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Medical Device Warnings for Home Use Devices

About the Presenters:

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Agenda

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- History of Medical Devices for In-Home Use
- IFUs for In-Home Medical Devices
- Recent Changes in Case Law
- The Future of In-Home Medical Devices

History of Medical Devices for In-Home Use

What Devices can be found in a Home?

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- Some common types of home devices are:
  - Deliver Medications/First Aid
  - Assistive Devices
  - Durable Medical Equipment
  - Respiratory Equipment

Some of History's "Medical" Devices

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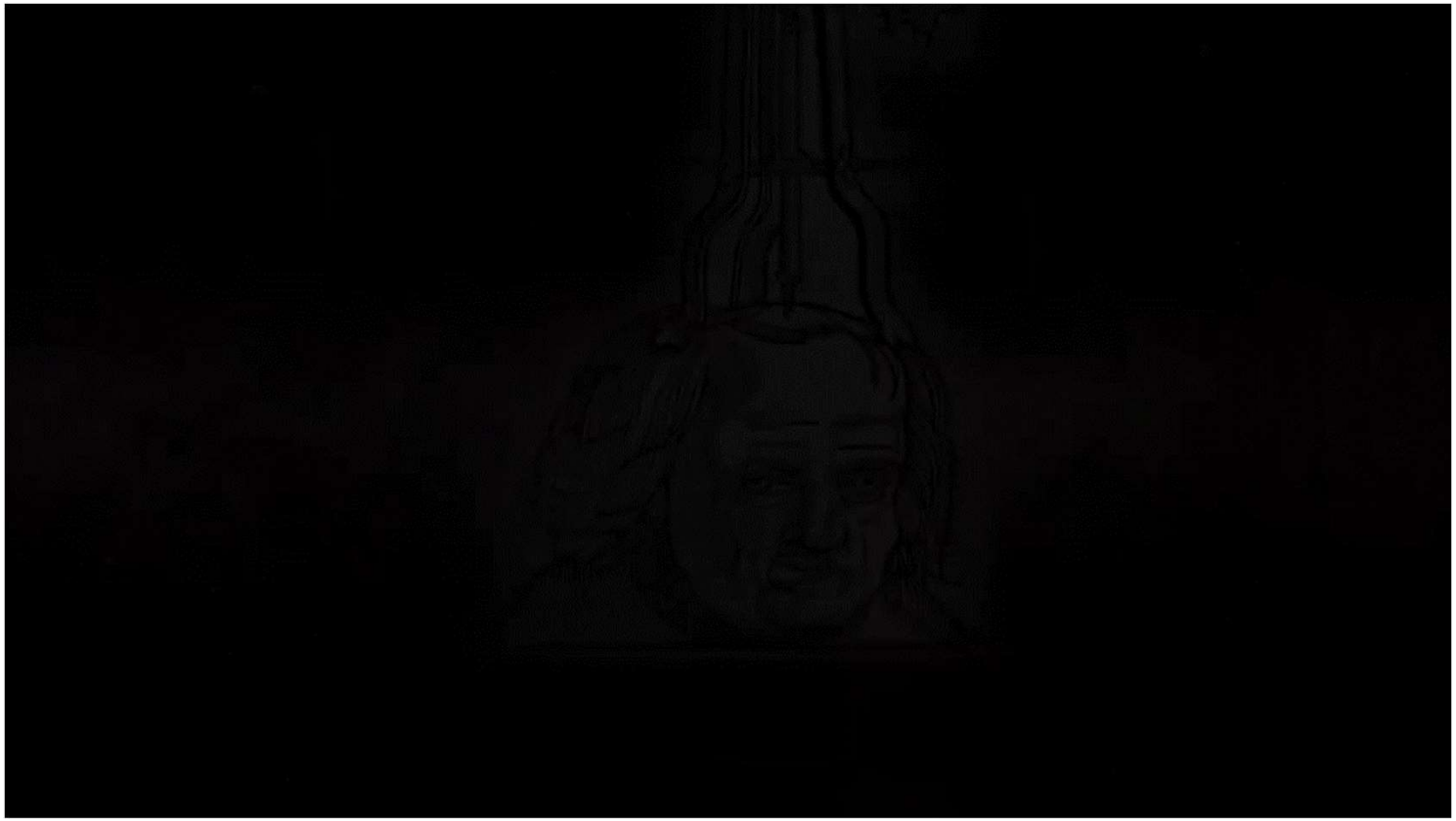

FDA Classification of Home Devices

- Home Medical Device: “a device intended for use in a nonclinical or transitory environment, [that] is managed partly or wholly by the user, requires adequate labeling for the user, and may require training for the user by a health care professional in order to be used safely and effectively” (U.S. Food and Drug Administration, 2009b).

Considerations for Home Devices:

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- Needs to be appropriate for the people and environments for which they are used
- Needs to account for professional user, lay caregivers or the care recipients themselves
- Account for diverse physical, sensory, cognitive, and emotional characteristics
- Environment of use and if the device will be portable to other environments during care

Why have devices left the Hospital?

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- Climbing health care costs
- Environmental factors that prevent hospitalization
- Availability of home technology
- Need for care in other nonclinical environments: workplaces, schools, hotels, stores, places of worship, entertainment venues, and transportation systems

Why is there a need for home devices?

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- Healthcare systems are stressed
  - Patients are released from hospitals but still are in need of care
- Specific in-home medical device issues
- Device human factor considerations

Benefits:

- Decreases hospital time
- Lowers costs of care
- Encourages patients to lead a healthier lifestyle
- Helps to monitor chronic diseases- asthma, cancer, and diabetes
- Can save a life in a medical emergency
- Increases patient safety

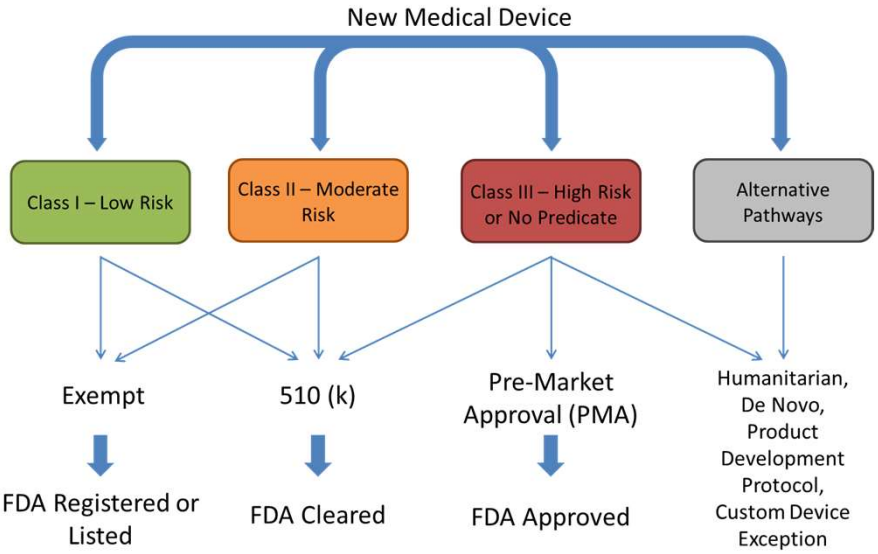
Disadvantages:

- Some devices not designed for in home use
- Some older hospital grade medical devices that are phased out of hospital use or upgraded are now available for home use
- Resale by users to third parties- may be improperly maintained or without IFUs
- Manufacturer Issue: The device user is often not the person who selected or purchased the product.
- Different environments can present challenges for device and user safety.

Instructions for Use for In-Home Medical Devices

Medical Devices: Classification

- The FDA classifies that all "Medical Devices" have a label and/or accompanying written information that instruct how to use medical devices.
- Medical Device Classes
  - Class I- Low Risk
  - Class II- Middle Risk
  - Class III- High Risk



Medical Devices Classification

- Class I- Low risk
  - Examples: Sun glasses, bandages, dental floss
- Class II- Middle Risk- 501 K required- Pre market notification- Application to FDA to clear
  - Examples: Glucose Monitoring Kit, Pregnancy Kit, Thermometer, Bassinet
- Class III- High Risk- Required to have pre-market approval, device has to be FDA approved.
  - Examples: Surgical Laser, PSA Test

Medical Devices Classification

- A **510(k**) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act). The submitter may market the device immediately after 510(k) clearance is granted

- **Pre-Market Approval-** most stringent type of device marketing application required by FDA. FDA must approve a PMA application prior to marketing a device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use

Instructions for Use

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- IFUs accompany every new medical device by manufacturer and are intended to enable safe use of the item- mandatory for sale
- IFU provide critical information on the application and preparation of a medical device for use. In the United States, the FDA regulates all medical devices
- IFU's verbiage is now sometimes catered toward home usage as versus physician terminology
- Older devices IFUS may be outdated and the intended uses or indications for use could be too broad

https://www.hpnonline.com/continuing-education/steris/article/21125972/making-sense-of-your-medical-device-ifu

Legal Update

Florida Still in Flux? New Exception to the Consumer Expectations Test in Product Design Claims

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- *Aubin v. Union Carbide Corp-* consumer expectations test, rather than the risk utility test, applies to design defects claims
- Product Design Defect Tests
  - Consumer expectations test
  - Risk utility test
  - And reasonable alternative design test

References:
Pierre 2020 WL 1240420
177 So. 3d 489, 510-511 (Fla.2015)

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Preemption for Class III Devices

- 21 U.S.C. § 360k(a)
- Class III medical devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness.
- Given the federal oversight, states may not establish any requirement different from or in addition to the federal requirement. Further, private litigants cannot bring suit for noncompliance with federal regulations.

Recent Legal News

- In December 2020, Apria Healthcare Group agreed to pay $40.5 million to settle a lawsuit claiming the medical device company had submitted false claims to federal health programs.
- Apria was seeking monthly payments for renting costly noninvasive ventilators to Medicare/Medicaid beneficiaries. Apria did not comply with the requirement that it ensure the ventilators were a basic medical requirement of the patient's treatment.
- Thus, Apria was renting equipment and devices to patients without determining whether they were medically necessary.
- *Consider* – a person is allegedly injured at home by a medical device that they did not even need.

Recent Legal News

- In early 2020, California enacted a connected devices security law, requiring manufacturers to equip connected devices with "reasonable security" that protects consumers from hackers.
- Experts believe the FDA is monitoring the law's implementation as it further develops recommendation on medical device cybersecurity.
- What is a "reasonable security feature"?
  - Password requirements; dual authentication.

The Future of In-Home Medical Devices

Internet, Connectivity and Home Medicine

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- Hospital and Physician can monitor people at home
  - Monitor vitals
  - Assess efficacy of treatment when administering medications
- Telehealth
- Improved devices
  - Smart bandages to detect bacteria
  - Smart Shirts to measure vitals
  - Hands-free control of devices
- Miniaturization and mobility with devices

Consumer-Driven Preventative Medicine

- Devices will allow people to monitor their own bodies and communicate with health care professionals on an ongoing or as needed basis
- Pandemic drove the need to increase telehealth networks
  - Increased surveillance and treatment with remote monitoring, point of care diagnosis and virtual care
  - Zoom has launched its own healthcare division
  - Smartphone apps, wearables, smart devices, and sensor embedded clothing were used in pilots

Dangers of connectivity with home medical devices

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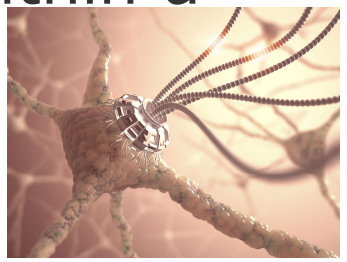
- Dangers of having Wi-Fi connected devices in the home
- New treatments are small electronic medical devices, controlled by a program devices like computers, smartphones or server
- If a single nanoparticle is hackable, a hacker could turn multiple nanoparticles into a network within a person
- Ransom ware



Hacking Medical Devices

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Q & A…

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