarding the off-label use to be included in the labeling for the device.

General/Specific Use Guidance

- When does general not encompass specific?
- FDA guidance provides guiding principles that FDA considers when a more specific indication for use may be reasonably included in the general indication for use
- Show substantial equivalence to device with general indication
- Submit 510(k) rather than PMA

more …

General/Specific Use Guidance

- **Decision factors:**
  - Risk – introduce new risks?
  - Public Health Impact - impact public health to a greater degree?
  - Knowledge Base - body of evidence available?
  - Endpoints - can the same performance or clinical endpoints be used?
  - Tool or Treatment?
  - Adjunctive Therapy – is use of another product required?
  - Design Changes – less applicable to general use?

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073945.pdf

Examples

- **Diagnostic Ultrasound**
  - General Indication: Evaluation of soft tissue
  - Specific Indication: Aid in differentiating benign from malignant breast lesions
  - Determination: **NSE** because:
    - Risk of false negatives higher in breast
    - Measurement of breast cancer has major public health impact
    - Major change in using ultrasound to recommend breast biopsy or not

Examples

- **Diagnostic Ultrasound**
  - General Indication: Evaluation of soft tissue
  - Specific Indication: Discrimination of small soft tissue parts (e.g., tendons, nerves)
  - Determination: **SE** because
    - No significant risk
    - Simply a statement of the types of anatomical detail

Device User Fees

FY15 User Fees (in U.S. Dollars)

application type	standard fee	small business fee†
510(k)‡	$5,018	$2,509
513(g)	$3,387	$1,694
PMA, PDP, PMR, BLA	$250,895	$62,724
panel-track supplement	$188,171	$47,043
180-day supplement	$37,634	$9,409
real-time supplement	$17,563	$4,391
BLA efficacy supplement	$250,895	$62,724
annual report	$8,781	$2,195
30-day notice	$4,014	$2,007

† For small businesses with an approved SBD.

What to Do if Your Device is Found NSE … or there is No Applicable Device Classification?

Do Not Forsake …

- **If an NSE decision is reached on 510(k), you can not go to market. Options then may include:**
  - Informal "Appeal"
  - Resubmit another 510(k) with new information or data
  - "De Novo Process"
  - File reclassification petition
  - Submit a PMA
- **Exploring reasons for NSE decision are the key to deciding which course of action to take**
- **Informal consultation with FDA, possibly followed by a meeting if necessary**

De Novo Review – Evaluation of Automatic Class III Designation

- **Since 1997, FDA permits manufacturers of certain novel, low risk devices to request that the agency reconsider automatic class III determinations (*i.e.,* a determination that a medical device is a class III device because it lacks a legally marketed predicate device)**
- **Intended for novel, but low to moderate risk devices – that can be handled under Class II or I**
- **"De novo classification" procedure --** can be invoked at any time to request that FDA place the device in class I or II despite the absence of a predicate device, based upon reasonable assurance that the device is safe and effective

De Novo Process …

- **If FDA grants the request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted**
- **Can be used as a predicate in future 510(k) submissions**
- **For more information:**
  - June 2013 -- Presentation by Michael Swit on *de novo* Process –
    - http://www.fdacounsel.com/files/Swit_DIA_2013_--De_Novo_Presentation.pdf
  - Matrix of *de novo* petitions – 1998 to 2012
    - http://www.fdacounsel.com/files/De_Novo_Decisions_--_1998_to_20123.xlsx

PMA vs. 510(k)

How Do PMAs and 510(k)s Differ?

- Volume of Information
- Clinical Study Requirements (follow-up and analysis)
- Bioresearch Monitoring Inspections
- Extensive Labeling Review
- Manufacturing Information and Pre-Approval Inspection
- Panel Review
- Time to Approval
- Postmarket Requirements

PMA

- **Safety and Effectiveness**
- **Scientific Evidence**
- **Almost Always Accompanied by Clinical Data –** usually a controlled randomized study
- **Detailed, Lengthy Application**
- **Must be "Approved" Prior to Marketing**
- **Average FDA review time: 225 days (08 FY)**
- **Pending PMA is Confidential; Following Approval, Summary Information is Released**
- **Conditions of Approval**
  - Annual Report
  - Post-approval Study
  - PMA Supplement for changes
  - Adverse reaction and device defect reporting
- **In 2009, 20 PMAs received (ODE only)**
- **Pre-approval inspection**

510(k)

- **Substantial Equivalence**
- **Comparison to Existing (Predicate) Device**
- **Possibly Contains Clinical Data (10 - 15% of 510(k)s)**
- **Shorter**
- **Must be "Cleared" Prior to Marketing**
- **Average FDA review time: 63 days (09 FY)**
- **Pending 510(k) is Confidential; Following SE Determination Entire 510(k), Less Company Proprietary Data, is Released; 510(k) Summary Available 30 Days After Clearance**
- **New 510(k) for significant changes**
- **In 2009, 3,597 510(k)s received (ODE only)**
- **No pre-approval inspection**

For Further Information

- **CDRH Web Site:** http://www.fda.gov/MedicalDevices/default.htm
- **"Device Advice" -- Premarket Notification:**

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
- **Recent 510(k) Guidances:**
  - *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* – July 28, 2014
    - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf
  - *Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements* – Aug. 6
    - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM407292.pdf

Mobile Medical Applications

a.k.a.

mHealth *or* Mobile Health *or* Digital Health

Mobile "Health Apps" – Many Are Medical Devices

- **FDA's Approach –** Sept. 2013 Final Guidance on Mobile Medical Applications
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
- **Three "Categories" of Mobile Medical Applications (MMAs)**

  (1) those that FDA does not regard as medical devices at all and thus are outside its legal control;

  (2) those that are or may be medical devices, but that present a low risk to patients and will be the subject of "enforcement discretion;" and

  (3) those that are medical devices and present enough of a risk that FDA will exercise regulatory control over them. I will refer to these hereafter as Categories 1, 2 and 3,

FDA Approach to MMA Regulation

- **Platform is irrelevant –** iOS vs. Android vs. PC vs. Bluetooth, etc.
- **Focus on Risk –**
  - FDA will regulate those mobile medical apps that present a potential risk of safety to patients when the app functions incorrectly – **Cat. 3**
  - In contrast, FDA will exercise *enforcement discretion* on mobile apps that, despite being legally medical devices, have a lower-risk profile in the event of a malfunction -- **Cat. 2**
    - However, where "lower risk" leaves off and a "risk of safety" begins is not clearly defined in the guidance.

Category 3 – Regulated Apps – *Three Types*

1. Apps that function as an extension of an existing medical device by connecting to it – either via wired or wireless links – to control the device, or display, store, analyze or transmit patient-specific data.

- **Example**: App that can control a blood pressure cuff.

2. Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to currently regulated medical devices.

- **Example:** device attaching electrocardiograph to smartphone - AliveCor®

Category 3 – Regulated Apps – *3 Types …*

3. Apps that use patient-specific information for analysis to provide patient specific diagnosis, or treatment recommendations.

- **Example:** apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

Category 2 – Enforcement Discretion – n=*6*

1. Apps that help patients self-manage diseases without providing specific treatment suggestions.

- **Example:** apps that coach patients with conditions such as diabetes with simple prompts to promote strategies for actions that will help their health situation such as maintaining healthy weight, getting optimal nutrition, etc.

2. Apps that help organize and track health information, but do not recommend any change in treatments.

- **Example:** apps the provide simple tools for patients with specific conditions or chronic disease to log, track, or trend their events or measurements (*e.g.*, blood pressure, drug intake, diet) and share this information with their healthcare provider (HCP) as part of a disease management plan.

Category 2 – Enforcement Discretion …

3. Apps that provide easy access to information regarding the patient's health condition or treatment by matching patient-specific information (*e.g.*, diagnosis, treatments, allergies, signs or symptoms) to reference information normally used in clinical practice.

- Example: apps that use a patient's diagnosis to provide an HCP with best practice treatment guidelines for common illnesses.

Category 2 – Enforcement Discretion …

4. Apps that help patients document and communicate potential medical conditions to providers that are not promoted for medical uses, but, due to other circumstances surrounding their distribution, may meet the medical device definition.

- **Example:** apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients and HCPs.

5. Apps that automate simple tasks for providers such as to perform basic calculations in clinical practice.

- **Example**: a medical calculator for body mass index (BMI).

Category 2 – Enforcement Discretion …

6. Apps that enable patients/providers to interact with personal health record (PHR) or electronic health records (EHR) and their systems.

- **Example**: an app that allows a patient a portal into their own health information.

Category 1 – Not Medical Devices

- Many of today's popular apps -- and related devices -- such as the FitBit® and Nike+®, if used for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions relating to developing or maintaining **general fitness, health or wellness** -- such as apps that log dietary intake, track normal sleep patterns, or calculate calories burned during exercise
  - ***Not medical devices*** unless they are marketed in a manner that meets the definition of a medical device.
    - *Source*: Footnote 32, in Appendix B, in 9/2013 Guidance

Basics of Medical Device Regulation and Mobile Medical Apps

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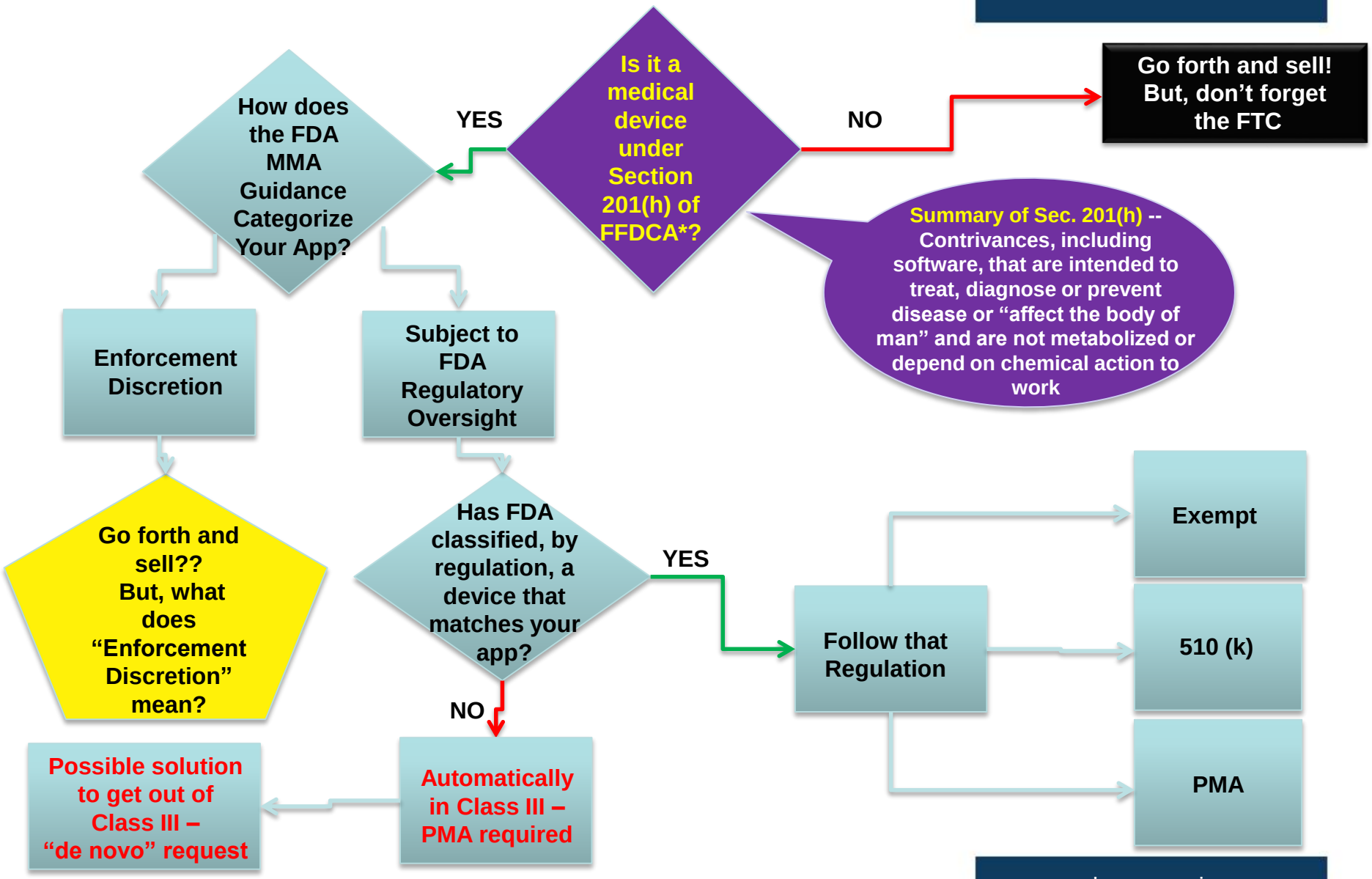

*FFDCA = Federal Food, Drug, and Cosmetic Act

MMA – For More Info

- **Duane Morris (DM) – Basics of FDA Medical Device Regulation And How They Interface with FDA's Final Guidance on Mobile Medical Applications**
  - http://www.fdacounsel.com/files/FDA_Basic_Device_Requirements_and_Mobile_Apps_with_3_appendices_20131116.pdf
    - **App. A** – DM – Oct. 2013 -- Summary of 9/2013 Guidance
    - **App. B** – DM -- Oct. 2013 -- Client Alert -- Key Unresolved Issues from 9/2013 Guidance
    - **App. C** – Flow Chart (see previous slide)
- **June 2014 – new Draft Guidance -- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices**
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf

What Happens if You Don't Comply With FDA Requirements?

… You Can Go To Jail …
But, First,
FDA Has a Lot of Other Powers To Enforce The Law

Enforcement Options

- **Inspections**
- **Warning Letter**
- **Recall, Notification, Refund**
  - Voluntary
  - Mandatory (Section 518)
- **Publicity**
- **Administrative Detention**
- **Import Detention**

Enforcement Options …

- **Withdrawal of Market Clearance or Approval**
- **Civil Monetary Penalties**
- **Debarment**
- **Seizure**
- **Injunction**
- **Consent Decree –** agreed-to injunction
- **Criminal Prosecution**

Examples of Prohibited Acts

- **Involving Adulteration or Misbranding:**
  - Introduction into Interstate Commerce
  - Adulterating or Misbranding in or after I/S
- **Shipment without necessary Market Clearance or Investigational Exemption**
- **Refusal to Permit Access to or Copying of Certain Records**
- **Refusal to Permit Inspection**
- **Counterfeiting Drugs**
- **Revealing of Trade Secret Information (by FDA Employees)**

Examples of Adulteration

- **Adulteration, *e.g.*,**
  - Filthy, Putrid, or Decomposed
  - Not Made in Conformance with Current Good Manufacturing Practice – for devices, the QSR
  - Prepared, Packed, or Held under Unsanitary conditions whereby it May have been Rendered Injurious to Health
  - Section 519 Violations (MDRs, Correction and Removal Reports)

Examples of Misbranding

- **Misbranding, *e.g.*,**
  - Labeling False or Misleading in Any Particular
  - Failure to have Adequate Directions for Use
  - Failure to have appropriate Warnings on Labeling
  - Failure to have a necessary 510(k)
  - Failure to follow Section 502(q) or 502(r) relative to restricted device advertising

Criminal Prosecutions

- **Individual Responsibility – Strict Liability**
  - No Criminal Intent Required
    - *Dotterweich* and *Park*
    - Responsible Position
  - Must stand in "Responsible Relation" to the Criminal Act
- **Felony –** intent required or inferable (or repeat violation)

Criminal Prosecutions …

- **Misdemeanor**
  - Up to $100,000 for Individual
  - Up to $200,000 for Corporation
  - Up to One Year In Jail
- **Felony**
  - Intent to Defraud or Mislead or Second Offense
  - Penalties
    - Up to $250,000 for Individual
    - Up to $500,000 for Corporation
    - Up to Three Years in Jail per violation (under the Act)

Title 18 Violations -- U.S. Criminal Code

- **False Statements – Section 1001**
  - Knowing and Willful Cover-ups of Material Facts
  - Materially False Representations
  - False Writings or Documents
    - Beware of Affidavits and Certifications
- **Mail Fraud**
- **Wire Fraud**
- **Obstruction of Justice**
- **Conspiracy**

The Final Straw – HHS Exclusion

- **Criminal Violations can lead HHS to "exclude" you from participating in federal health care programs (e.g., Medicare, Medicaid, CHIP)**
  - Can arise even for misdemeanor/strict liability violations of the Federal Food, Drug, and Cosmetic Act
    - ***See***: **Duane Morris Client Alert**: **"*D.C. Circuit Affirms HHS Power to Disqualify Corporate Officials Convicted of Misdemeanors Under the "Responsible Corporate Official" (RCO) Doctrine*" at:**

      http://www.duanemorris.com/alerts/dc_circuit_affirms_hhs_power_disqualify_corp_officials_convicted_misdemeanors_rco_doctrine_4559.html

Questions?

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About Your Speaker

***Michael A. Swit, Esq.*, is a Special Counsel in the San Diego office of the international law firm, Duane Morris, LLP, where he focuses his practice on solving FDA legal challenges faced by highly-regulated pharmaceutical and medical device companies. Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences. His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics and therapeutic biotech products. Mr. Swit has been addressing vital FDA legal and regulatory issues since 1984, both in private practice with McKenna & Cuneo and Heller Ehrman, and as vice president, general counsel and secretary of Par Pharmaceutical, a top public generic and specialty drug firm. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms. He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board. He earned his A.B., *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University. He is a member of the California Bar and was also admitted in Virginia and the District of Columbia, but is inactive in those jurisdictions.**