Clark Hill

Medical Device v2.0: Safer but Riskier?

Litigation and Compliance Implications for Medical Device Improvements

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Summary of Presentation

- What is meant by “continuous improvement” in the medical device context and why is it important?
- How does continuous improvement potentially impact litigation?
- How does continuous improvement implicate regulatory concerns?
- What are some best practices when it comes to device improvements?

What is Continuous Improvement?

Continuous improvement is the ongoing process of identifying, analyzing, and making incremental improvements to systems, processes, products, or services.

“Without continual growth and progress, such words as improvement, achievement, and success have no meaning.”

- Benjamin Franklin

Continuous Improvement

Continuous Improvement is an ongoing effort to improve your organization's products, services, and/or processes.

- ISO 9001:2015 subclause 10.3

Continuous Improvement – 510(k) Clearance

- It is required by 21 CFR Part 820.
- Compliance with 21 CFR Part 820 is a required condition of a 510(k) Clearance.

Continuous Improvement – 510(k) Clearance

“You must comply with all the Act’s requirements including, but not limited to…good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820)…”

Continuous Improvement - 21 CFR Part 820

On January 31, 2024, the FDA issued a final rule amending the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation under 21 CFR 820 to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world.

Continuous Improvement - 21 CFR Part 820

This rule amends 21 CFR 820 by incorporating by reference the QMS requirements of the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO) in ISO 13485:2016.

Continuous Improvement - 21 CFR Part 820

FDA has determined that the requirements in ISO 13485 are:

- substantially similar to the requirements of the QSR (21 CFR 820);
- provide similar level of assurance in a firm's QMS and ability to consistently manufacture devices that are safe and effective and in compliance with FD&CA.

Continuous Improvement - ISO 13485:2016

- ISO 13485:2016 is a globally recognized standard for Quality Management Systems (QMS) for the medical device industry.
- ISO 13485:2016 requires all organizations to focus on continually improving.

Continuous Improvement - ISO 13485:2016

European Union, Canada, and Japan, also require ISO 13485 certification as a prerequisite for market entry.

“After the event, even a fool is wise.”

- Homer

Device Improvements – Litigation Concerns

- Device improvements are necessarily subsequent remedial measures.

- An improvement to a device's design, manufacture or labeling that occurs after an injury-inducing incident caused by the device.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407

But the court may admit this evidence for another purpose, such as

- **impeachment or**
- **if disputed, proving ownership, control, or the feasibility of precautionary measures.**

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407 – Exceptions

Feasibility of precautionary measures:

- too expensive;
- would have raised other safety concerns;
- not permitted under 510(k) clearance.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407

Prior rule (pre-1997 Amendment):

Evidence of measures taken after an event, which measures if taken before it occurred would have made the event less likely to occur, is not admissible to prove negligence or culpable conduct in connection with the event.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407

Rule 407 was amended to provide that evidence of subsequent remedial measures may not be used to prove "a defect in a product or its design, or that a warning or instruction should have accompanied a product."

Device Improvements - Litigation Concerns

Subsequent Remedial Measures - FRE 407

The amendment adopted the view of a majority of the circuits that had interpreted Rule 407 to apply to products liability actions and not just negligence actions.

Device Improvements - Litigation Concerns

A minority of courts had read into the prior rule an exception for strict liability, since strict liability is not determined by culpable, i.e. negligent, conduct, but rather, the existence of a defect that cause the alleged injury.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CA

Evid. Code Sec. 1151:

When, after the occurrence of an event, remedial or precautionary measures are taken, which, if taken previously, would have tended to make the event less likely to occur, evidence of such subsequent measures is inadmissible to prove negligence or culpable conduct in connection with the event.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CA

The exclusionary rule of *Evid. Code* Sec. 1151 generally does not apply to an action based on strict liability.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CA

Ault v. International Harvester Co. (1974) 13 C.3d 113:

- Plaintiff injured when car in which he was a passenger plunged 500 feet to the bottom of a canyon.
- Key evidence was a broken gearbox.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CA

- Three years after the accident, defendant substituted malleable iron for aluminum 380 in the manufacture of the gearbox.
- *Held,* the evidence was properly admitted.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CA

Ault **exception to** ***Evid. Code*** **Sec. 1151 extends to all categories of strict product liability claims.**

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

CRE 407: When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of subsequent remedial conduct is not admissible to prove negligent or culpable conduct in connection with the event.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

CRE 407 (continued): This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

CRE 407 does not contain amendments to FRE 407 that expanded scope of rule to exclude evidence of subsequent measures to prove a defect in a product or its design or a need for a warning or instruction.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

- Rule does not apply to strict liability design defect cases. *Forma Scientific, Inc. v. Biosera, Inc.*, 941 P.2d 284 (Colo. App. 1996)(agreeing with *Ault* rationale)

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

- *Forma* holding was based on Colorado Committee Comment to CRE 407: "The phrase 'culpable conduct' is not deemed to include proof of liability in a 'strict liability' case based on defect, where the subsequent measures are properly admitted as evidence of the original defect.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures – CO

- Likely does not apply to strict liability failure to warn cases as well.
- Does not apply to strict liability design defect cases in federal cases in District of Colorado cases under *Erie Doctrine*.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Alaska *Rules of Evidence*, Rule 407: "…This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as impeachment or, if controverted, proving ownership, control, feasibility of precautionary measures, or *defective condition in a products liability action*.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Connecticut *Code of Evidence*, Sec. 4-7(b):

"***Strict Product Liability of Goods***. Where a theory of liability relied on by a party is strict product liability, evidence of such measures taken after an event ***is admissible***."

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Hawaii HRS § 626-1, Rule 407:
"This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving *dangerous defect in products liability cases*, ownership, control, or feasibility of precautionary measures, if controverted, or impeachment."

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Missouri: Admissible in strict liability cases under *Pollard v. Ashby*, 793 S.W.2d 394, 403, Prod. Liab. Rep. (CCH) P 12327 (Mo. Ct. App. E.D. 1990).

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Maine *Rules of Evidence*, Rule 407(b): *Notification of defect*. Notwithstanding subdivision (a) of this rule, a manufacturer's written notification to purchasers of a defect in its product is admissible to prove the existence of the defect.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Texas *Rules of Evidence*, Rule 407:
(b) *Notification of Defect*. A manufacturer's written notification to a purchaser of a defect in one of its products is admissible against the manufacturer to prove the defect.

Device Improvements - Litigation Concerns

Subsequent Remedial Measures

Rhode Island *Rule of Evidence* 407: *Subsequent Remedial Measures*. — When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, *evidence of the subsequent measures is admissible*.

“It's not just a matter of saying we want the world to be safer; we have to create technology.”

- George M. Church

Device Improvements – Regulatory Concerns

If a device improvement is desired:

- Is a 510(k) necessary?
- FDA Guidance: https://www.fda.gov/media/99812/download

Device Improvements – Regulatory Concerns

A 510(k) is required when a device in commercial distribution is about to be significantly changed or modified in design, components, method of manufacture, or intended use.

Device Improvements – Regulatory Concerns

"Significant changes or modifications" are:

- A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process; and/or

- A major change or modification in the intended use of the device.

Device Improvements – Regulatory Concerns

- Company must perform a risk-based assessment to determine if proposed improvements/changes significantly affect the safety or effectiveness of the device.
- If so, a 510(k) is necessary.

Device Improvements – Regulatory Concerns

If company determines after a risk-based assessment that a 510(k) is *not* necessary for the proposed change, GMP require that it prepare a Memorandum to File, setting forth the results of the assessment and the rationale not to submit the 510(k).

“The safety of the people shall be the highest law.”

- Marcus Tullius Cicero

Device Improvements – Regulatory Concerns

Unauthorized Changes:

- Failure to submit 510(k) for changes = misbranded and adulterated.
- Can be any aspect of the device (design, manufacturing, labeling).
- In Q1 2025, FDA issued warning letters to Dexcom, Inc. and Q'Apel Medical, Inc.

Device Improvements – Regulatory Concerns

Unauthorized Changes:

- Dexcom: Had changed the design in a component used in the coating on sensors for its continuous glucose monitors.

- FDA: The changed coating "cause[d] higher risks for users who rely on the sensors to dose insulin."

Device Improvements – Regulatory Concerns

Unauthorized Changes:

- Q'Apel Medical: Aspiration Catheter with a designated inner and outer diameter.

- Device was promoted as being capable of expansion of the distal tip to larger diameters or compression of the distal tip during clinical use, which was not included in the original submission.

“There’s a way to do it better – find it.”

- Thomas Edison

Device Improvements – Litigation Concerns

- Duty to Innovate: Drug is not defective but is there a duty to develop an alternative drug that is allegedly safer for some users?
- *Gilead Life Sciences v. Superior Court*
- Currently pending before the California Supreme Court.

Device Improvements – Litigation Concerns

- In the underlying complaint, plaintiffs contended that although the drug they took was effective in suppressing HIV, the active ingredient caused harmful side effects.

- Plaintiffs argued that Gilead did not timely develop a different, equally effective but safer drug (or intentionally delayed its development.)

Device Improvements – Litigation Concerns

- Gilead filed a motion for summary judgment, arguing that the plaintiffs were required to prove that the product is defective.
- The trial court denied the MSJ, permitting plaintiffs to proceed on negligence theory premised on a purported delay in developing a safer, alternative drug.
- On appeal, the Court of Appeal affirmed.

Device Improvements – Litigation Concerns

- Gilead's briefing cited to virtually every case on which we usually base MSJs in all CA products cases.

- Plaintiff must prove (1) a defect (2) caused the injury.

Device Improvements – Litigation Concerns

- Court of Appeals focused on the viability of negligence claims in product liability cases in light of the availability of asserting strict liability.

- Virtually ignored the 'elephant in the room' in that unlike the cases cited by the COA, the *Gilead* case involved a similar but ***different*** product and not the product actually ingested by Plaintiffs.

Device Improvements – Litigation Concerns

Potential implications:

- Discourages continuous improvement.
- Harm innovation by encouraging companies *not* to invest in R&D.
- Result in uncertainty in what constitutes "safer but equally effective" and at what point of product development is this determination made.

Device Improvements – Litigation Concerns

Potential implications:

- Duty will extend to other non-drug products where it is arguably less expensive to develop product improvements.

Device Improvements – Litigation Concerns

Potential implications:

- *Hasson:* Auto/brakes case
- *Mexicali Rose:* Chicken enchilada
- *Lunghi:* Bobcat loader
- *Hernandez:* Crane

Device Improvements – Litigation Concerns

Potential implications:

- Cause manufacturers to prioritize new products with only *incremental* improvements rather than truly *innovative* products.

- Discourage manufacturers from prioritizing research into treatments for rare medical conditions.

Device Improvements – Litigation Concerns

Potential implications:

- Companies are not structured to develop products with CA product liability law in mind – international outlook.
- Will safety suffer?

Device Improvements – Litigation Concerns

Potential implications:

- Death knell for Restatement (Third) of Torts Sec. 6(c)?

Device Improvements – Litigation Concerns

- Sec. 6(c): A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, *would not prescribe the drug or medical device for any class of patients*.

Device Improvements – Litigation Concerns

- Sec. 6(c)(restated): If a reasonable doctor would choose to use the drug or device for any class of patients, knowing the risks, it is not defectively designed – regardless of whether there might be an alternative design.

Device Improvements – Litigation Concerns

- Not much case law that discusses or specifically adopts Sec. 6(c).
- One CO federal district court case has adopted Sec. 6(c) (design defect), another has limited its application.
- Many states have adopted 6(d) (LID).
- *Gilead* COA holding contradicts Sec. 6(c).

“Progressive improvement beats delayed perfection.”

- Mark Twain

Device Improvements – Best Practices

- Continuous improvement is not optional.

Device Improvements – Best Practices

Safer or Upgraded Alternative in Product Line

- Recall or retrofit
- Offer upgrade
- Labeling change
- Discontinue prior version altogether

Device Improvements – Best Practices

- Is a 510(k) required?
- If no 510(k), document with a Memorandum to File

Device Improvements – Best Practices

Are improvements and innovations mandatory for purposes of litigation risk management?

In California, perhaps…

Thank You

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