Review Article

Medical Device Ban in United States

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ABSTRACT

Medical devices are unique part of healthcare management where it requires regular teaching and education for patients and practitioner to ensure that they are competent in the use of medical devices. A Stringent regulatory standards are required to ensure that the devices are safe, well studied and have least adverse reactions. A medical device ban is a total prohibition on the current and future sales, distribution, and manufacturing of a medical device. The FDA has the authority to ban a medical device intended for human use if it finds, on the basis of all available data and information, that the device presents a substantial deception to patients or users about the benefits of the device, or an unreasonable and substantial risk of illness or injury, which cannot be corrected by a change in the labeling.

Keywords: Medical device, FDA, Ban, Prohibition, 21CFR 895.

INTRODUCTION

Medical Devices ranges from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include *in-vitro* diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers. If a product is labelled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and post-marketing regulatory controls. A device is:

- "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 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."[1]

Regulation of High-Risk Devices in the US[2]

Standard for approval	Safety Effectiveness: Proof of actual benefit to patients
Evidence required	Valid clinical trials- generally randomized and controlled
Approval granted by	Central Regulatory Authority: FDA
Transparency of approval decisions	Approval and their evidentiary basis disclosed to public
Post-approval reporting requirements and transparency	Side effects and recalls must be reported to FDA and are publicly disclosed on its website.

DISCUSSION

Medical Device Ban

A medical device ban is a total prohibition on the current and future sales, distribution, and manufacturing of a medical device.

The FDA has the authority to ban a medical device intended for human use if it finds, on the basis of all available data and information, that the device presents a substantial deception to patients or users about the benefits of the device, or an unreasonable and substantial risk of illness or injury, which cannot be corrected by a change in the labelling. (Section 516(a) of the Federal Food, Drug and Cosmetic Act; 21 CFR 895.20)

21 CFR Part 895 describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device and 21 CFR Part 895 applies to any "device", as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labelling of the device that is banned cannot avoid the ban by relabelling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use may be marketed for use as a veterinary device only under the following conditions:

- The device shall comply with all requirements applicable to veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and
- The label for the device shall bear the following statement: "For Veterinary Use Only.

Caution: Federal law prohibits the distribution of this device for human use."

A device so labeled, however, that is determined by the FDA to be intended for human use will be considered to be a banned device. In determining whether such a device is intended for human use, the FDA will consider, among other things, the ultimate destination of the device.

The Commissioner may initiate a proceeding to make a device a banned device whenever the Commissioner finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that the Commissioner determines cannot be, or has not been, corrected or eliminated by labeling or by a change in labelling, or by a change in advertising if the device is a restricted device.

A) Procedure for banning a medical device

- Before initiating a proceeding to make a banned device, the commissioner shall find that the continued marketing of the device presents any unreasonable and substantial risk of illness or injury.
- In determining whether a device is deceptive, the Commissioner will consider whether users of the device may be misled or otherwise harmed by the device.
- The Commissioner is not required to determine that there was an intent on the part of the manufacturer, distributor, importer, or any other responsible person(s) to mislead or otherwise harm users of the device or that there exists any actual proof of deception of, or injury to, an individual.
- In determining whether a device presents deception or risk of illness or injury, the Commissioner will consider all available data and information, including data and information that the Commissioner may obtain under other provisions of the act, data and information that may be supplied by the manufacturer, distributor, or importer of the device under 895.22, and data and information voluntarily submitted by any other interested persons.
- Before initiating a proceeding to make a device a banned device, the Commissioner of Food and Drugs may consult with the panel established under section 513 of the act that has expertise with respect to the type of device under consideration. The consultation with the panel may occur at a regular or specially scheduled panel meeting or may be accomplished by correspondence or telephone conversation with panel members. The Commissioner may request that the panel submit in writing any advice on the device under consideration. The Commissioner will record in written memoranda any oral communications with a panel or its members.
- If the Commissioner determines that any substantial deception or unreasonable and substantial risk of illness or injury or any unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labelling or change in labelling, or change in advertising if the device is a restricted device, the Commissioner will notify the responsible person of the required labelling or change in labelling or change in advertising in accordance with 895.25. If such required relabeling or change in advertising is not accomplished in accordance with 895.25, the Commissioner may initiate a proceeding to ban the device in accordance with 895.21(d) and, when appropriate, may establish a special effective date in accordance with 895.30.
- A notice of proposed rulemaking will be published in the Federal Register, If the Commissioner decides to initiate a proceeding to make a device a banned device. The notice will briefly summarize
  - The Commissioner's finding, whether the device presents substantial deception or an unreasonable and substantial risk of illness or injury.

- The reasons why the Commissioner initiated the proceeding;
- The evaluation of data and information obtained under other provisions of the act, submitted by the manufacturer, distributer, or importer of the device, or voluntarily submitted by any other interested persons
- The consultation with the panel
- The determination as to whether the deception or risk of illness or injury or the danger to the health of individuals could be corrected by labelling or change in labelling, or change in advertising if the device is a restricted device;
- The determination as to whether, and the reasons why, the banning should apply to devices already in commercial distribution or those already sold to the ultimate user, or both;
- Any other data and information that the Commissioner believes are pertinent to the proceeding. The notice will afford all interested persons an opportunity to submit written comments within 30 days after the date of publication of the proposed regulation. All non-confidential information, upon which the proposed finding is based, including the recommendations of the panel, will be available for public review in the Division of Dockets Management, Food and Drug Administration.

- After the review of administrative record of the regulatory hearing, if any, the written comments received on the proposed regulation, and any additional available data and information, the Commissioner determines to ban a device, a final regulation to this effect will be published in the Federal Register.
- If the Commissioner determines not to ban the device, a notice of withdrawal and termination of rulemaking proceedings and reasons therefor will be published in the Federal Register.[3]

There are 2 types of medical device ban which include:

Proposed ban and Final ban

Proposed Ban

A Proposed ban is the FDA's statement of intent to ban a device. The FDA outlines its assessment of the benefit-risk profile of the device. Specifically, a proposal to ban a device requires a summary of the:

1. Agency's findings regarding substantial deception or the unreasonable and substantial risk of illness or injury;
2. Reasons why the FDA initiated the proceeding;
3. Evaluation of the data and information the FDA obtained under provisions (other than section 516) of the FD&C Act, as well as information submitted by the device manufacturer, distributer, or importer, or any other interested party;
4. Consultation with a panel of experts that classify a device if conducted;
5. Determination of whether, and the reasons why, the ban should apply to devices already in commercial distribution, sold to ultimate users, or both; and
6. Other data and information the FDA believes are pertinent to the proceeding.

The Public can comment during the comment period, which is at least 30 days.

Special Effective Date

In some cases, the FDA can put a special effective date in the proposed ban which puts the ban immediately into place as soon as it is published in the Federal Register.

This procedure may be used when the FDA determines that the potential or actual injury involved is serious enough that the agency believes will endanger the health of individuals who have been, or will be exposed to the device. For a proposed ban with a special effective date, the FDA will finalize the rule by affirming, modifying, or revoking the proposed rule. Even if the proposed ban has a special effective date, the public can comment during the comment period. Interested persons may request an informal hearing to discuss the ban.

Final Ban

A final ban is the FDA's statement of action and tells the public what device the FDA is banning and when that ban will go into effect.

The FDA considers any comments it receives on the proposed ban and determines whether to affirm, modify, or revoke the proposed regulation. If the proposal is affirmed or modified, the FDA will publish a final regulation banning the device. In this case, the device can no longer be legally marketed on or after the date of publication of the final regulation, except under an approved investigational device exemption. If the proposed regulation is revoked, the FDA will publish a notice to this effect in the Federal Register.[4]

Submission of data and information by the manufacturer, distributor, or importer

- A manufacturer, distributor, or importer of a device may be required to submit to the Food and Drug Administration all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable

and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

List of Medical Device Bans[4]

The list below contains bans that have been proposed or issued.

Device Name	Date
Electrical Stimulation Devices (ESDs) Used for Self-injurious or Aggressive Behaviour	Proposed April 22, 2016
Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove	Effective January 18, 2017
Prosthetic Hair Fibers	Effective June 3, 1983

- The data and information required by the commissioner may include scientific or test data, reports, records on whether the device is safe and effectiveness for the intended use.
- The data and information submitted by the manufacturer, distributor, or importer of a device will be notified in writing by the Food and Administration (FDA) that such data and information shall be submitted.
- The written notification will advise the manufacturer, distributor, or importer of the device that the purpose for the request is to enable the Commissioner to determine whether any of the conditions listed in paragraph (a) of 21 CFR Part 895.30(a)(1) exists with respect to the device such that a proceeding should be initiated to make the device a banned device. When the required data and information can be identified by the FDA at the time of the notification, the agency will provide such identification to the manufacturer, distributor, or importer of the device.
- The required data and information shall be submitted to the FDA within 30 days after the date of receipt of the request.
- If the data or information submitted to FDA is sufficient to persuade the Commissioner that the deception or risk of illness or injury or the danger to the health of individuals presented by a device could be corrected or eliminated by labelling or change in labelling, or change in advertising if the device is a restricted device, the Commissioner will proceed in accordance with 895.25.
- If the data or information submitted to FDA is insufficient to show that the device does not present a substantial deception or an unreasonable risk or injury to the health of individuals, or if the manufacturer, distributor, or importer fails to submit the required information, the Commissioner may rely upon this insufficiency or failure to submit the required information in considering whether to initiate a proceeding to make the device a banned device under 895.21(d) and, when appropriate, to establish a special effective date in accordance with 895.30. The Commissioner may also initiate other regulatory action as provided in the act or this chapter.[5]

Labelling

(1) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to health individuals presented by a device can be corrected or eliminated by labeling or a change in labelling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labelling or advertising of the device specifying:

- The risk of illness or injury or the danger to the health of individuals,
- The labelling or change in labelling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and
- The period of time within which the labelling, change in labelling, or change in advertising must be accomplished.

(2) In specifying the labelling or change in labelling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor, importer, or any other person(s) responsible for the labelling or advertising of the device to include in labelling for the device, and in advertising if the device is a restricted device, a statement, notice, or warning.

(3) Such statement, notice, or warning shall be used in the labelling and advertising of the device for a time period specified by the Commissioner on the basis of the degree of deception, risk of illness or injury, or danger to health; the frequency of sale of the device; the length of time the device has been on the market; the intended uses of the device; the method of its use; and any other factors that the Commissioner considers pertinent.

(4) The Commissioner will allow a manufacturer, distributor, importer, or any other person(s) responsible for the labelling or advertising of the device a reasonable time, considering the deception or risk of illness or injury

or the danger to the health of individuals presented by the device, within which to accomplish the required labelling, change in labelling, and, if the device is a restricted device, any change in advertising. The Commissioner may, however, request that no additional devices be introduced into commerce until the labelling or change in labelling, or change in advertising is accomplished by the manufacturer, distributor, importer, or other person(s) responsible for the labelling or advertising of the device.

(5) If such voluntary action is not taken, the Commissioner may take action under other sections of the act to prevent the introduction of the devices into commerce. The Commissioner may consider the failure of a manufacturer, distributor, importer, or any other person(s) responsible for the labelling or advertising of the device to accomplish the required labelling or change in labelling, or change in advertising in accordance with this section as a basis for initiating a proceeding to make a device a banned device in accordance with 895.21(d) and when appropriate to establish a special effective date in accordance with 895.30.[6]

CONCLUSION

A Stringent regulatory standards are required to ensure that the devices are safe, well studied and have least adverse reactions. A medical device ban is a total prohibition on the current and future sales, distribution, and manufacturing of a medical device. The FDA has the authority to ban a medical device intended for human use if it finds, on the basis of all available data and information, that the device presents a substantial deception to patients or users about the benefits of the device, or an unreasonable and substantial risk of illness or injury, which cannot be corrected by a change in the labelling.

REFERENCES

1. Health C for D and R. Classify Your Medical Device - Is The Product A Medical Device[online] Available from: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm, [cited 2017 Jul 14]
2. FDA_EU_Devices_Report.pdf. [online] Available from https://www.gkv-spitzenverband.de/media/dokumente/presse/pressekonferenzen_gespraeche/2012_2/121107_medizinprodukte/8___FDA_EU_Devices_Report.pdf, [cited 2017 Jul 15]
3. CFR - Code of Federal Regulations Title 21 Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=895, [cited 2017 Jul 14].
4. Health C for D and R. Medical Device Bans Available from: https://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm [cited 2017 Jul 13]
5. CFR - Code of Federal Regulations Title 21 Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=895.22 [cited 2017 Jul 16]
6. CFR - Code of Federal Regulations Title 21 Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=895.25 [cited 2017 Jul 18].

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