
# How FDA's Newly Proposed Medical Device Safety Action Plan Will Change the Recall Landscape

October 18th, 2018

# Agenda

Overview of FDA's Voluntary Recall Provisions

Deeper look at what triggers a recall

Deeper look at the scope of the recall

Mandatory Recalls and Other Enforcement: How Big Is FDA's Stick Already?

Concerns About the New World Order

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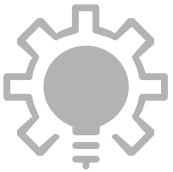
# Overview of voluntary recall provisions

# Summary

## The whole law boiled down to one slide

Recall ***trigger*** is a significant violation of the Act that would lead to FDA legal action.



Recall ***scope*** is determined by the risk of injury, either physical or economic.

- Burden of proof is on the manufacturer.

# Framework: Voluntary recalls

**Part 7—FDA's voluntary recall regulations -- does not include a mandate for when recalls must be conducted.**

**Instead, the regulations say,**

- "Recall means a firm's removal or correction of a marketed product that … [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 CFR § 7.3(g)
- "Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." 21 CFR § 7.40(a).

# Take aways from recall definition

Triggered by violation that is significant enough to warrant FDA enforcement action.

Recall includes **removal <u>or</u> correction**

- **Removal** means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.
- **Correction** means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
  - Notification can be a form of relabeling, so it may be a recall.

Recall scope is driven by risk of harm, either physical or economic.

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# Deeper look at what triggers a recall

# Summary

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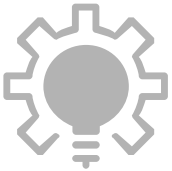


# Step 1: Is there a violation of the Act?

**Adulteration**, includes

- If it is contaminated with something harmful.
- GMP violation.

**Misbranded**, includes

- False and misleading labeling.
- No adequate directions and warnings.
- Dangerous to health when used … [as] suggested in the labeling.
- Distributed without a required 510(k) clearance.

# Step 2: Would FDA seek legal action?

**We could find a violation of GMPs in any medical device facility.**

- Section 309 of the Act allows FDA not to pursue minor violations.

# Step 2: Would the violation trigger legal action?

**Starter question: what is "legal action"?**

- Regulation gives seizure action as example.
- A warning letter threatens enforcement action.
  - FDA's Regulatory Procedures Manual states, "The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected."
- Ambiguity: FDA characterizes a warning letter as a pre-enforcement communication, something "informal and advisory [that] communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action."
- Bottom line, not all warning letters are equal.

# When would FDA consider legal action?

## Answer: Study what FDA has done


- Over-inclusive in that not all warning letters trigger the need for a recall


- Under-inclusive in that some device recalls are not reported to FDA.
- Medical device recalls that do not involve a risk to health are not required to be reported to FDA under part 806.

# Difference in scope

## Recall (part 7) vs Reporting (part 806)

## Under 21 CFR 806:

**Manufacturers must report to FDA of any correction or removal of a medical device(s) if it was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health.**

- The definition of ``risk to health'' under 21 CFR 806 tracks the definitions of class I and class II recall in 21 CFR 7.3(m). Therefore, reports of corrections and removals are required for class I and class II recalls.

**Manufacturers need not report events categorized as class III recalls under 21 CFR § 7; only record keeping requirements would apply.**

- FDA characterizes class III recalls as recalls conducted for: “Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food.”

Nowhere does FDA suggest that class III recalls are unnecessary. They just don’t need to be reported to FDA.

# What the FDA recall trigger is not


Triggered only if the product fails to meet specs


About assessing blame


Based on business considerations such as cost

# Uneven Defect Rates

01

A violation can be very localized, and it is still a violation.

02

That violation doesn't go away just because someone averages those numbers over a larger batch to make the incident rate go down.

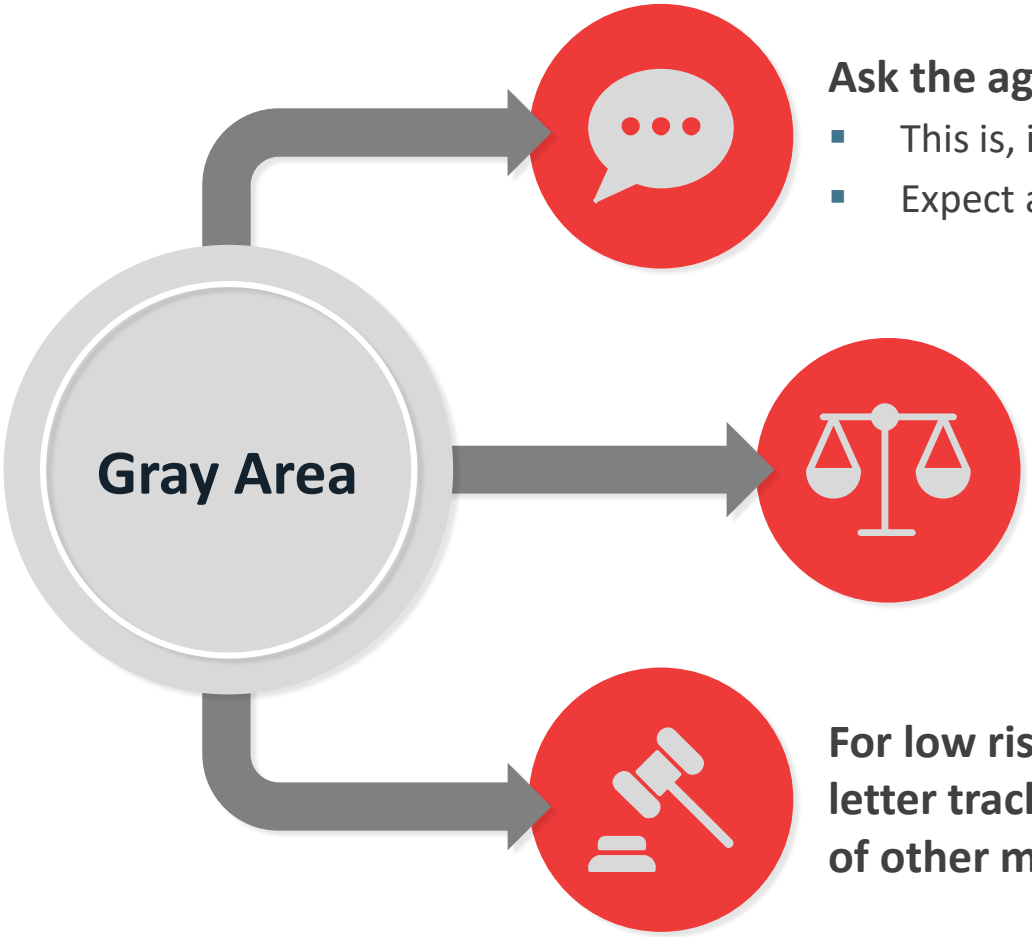
03

**While the law accepts the fact that both machine and human processes will vary, and humans will make mistakes and machine processes will exceed limits even when relatively well-controlled, certain actions by humans cannot be dismissed as merely inherent parts of the production process.**

- Intentional acts that result in dangerous products
- Contaminants added, whether intentionally or accidentally, to the product that result in the product being dangerous
- Violation of GMPs, e.g. lack of adequate process controls

# If no database has all of the answers, how do we decide?

## Approaches for the gray area




**Ask the agency.**

- This is, in fact, what FDA would like you to do
- Expect a conservative response

**Consider the risk of physical and/or economic injury.**

- If there is material physical risk, you can be assured that FDA will consider it significant enough for legal action
- But also look carefully at economic injury, because that's the category that often doesn't show up in the part 806 reports

**For low risk issues, focus more on FDA's warning letter track record and the enforcement experience of other manufacturers.**

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# Deeper look at the scope of the recall

# Summary

## The whole law boiled down to one slide

Recall ***scope*** is determined by the risk of injury, either physical or economic.

- Burden of proof is on the manufacturer.

# FDA has a broad view of risk

## The agency protects the health and wellbeing of consumers

**Economic injury is a common cause of food recalls, and often neglected by medical device manufacturers.**

**FDA allows an expansive consideration of the best interest of the patient**

- Ease in identifying the product.
- Degree to which the product's deficiency is obvious to the consumer or user.
- Degree to which the product remains unused in the market-place.
- Continued availability of essential products.

# Health Hazard Evaluation

- Whether any disease or injuries have already occurred from the use of the product.
- Whether any existing conditions could contribute to exposure to a health hazard.
- Assessment of hazard to various segments of the population, e.g., children, surgical patients, …etc., with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.
- Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

# Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions”

## FDA’s 2016 draft guidance

**Factors for the Assessment of Medical Device Benefits**

- Type of benefit(s)
- Magnitude of benefit(s)
- Likelihood of patients experiencing one or more benefits
- Duration of effects
- Patient perspective on benefit
- Benefit factors for healthcare professionals or caregivers
- Medical necessity

# Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions”

## FDA’s 2016 draft guidance

**Factors for the Assessment of Medical Device Risks**

- Severity of harm
- Likelihood of risk
- Distribution of nonconforming devices
- Duration of exposure to population
- False-positive or false-negative results
- Patient tolerance of risk
- Risk factors for healthcare professionals or caregivers

# Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions”

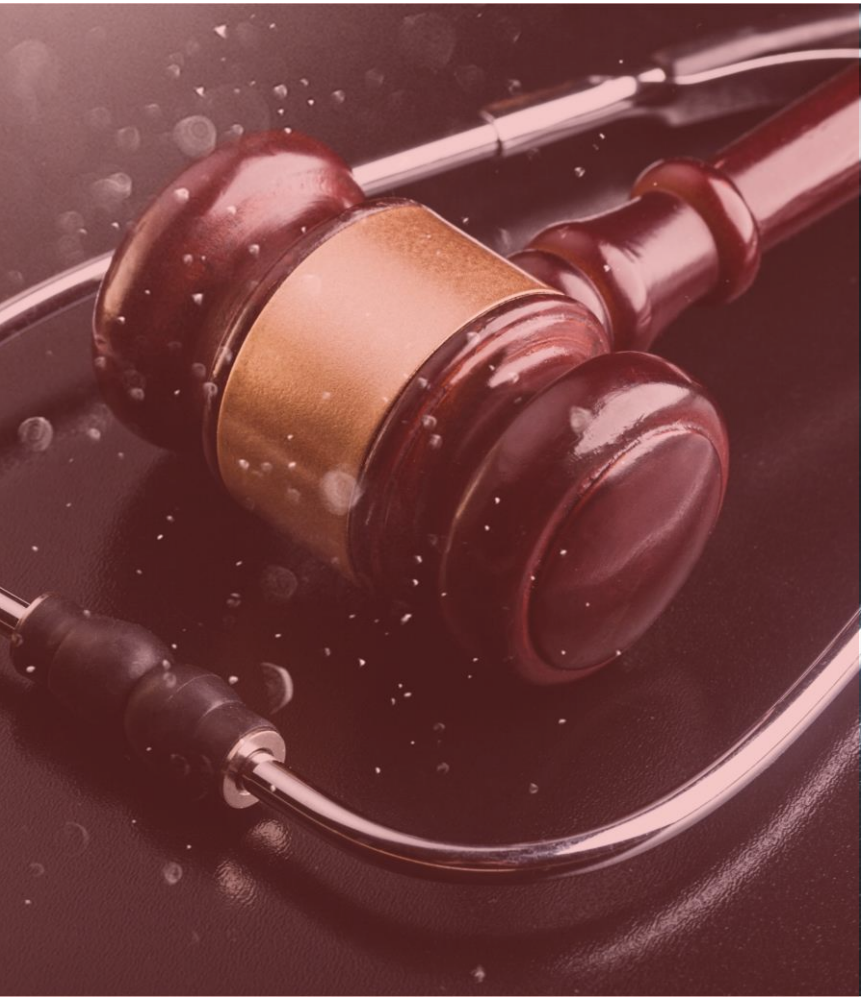
## FDA’s 2016 draft guidance

**Additional Benefit-Risk Factors to Consider**

- Uncertainty
- Mitigations
- Detectability
- Failure mode
- Scope of the device issue
- Patient impact
- Preference for availability
- Nature of violations/ Nonconforming product
- Firm compliance history

# Legal health risk

## The effects of the burden of proof



- Failure to submit 510(k) when needed
- Failure to follow a GMP in a material way
- Failure to have clinical or scientific evidence needed to assess the risk
- Failure to warn
- Failure to have evidence on actual use or clinical practice

# Customer Recall Fatigue

## What is the relevance?

- Often customers don't want products to be recalled
  - Burdensome on customers
  - Create product shortages harmful to patients.
  - Customers start discounting the recall notices they receive.
- Recall fatigue is a serious concern.
- However, the concept has to be handled with great care so that it doesn't become self-serving to the manufacturer.
- A decision to forgo a recall entirely – meaning that the company will not even notify customers– is hard to justify without strong objective evidence.
- FDA's default is to believe it is best, at a minimum, to inform customers about a problem so they can make an informed decision about what to do.

# Qualitative Evidence

## If quantitative evidence is not available

**Important to document that quantitative evidence does not exist**

- That judgment, experience, and general knowledge are being used to fill in the gap.

**This is not an excuse to be undisciplined or fail to rely on objective facts.**

- Once a significant violation has been established, the burden flips to the manufacturer to prove that a recall is not necessary.
- In that calculus, wherever there is a gap in the facts, those facts need to be construed in favor of protecting the customer and/or patient.

# Risk drives the recall scope and strategy

1. **Removal vs field corrective action, including customer notifications**

2. **Depth of recall.** Consumer or user level; or
   - Retail level; or
   - Wholesale level.

3. **Public warning.**

4. **Effectiveness checks.**
   - Verify that consignees (at the recall depth specified by the strategy) have received notification and have taken appropriate action.

# Checking Our Work:

## Does this Approach Make Sense?

### Summary approach

- Recall trigger is a significant violation of the Act that would lead to FDA enforcement.

If yes, then

- Recall scope is determined by the risk of injury, either physical or economic.
  - And the burden of proof is on the manufacturer.

### Does that make policy sense?

- First screen is about compliance, and is focused on significant issues.
- Second screen gets practical—what remedy matches the harm.
- When is doubt, protect the public

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# Mandatory Recalls and Other Enforcement: How Big Is FDA's Stick Already?

# FDA-requested voluntary recalls

FDA can request "a firm to initiate a recall when a product that has been distributed presents a risk of illness or injury or gross consumer deception and agency action is necessary to protect the public health and welfare." 21 CFR § 7.45(a).

# Mandatory recalls

- If a manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order under 21 CFR § 810.
- FDA must find there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.
- Initially, FDA is limited to issuing a cease distribution and notification order
- The person named in the order can ask for a regulatory hearing or provide a written request to FDA asking that the order be modified.
- FDA may later amend the order to require a recall of the device.

# Order to notify

## Notification procedures

**Under Section 518, FDA may require manufacturers etc. to notify all health professionals who prescribe or use the device and any other person of a health risk resulting from the use of the device.**

**Appropriate when:**

- A device presents an unreasonable risk of substantial harm to public health;
- Notification is necessary to eliminate the risk; and
- No more practicable means are available under the Act to eliminate the risk.

**The procedures require prior consultation with the persons who are to provide the notification.**

# Order to refund or repair

## Repair, replace, or refund procedures

**Section 518(b) authorizes FDA, after offering an opportunity for an informal hearing, to order manufacturers to repair, replace, or refund the purchase price of devices that present unreasonable health risks.**

**FDA can order these remedies if it determines that:**

- The device represents an unreasonable risk of substantial harm to the public health;
- The device was not designed and manufactured in accordance with the then prevailing state of the art;
- The risk is not due to negligent installation, maintenance, repair, or use of the device by persons other than a manufacturer, importer, distributor, or retailer; and
- Notification alone is insufficient, and repair, replacement, or refund is necessary.

# Adverse Publicity

Section 705(b) of the Act authorizes FDA to disseminate information regarding devices in situations involving, in the opinion of FDA, "imminent danger to health or gross deception of the consumer."

FDA is obliged to follow procedural rules set up by the U.S. Department of Health and Human Services at 45 CFR part 17.

Those regulations, in very broad terms, require that FDA only disseminate accurate, factual information.

In practice, these requirements offer manufacturers virtually no Due Process protection and have been roundly criticized over the last nearly 50 years.

But the lack of Due Process is what seems to make this FDA's option of choice.

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# Concerns About the New World Order

# Changes CDRH wants in its postmarket regulatory oversight

## Medical Device Safety Action Plan released in April 2018

**CDRH is apparently contemplating a global *special control* that would apply to a broad swath of medical devices to give the Center the ability to order postmarket risk mitigations.**

- "it is currently cumbersome for CDRH to require that a company implement new mitigations, such as labeling and user training, to address new or increased known safety risks of a device. For example, if new information about an increased known risk changes the benefit-risk profile of a type of marketed device, CDRH must engage in rulemaking to create or amend the applicable special controls—a process that is time- and resource-intensive."
- "As a result, CDRH often works with individual manufacturers to voluntarily implement mitigations, an approach that is not always effective."
- CDRH wants to explore "whether, under current statutory authorities, FDA can impose special controls, when warranted to address new or increased known risks, more quickly through the issuance of an umbrella regulation; and if not, explore what additional actions might be taken, including considering potential new authorities."

# Pre-certification Program for software medical devices

## FDA wants more power


- Companies can volunteer to be appraised in how they measure up against standards for "excellence" in software design.
- In return, they may be able to qualify for reduced pre-market requirements to market new software.
- But a crucial underlying component of the program is that companies will agree to engage in heightened postmarket data collection and comply with CDRH postmarket standards.
  - While the program has not be published yet, FDA is hinting that it may expect companies to do as FDA wishes postmarket, or be expelled from the program

# NEST safety net

## FDA gets greater leverage

**New NEST safety net to not just to collect data, but also to disseminate information.**

- NEST "should support FDA's process for disseminating warnings and safety information. To do this, the Coordinating Center should create and maintain a platform for sharing CDRH information in clear, accessible, and understandable language for patients, doctors, and caregivers."

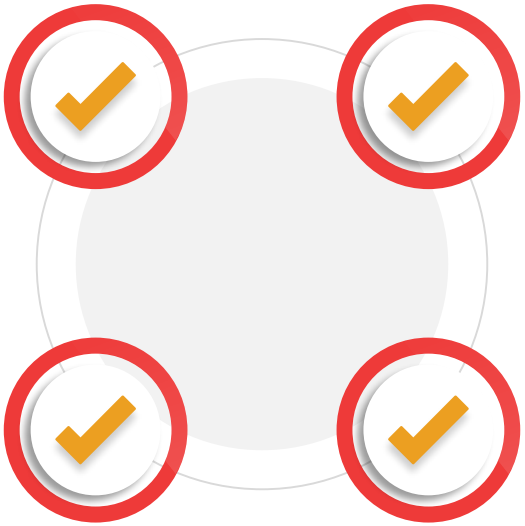
**That ability significantly expands FDA's leverage to get manufacturers to do as the agency wishes in recalls and corrections.**

# Balanced decision-making in initiating recalls

## Negative effects of recalls

Disruption, burden, cost and confusion for users.

Recall fatigue.



Product shortages.

Recalls are expensive for the manufacturers.

# Recall decision-making can be highly subjective

## Examples

**Field actions with respect to IVDs often include uncertainty because most are cleared as aids to clinical diagnosis as opposed to stand alone tests.**

- How a potential error will effect clinical decision making often cannot be quantitatively assessed.

**Literature to assess the risk of a device may not exist.**

- For example, assume a device failure increases dermal exposure to a pathogen, but transmission from dermal exposure has not been studied.
- There may be factors (vaccinations, prophylactic measures) which substantially mitigate risks, but in ways that cannot be reduced to a single number.

**Often the source of a manufacturing problem cannot be determined with 100% certainty, and understanding what product lots are affected requires judgment.**

# Both FDA and Industry are biased

## Industry's biases are well known

**01**

Industry has the profit motive. Selling more generally means making more money.

**02**

Industry is very close to the technology and has the maker's bias. Inventors fall in love with their inventions.

**03**

Those in the weeds on a daily basis can sometimes miss the bigger picture.

**Those biases are tempered by the very real threat of product liability as well as the loss of reputation that can destroy a business.**

# Both FDA and Industry are biased

## Center's biases are less well-known, but still very real

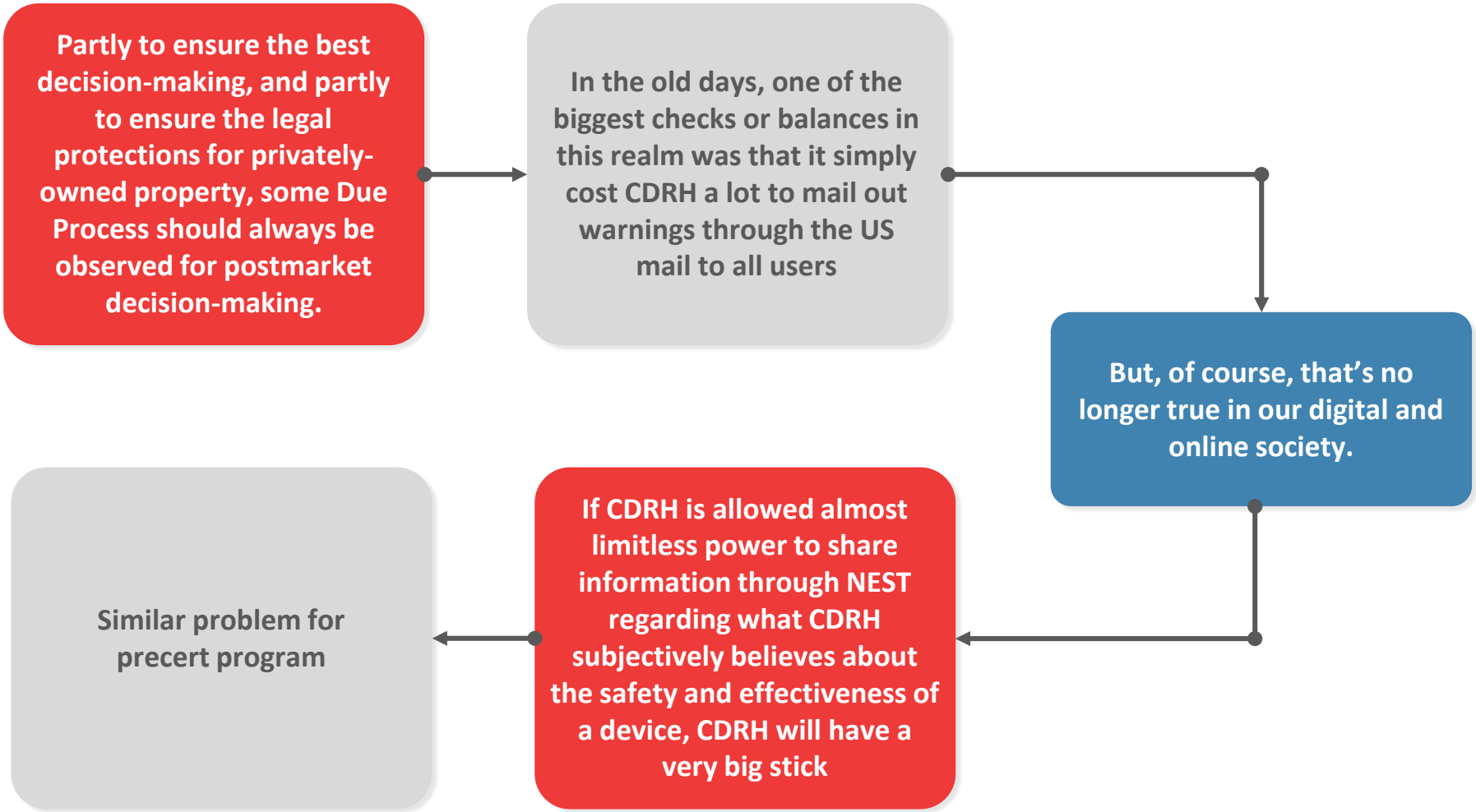

CDRH has a structural bias toward avoiding the mistake of allowing an unsafe product on the market.


CDRH has a recruiting strategy that targets people with activist personalities. People are recruited CDRH to "come and make a difference."


While CDRH employees have a broader perspective than many people in industry because they see a wide variety of technologies, the Center will also always know less about a particular problem involving a particular product than the manufacturer.

# These New Powers Require Due Process

## Only through some observance of Due Process will the best decisions be made.



# The limits on CDRH's use special controls

## CDRH only has the powers the statute provides

**Special controls are necessary for class II devices**

- "promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions…), recommendations, and other appropriate actions" required to regulate a particular device in class II.

**CDRH is trying to push an elephant through a keyhole**

**Medical Device Amendments specify the agency's postmarket authority.**

**Congress did not intend to give FDA the power to ignore all of that by publishing a special control**

**Special controls limited to filling in the specific blanks needed to regulate specific class II devices**

# Conclusion

## What does industry need to do?

FDA correctly tells Capitol Hill that in order to protect the public, it needs to be able to move quickly with respect to postmarket problems.

FDA also tells everyone who will listen that it is underfunded.

While there is merit in CDRH's arguments, those arguments are only one side of the issue.

There are problems with CDRH having too much power in this realm.

Congress needs to update FDA's postmarket powers, to reflect the reality that the agency can disseminate its own messages, whether the manufacturer agrees or not.

# Presented by


**Bradley Merrill Thompson**

Member of the Firm

bthompson@ebglaw.com

202-861-1817