PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
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June 2, 2026

Office of the Ombudsman
Food and Drug Administration
10903 New Hampshire Avenue
WO Building 32, Room 4260
Silver Spring, MD 20993

Submitted by U.S. Mail and electronically to OMBUDS@OC.FDA.HHS.gov

Re: Request for Reconsideration of Agency Response to Demand for Correction under the Information Quality Act of CT Scan Dose Reduction Evaluation Information

To Whom It May Concern:

Public Employees for Environmental Responsibility (PEER) on its own behalf and on behalf of Xin He, PhD, a scientist employed by the U.S. Food and Drug Administration (FDA), hereby submits this Request for Reconsideration of FDA's response to our Demand for Correction under the Information Quality Act (IQA) of 2000 [Section 515 of the Fiscal Year 2001 Treasury and General Government Appropriations Act, Pub. L. No. 106-554],[1] the Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Utility, and Integrity of Information disseminated by Federal Agencies (hereinafter "OMB Guidelines")[2], and the Department of Health and Human Services (HHS) "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public").[3]

Our August 7, 2025, Demand for Correction (hereinafter "Demand") sought correction of the unfalsifiable and unreliable method used in regulatory science: the Channelized Hotelling Observer (CHO), which is the core technology in the LCD-CT tool (*Low-contrast Detectability Test for Assessing Advanced Nonlinear CT Image Reconstruction and Denoising Methods*[4]), listed in the FDA Catalog of Regulatory Science Tools to Help Assess New Medical Devices. [ATTACHMENT I]

[1] Treasury and General Government Appropriations Act, Pub. L. No. 106-554, §515 (Fiscal Year 2001).
[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002).
[3] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public | ASPE [hereinafter *HHS Guidelines*].
[4] https://cdrh-rst.fda.gov/lcd-ct-low-contrast-detectability-lcd-test-assessing-advanced-nonlinear-ct-image-reconstruction-and

In its response dated May 4, 2026, FDA rejected our Demand. [ATTACHMENT II] By this submission, we hereby request reconsideration of that rejection under Section VI d) of the afore referenced HHS Guidelines.

Summary

Notably, the Agency did not contest that the challenged material was subject to the requirements of the IQA. Nor did the Agency contest our standing to seek correction.

Our demand pointed out that the challenged material has resulted in concrete patient harm and regulatory violations and therefore fails the IQA requirements of utility and objectivity. However, the Agency did not engage with the specific analyses, arguments, or evidence we presented, let alone refute them.

The Agency also concedes that the challenged information is "influential information", defined by OMB Guidelines as information that will have or does have a *clear and substantial impact* on important public policies or important private sector decisions[5] and which has "a clear and substantial impact on important public policies or important private sector decisions."[6]

Further, the Agency does not argue with the fact that the LCD-CT tool in the Catalog has already influenced public policy (FDA regulatory decisions) and private sector activity (device development and labeling by major manufacturers) and has direct consequences for the millions of patients undergoing CT scans each year, as approximately 375–450 million CT scans are performed worldwide each year, with 85–90 million in the United States alone.[7]

Nor is it disputed that for influential information the FDA is held to a higher standard of transparency and reproducibility. As detailed below, the Agency's opaque and confusing response was legally and scientifically inadequate and fell well short of the high degree of integrity and utility required of influential information.

1. Ignored Physical Harm Caused by FDA

Our Demand specified how the LCD-CT/CHO tool fails to satisfy the IQA requirements of utility and objectivity because its use has contributed to patient harm as evidenced by:

a. A documented 2018 adverse event that remains unlogged in the MAUDE database.[8]
b. Post-market data showing FDA-cleared dose-reduction percentages of approximately 52–80%, substantially exceeding the 0–25% range generally reported as safe in post-market studies.
c. FDA's repeated written admissions that the LCD-CT/CHO tool cannot determine safe dose-reduction percentages, and that FDA "always knew" the cleared percentages were too high to support reasonable assurance of safety.

[5] 67 FR 8452; February 22, 2002
[6] HHS Guidelines, Part 1 C (i)(2)
[7] https://readmymri.com/blog/how-many-medical-imaging-scans-are-done-per-year
[8] Manufacturer and User Facility Device Experience (MAUDE) Database

The Agency's response did not dispute this evidence at all.

2. Leaves Dangerous Confusion

By declining to clarify whether the dose-reduction percentages appearing in device labeling and device default settings are intended to be clinically interpretable, scientifically meaningful, or actionable in any practical sense for physicians, patients, or other users, it is unclear how the LCD-CT/CHO tool satisfies the IQA requirement of utility, and why quantitative outputs that FDA acknowledges are not reliable indicators of safe clinical dose reduction should remain in device labeling, device default setting, or regulatory decision-making.

This concern is heightened by the Agency's failure to log the 2018 adverse event into FDA's MAUDE database, despite a formal request in this legal filing as well as congressional inquiries during the course of the filing. Unlike the broader dispute, MAUDE entry is a routine adverse-event documentation function performed by the Agency in the ordinary course of its work.

3. Ignored Regulatory Violations

Our Demand specified precisely how the LCD-CT/CHO tool fails the IQA requirements of utility and objectivity because its use has resulted in regulatory violations, including violations of 21 CFR 860.7(c)(2) (valid scientific evidence), 21 CFR 801.109 (labeling), and 21 U.S.C. § 352(f) and (j) (device misbranding). We provided itemized scientific and legal analysis supporting these claims.

The central legal issue is straightforward: the strongest evidence supporting these alleged violations is FDA's repeated acknowledgement, in official decision documents, signed by high-ranking officials, that the cleared dose-reduction percentages do not support reasonable assurance of safe clinical use, or are not intended to represent safe clinical use. Those acknowledgements prove our point.

The Agency's response did not dispute the legal analysis or the documentary evidence at all.

4. Fails Falsifiability Requirement of Executive Order 14303

The Agency did respond to our pointing to the Executive Order (EO) 14303 requirement that science should be "structured for the falsifiability of hypotheses", by stating that our Demand:

> "*inappropriately conflates research, which should be structured for falsifiability of hypotheses, with a tool designed to be used in that research … a method or tool (and its development) is not intrinsically falsifiable. Instead, a validated method, such as the LCD-CT tool, can be used to gather empirical evidence to objectively assess/test a scientific hypothesis and demonstrate whether that hypothesis is false. In other words, it is the hypothesis that needs to be falsified and not the methods used to assess the falsifiability.*"

The EO 14303 requirement of falsifiability is a core principle of the scientific method, introduced by Philosopher Karl Popper "*to distinguish science from pseudo-science*."[9] Accordingly, by alleging that LCD-CT/CHO fails the falsifiability requirement, we are effectively alleging that the Agency is engaging in what Philosopher Karl Popper defined as pseudo-science. Refuting this claim should be straightforward. The Agency need only answer the most basic and universally expected questions in science:

What is the claim of the tool? What it is valid for? or "What can it accomplish? The Agency, again, avoided answering these most basic questions.

Moreover, the Agency's reasoning appears inconsistent with standard scientific practice and can be refuted by routine examples from virtually any genuine scientific discipline. First, *the statement "a method or tool (and its development) is not intrinsically falsifiable*" is philosophically false. Modern scientific research necessarily depends on the validity of the tools used in that research, and the scientific validity of tools depends on empirically testable or falsifiable claims concerning their performance, applicability, etc. Standard scientific practice illustrates this principle:

a. Assume a pharmaceutical laboratory is testing the hypothesis that a new drug reduces fever. A thermometer is essential for collecting data. In this scenario, the thermometer itself is the product of scientific research that must test falsifiable hypotheses, such as whether the thermometer can accurately measure temperature within specified ranges and tolerances. If those falsifiable claims are not tested, the thermometer cannot function as a scientifically valid instrument.

b. Even seemingly minor components used in research are subject to falsifiable claims. For example, interventional radiology research may rely on adhesive materials to secure catheters and connectors. The underlying adhesive research must test falsifiable hypotheses concerning bond strength, drying behavior, shelf life, durability, and failure conditions.

These examples illustrate a general principle: scientific research depends on chains of empirically falsifiable claims extending from the primary hypothesis to the methods, instruments, materials, and analytical frameworks used to test that hypothesis. Accordingly, the assertion that "*a method or tool … is not intrinsically falsifiable*" is philosophically false and inconsistent with standard scientific practice. The statement that "*it is the hypothesis that needs to be falsified and not the methods…*" appears to be a language game that distracts from the fact that scientific methods and tools can themselves be proven wrong or invalid through empirically falsifiable claims and hypotheses.

Second, the statement that "*a method or tool … is not intrinsically falsifiable*" and "*a validated method, such as the LCD-CT tool, can be used*" hints that LCD-CT/CHO tool is not intrinsically falsifiable, but it is validated. This is logically contradictory. A method can only be "validated" if it is falsifiable, i.e., there exists some empirical basis upon which the method could fail. Otherwise, there is no meaningful distinction between validity and invalidity. In the

[9] Science as Falsification by Karl R. Popper Excerpt from Conjectures and Refutations (1963). PopperK-Science-as-Falsification.pdf

examples above, the thermometer and adhesive materials can be scientifically validated because their research was structured to test concrete, falsifiable claims.

Third, taken together, it appears the Agency attempts to exempt LCD-CT/CHO from the EO 14303 requirement of falsifiability by redefining methods and tools as outside the scope of falsifiability. This is done by alleging "*a tool designed to be used in that research*" "*is not intrinsically falsifiable*". This is contradictory to Philosopher Karl Popper's thesis and inconsistent with what is described in EO 14303, where "science" is required to be structured for the falsifiability of hypotheses, where "science" necessarily includes scientific tools and methods used in research. If the Agency alleges LCD-CT/CHO to be a scientific method or tool, it is within the scope of EO 14303.

If CHO research were genuinely structured for falsifiability, the Agency should be able to answer the most basic scientific questions: "what is the claim of the CHO?". Yet across the written records provided by the Agency – including the 2022 dispute resolution response, the 2023 dispute resolution appeal response, and the present response – the Agency repeatedly avoids directly answering this question.

5. RST Is a Shadow System

Without explaining its reasoning, the Agency response compares the Medical Device Development Tool (MDDT)[10] and RST catalogs. The MDDT framework appears to reflect a common-sense scientific standard: a tool is developed with a specific claim what it can accomplish and is validated against that claim. The RST pathway appears to function as a parallel or shadow evidentiary regime through which tools that would not satisfy common-sense scientific validation standards may nevertheless influence regulatory and clinical decision-making.

It is not clear why the existence of MDDT is responsive to the concerns regarding the utility and validity of the LCD-CT/CHO tool. However, a comparison of the two catalogs suggests that FDA's device-testing framework operates through two parallel evidentiary regimes:

- a high-bar qualification pathway (MDDT) which requires validated context of use.
- a low-bar parallel pathway (RST) which explicitly disclaims evaluation within any context of use.

It is common sense that any scientific tool developer should be able to articulate what the tool is intended to accomplish or be valid for in a specific context. A defined context of use establishes the boundaries within which falsifiability, validation, evidentiary relevance, and scientific accountability can be meaningfully assessed. Without such boundaries, there is no clear framework by which a method's outputs can be meaningfully evaluated, confirmed, or refuted in real-world practice.

The high-bar MDDT program was launched in 2014 and is open to public submissions. Six years later, FDA launched the lower-bar RST pathway without a clearly defined qualification framework comparable to MDDT to host FDA-developed testing tools. The RST homepage

[10] Medical Device Development Tools (MDDT) | FDA

states FDA has "*not evaluated for suitability of these tools within any specific context of use*". This creates a fundamental scientific and regulatory inconsistency.

If a private manufacturer were to state: "We sell 90+ drugs or devices but have not evaluated their suitability within any specific indications or context of use," such a position would plainly be incompatible with common sense expectations. Yet FDA's own scientific products, including LCD-CT/CHO, appear exempt from the same foundational requirement to define a specific claim or validated context of use.

The Office of Science and Engineering Laboratories (OSEL) Director Edward Margerrison stated that "*regulatory science tools will grow up to become MDDTs once they have a defined Context of Use*" [11]. Yet more than a decade after the launch of MDDT, among the 90+ tools in RST, only two have progressed to MDDT qualification. The RST website suggests that these tools are evaluated case-by-case when used in device-clearance decisions. However, device clearances necessarily involve specific contexts of use.

The resulting inconsistency is that these tools are described as "determined to be acceptable for the designated purposes… to streamline the review process"[12], while not evaluated "within any specific context of use" and yet used in device clearances that involve "specific context of use."

The LCD-CT/CHO tool has been used in more than 20 clearances to generate dose-reduction estimates, yet FDA has repeatedly acknowledged that the tool is "not meant to provide clinical levels of performance." It is therefore unclear how the validity of an RST tool is established when its outputs are acknowledged not to represent safe clinical performance within the specific contexts of use involved in those clearances. If LCD-CT/CHO is not validated for any defined context of use, how can it nevertheless be relied upon to support conclusions regarding device safety and effectiveness within specific clinical contexts?

6. Agency's Response Relies upon Specious and Misleading Reasoning

The Agency's response included several arguments that appear reasonable on the surface but rely on reasoning that does not directly address the underlying scientific and regulatory questions:

A. The response states "Model observers, such as CHO, are considered scientifically valid and have been used by the scientific community for assessing image quality for over two decades."

The scientific validity of a method or tool is established by its empirically testable claims and the evidence supporting those claims, not by its duration of use or level of professional acceptance.

The Agency's response not identify the empirically testable or falsifiable claims of the tool.

[11] FDA Regulatory Science Tools & MDDTs Guide | StarFish Medical
[12] FDA Regulatory Science Tools & MDDTs Guide | StarFish Medical

B. The response states “The LCD-CT tool alone is insufficient to make patient or disease specific claims. If used, the information from the LCD-CT tool is just one aspect, among many others, that FDA review teams will consider.”

The issue is not what LCD-CT/CHO “is *insufficient*”, but what it *is sufficient* to do. Specifically, the issue is whether the 50–82% dose-reduction percentages already appearing in device labeling and device default settings are scientifically supportable, non-misleading, and compliant with FDA regulations and Statute. That is, do the percentages in device labeling have any validity and practical utility at all, or whether they are purely misleading.

This still leaves unanswered what scientific proposition the tool is claimed to support.

C. The response states “Limitations of the LCD-CT tool are well understood by FDA review teams and have been identified in the FDA RST Catalog for device developers to take into consideration.”

Again, this does not address the central question of what the tool claims to accomplish. Acknowledging “limitations” may be scientifically appropriate only when a tool has a defined claim or validated context of use. Limitations and disclaimers may qualify a claim, but they do not substitute for one.

If LCD-CT/CHO is scientifically valid, the Agency should be able to identify what underlying claim is being limited or qualified, *i.e.*, “what is the claim of the CHO?” “what it is valid for?”.

D. The response states “FDA identifies the LCD-CT tool’s intended users on its website, along with the testing performed to ensure that the tool functions as designed, the limitations of the tool, and supporting documentation and references, including peer-reviewed journal articles.”

Again, this response avoids the central scientific issue: what exactly can the tool accomplish, and what is the tool valid for?

On Page 7 of the IQA Demand, we provided detailed analysis explaining why the website descriptions are misleading, including specific arguments and supporting evidence. The Agency response did not engage with those arguments or evidence.

E. The response states “RSTs are voluntary tools that developers may or may not choose to use. If a developer chooses to use an RST, the developer must assess whether it is fit-for-purpose as part of the development, validation, or labeling process.”

Again, this avoids the central issue of what the tool can accomplish, what it is valid for?

The tools at issue are developed, published, and promoted by FDA. As such, FDA bears the responsibility for identifying what the tool is intended to accomplish, the context in which the tool is considered valid, and the evidentiary basis supporting those claims. Without a validated claim, it is unclear how a user could meaningfully determine whether the tool is “fit-for-purpose.”

As of 2023, these tools had already been used in more than 20 premarket submissions. Once FDA-developed tools are incorporated into regulatory submissions, device labeling, or default device settings, they can materially influence clinical practice and patient exposure.

The fact that a product or methodology is voluntary to use does not exempt its researchers from defining and validating its claims. Prescription drugs and devices are likewise voluntary for patients to use, yet manufacturers must still define indications for use and provide evidence supporting those claims. Similarly, FDA's publication of a "voluntary" regulatory science tool does not remove the need to define and support a scientifically testable claim for that tool.

G. The response states "FDA recognizes that the requestor holds a differing scientific opinion regarding the Channelized Hotelling Observer (or CHO) and its incorporation into the LCD-CT tool."

This is a mischaracterization. The central concern is not differing scientific opinions. Rather, the concern is the Agency's repeated refusal to state its own scientific opinion.

The tool lacks a clearly defined, empirically testable claim regarding what its outputs are valid for and therefore functions in a manner consistent with what Popper defined as pseudoscience. The Agency continues to avoid refuting us by stating its scientific opinion concerning what the tool is valid for.

As stated above, the issue is whether the challenged practice constitutes science or instead falls into what Philosopher Karl Popper defined as pseudo-science: a framework insulated from empirical refutation because no clear claim is ever articulated that could be proven wrong.

Conclusion

As pointed out in our August 7, 2025 Demand, the FDA is legally obligated to assure that medical devices are reasonably safe and effective *in clinical use*. However, because the LCD-CT tool is not "structured for the falsifiability of hypothesis," i.e., it makes no hypothesis or claims concerning what its outcome can accomplish or interpretable, it is shielded from validation – thus evading the very requirements that govern standard scientific practice. In the response, the Agency repeatedly called the LCD-CT "valid" or "validated", yet continued to evade the most basic questions "what it is valid for?" "what can it accomplish?" "what is the claim of the tool?"

The issue is whether the challenged practice constitutes science or instead falls into what Philosopher Karl Popper defined as pseudo-science: a framework insulated from empirical refutation because no clear claim is ever articulated that could be proven wrong.

The practical concern is that the FDA has approved devices with reductions ranging from 50% to 82%. At these levels, image quality is significantly compromised. particularly in the visibility of low-contrast objects. This substantially increases the risk of missing tumors or other abnormalities, especially in early-stage disease when early detection is most critical. The existence of 90+ FDA developed tools, with an explicit cover-all disclaimer that FDA has "*not evaluated for suitability of these tools within any specific context of use*", is concerning.

In its response, the Agency did not dispute the negative post-market outcome and the causal relationship to the LCD-CT tool, yet it continues to maintain it is not accountable. That position is both irresponsible and illegal in that it runs afoul of the IQA.

Thus, we reiterate our 2025 Demand for Prompt Correction that the Agency:

1) Remove LCD-CT from the Catalog.

2) Publicly acknowledge that the tool is not "structured for falsifiability of hypotheses, or explicitly answer "What is the claim of the LCD-CT tool?" "What it is valid for?" "What can it accomplish?" If the Agency believes the falsifiability requirement of EO 14303 does not apply to the LCD-CT tool, please explicitly state so.

3) Consider recall devices that are related to this complaint or justify why the devices should not be recalled, or explicitly explain: how doctors and physicists should interpret the dose-reduction percentages in a manner that is beneficial and non-misleading to patients.

4) Review all diagnostic imaging tools for falsifiability and publish results.

5) Conduct an internal seminar examining the systemic failures evidenced by this case

6) Log the 2018 adverse event into the Manufacturer and User Facility Device Experience (MAUDE) Database, or answer "on what ground, a routine adverse event data entry job cannot be performed?"

7) Disclose Dispute Resolution documents on this matter to the public to promote transparency and public trust.

In addition, we again emphasize the grounds for this reconsideration: the use of the LCD-CT tool has caused patient harm and resulted in multiple regulatory violations. By failing to meet the EO 14303 requirement of falsifiability, the LCD-CT tool constitutes what philosopher Karl Popper defined as pseudoscience

Finally, the issue would be substantially clarified if FDA articulated a concrete, empirically testable statement describing what the LCD-CT tool is valid for, under what conditions, and what evidence would falsify or invalidate its outputs.

We look forward to receiving your response transmitted to the contact information below. Thank you in advance for your prompt attention to this Request for Reconsideration.

Sincerely,

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