PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
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August 7, 2025

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: Demand for Correction under the Information Quality Act: CT Scan Dose Reduction Evaluation Information

To Whom It May Concern:

Public Employees for Environmental Responsibility (PEER) hereby submits this 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 "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public").[3] PEER is submitting this Demand on its own behalf and on behalf of ___, PhD, a scientist employed by the U.S. Food and Drug Administration (FDA).

Summary

This complaint concerns an 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. The LCD-CT tool has already been used in the FDA clearance decisions involving CT dose reduction devices.

A computed tomography (CT) scan is an imaging test that helps healthcare providers detect diseases and injuries. The CT scan uses a series of X-rays and a computer to create detailed 3D images of bones and soft tissues. CT scans help detect diseases like cancer but

[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

expose patients to radiation, which carries its own cancer risks. To reduce this risk, manufacturers have developed different techniques claiming to lower dose while maintaining image quality. However, overly aggressive dose reduction can degrade images and make it harder to detect abnormalities like tumors.

According to published data, approximately 375–450 million CT scans are performed worldwide each year, with 85–90 million in the United States alone[5].

In the 2010s, several companies asked the FDA to clear iterative reconstruction (IR) algorithms that claim to reduce radiation dose without compromising image quality. After decades of internal research, the FDA recommended the CHO (and similar methods) to calculate these percentages, resulting in dose reduction claims of 50–82% in cleared device labeling[6].

But the CHO, as a purported scientific tool, does not make a claim open to scientific validation—such as how its outcome relates to dose reduction without compromising image quality in clinical use. Thus, without making such a claim, no validation was performed to assess the CHO's ability to accomplish the regulatory goal, i.e., to reduce dose without compromising image quality in clinical use. Nevertheless, the CHO was used to support regulatory decisions.

Post-market problems emerged in 2018, including an adverse event and data showing that safe reduction percentages ranged from 0–25%, significantly lower than those in cleared labeling. The FDA never disputed the data and has always acknowledged these issues. Yet the FDA did not take necessary actions to protect patients. Instead, the FDA officials **defended** the continual use of the tool by stating:

- "We always knew [the CHO study] would give optimistic numbers..."
- "[the CHO study] is not meant to indicate clinical levels of performance…"

In other words, when problems arose, the FDA argued that it "always knew" the tool will give unsafe results and that the tool was never intended to reasonably assure the safety and effectiveness of devices in clinical use — precisely the FDA's mission.

On September 24, 2023, the FDA formally added the disputed LCD-CT tool to its *Catalog of Regulatory Science Tools to Help Assess New Medical Devices*. The Agency has been using it to clear new CT dose reduction devices.

In the specific case of CT dose reduction, the result is a public health risk: patients may undergo CT scans using protocols less likely to detect disease, unaware that the percentages in device labeling have no established clinical validity. Hospitals may not be aware of the issue or how to correct it.

Furthermore, the FDA has normalized a practice in which it develops and uses a tool that explicitly disclaims the FDA's responsibility for safety and effectiveness—yet still allowing the tool to influence regulatory decisions. When safety or effectiveness problems occur in the post-market period, the agency disclaims accountability on the grounds that it never intended the tool to ensure safety in the first place.

[5] https://readmymri.com/blog/how-many-medical-imaging-scans-are-done-per-year
[6] https://pubmed.ncbi.nlm.nih.gov/24989382/

I. Challenged Information

The LCD-CT tool is published in the *Catalog of Regulatory Science Tools to Help Assess New Medical Devices.* However, the tool does not meet the basic standards for scientific legitimacy, as outlined in the 21 CFR 860.7(c)(2) and EO 14303 Sec. 3(vi), detailed below. Therefore, it should not be included in a catalog of "Science" tools. For this reason, and for the additional reasons detailed below, we request the retraction of the LCD-CT tool from the Catalog.

II. Challenged Material Is Subject to Information Quality Act

A. Challenged Material Is "Information" Subject to the IQA

The HHS Guidelines define "Information" to mean "any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page…"[7]

The FDA's *Catalog of Regulatory Science Tools to Help Assess New Medical Devices* clearly appears to fall within this definition.

B. Challenged Information Was Publicly Disseminated by the FDA

The OMB Guidelines define "Dissemination" to mean "agency initiated or sponsored distribution of information to the public."[8]

In this case, the challenged information is posted on the FDA website and made publicly accessible without restriction. By making this information available online for manufacturers, hospitals, researchers, and the general public to consult and rely upon, the FDA has clearly engaged in dissemination within the meaning of the Information Quality Act. Consequently, the challenged material meets the standard for distributed government information.

C. Complainants Have Standing to Challenge

___ holds a Ph.D. in Biomedical Engineering and is an expert in diagnostic image quality assessment methods, with 15 years of research experience in the field. Dr.__ also has 12 years of regulatory review experience.

Since the adverse event was reported to the FDA in 2018, Dr. __ has pursued multiple formal and informal channels – including formal dispute resolution processes and direct engagement with the United States Congress—urging the Agency to at least open the issue to internal scientific dialogue and explore potential solutions to protect patients. To date, the Agency has not permitted even a small internal scientific seminar to take place.

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[7] HHS Guidelines, Part 1, D (e)

[8] _____

PEER, a nonprofit organization chartered in the District of Columbia with members throughout the country. For more than 30 years, PEER has been a leading advocate for scientific integrity within the federal government and for more than 20 years, PEER has filed actions to enforce the standards of the Information Quality Act. In addition, PEER supporters, staff, and board members are at risk for false negatives or false positives due to improper CT scan protocols.

More broadly, unfalsifiable tools render the FDA unaccountable to its legal mandate. If this problem extends beyond a single example like the LCD-CT tool, it raises systemic concerns. PEER should take interest not only in this individual case, but in the broader regulatory failure it reflects—one that may compromise the safety and effectiveness of many medical devices.

III. Challenged Material Is Categorized as "Influential" and Thus Subject to Most Rigorous Scientific Standards

The term "influential information", when used in the OMB Guideline in the phrase "influential scientific, financial, or statistical information," applies when the Agency can "reasonably determine that dissemination of the information will have or does have a *clear and substantial impact* on important public policies or important private sector decisions.[9]

The HHS Guidelines further specify that "influential information" is defined as disseminated information that has "a clear and substantial impact on important public policies or important private sector decisions."[10]

In this instance, the Catalog meets this definition because the LCD-CT tool has already been used and is likely to continue to be used in diagnostic imaging device clearance processes. Given the complexity of CT systems, there are only 6 to 8 major global manufacturers, meaning that the FDA clearance decisions based on the tool have potentially affected millions of scans annually.

An FDA-authored 2014 publication promoting the use of the CHO in CT dose reduction cited four cleared dose reduction devices from four major vendors[11], two were cleared with the CHO and one with a similar method, demonstrating direct influence on private sector design, regulatory strategy, and product labeling. By 2023, FDA has made more than 20 clearances encompassing new CT image reconstruction algorithms based on iterative, statistical and more recently, deep learning techniques[12]. In addition, the CHO has been used in at least one nuclear medicine dose reduction clearance, extending its influence beyond CT.

Thus, the information included in 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 millions of patients undergoing CT scans each year.

IV. Challenged Materials Violate the Information Quality Act

[9] 67 FR 8452; February 22, 2002

[10] HHS Guidelines, Part 1 C (i)(2)

[11] https://pubmed.ncbi.nlm.nih.gov/24989382/

[12] Attachment to the Agency Dispute Resolution Decision Letter dated July 17, 2023.

The LCD-CT tool in the Catalog of Regulatory Science Tools does not meet two core standards for scientific legitimacy (Section A and B below). In addition, its use in updating dose reduction device labeling causes violations of the labeling related provisions (Section C below).Furthermore, the information provided by LCD-CT tool does not meet the higher standards of influential information (Section D).

A. Federal Regulations Governing Valid Scientific Evidence on the Safety and Effectiveness of Medical Devices

21 CFR § 860.7 is the regulation which governs determinations concerning the safety and effectiveness of a medical device. In pertinent part, it provides –

> "(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly **be concluded by qualified experts** that **there is reasonable assurance of the safety and effectiveness of a device under its conditions of use**. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device with questionable safety or effectiveness."[13] (emphasis added)

The Catalog fails this standard on multiple grounds.

First, the regulation requires "qualified experts" to "conclude" there is "reasonable assurance of safety and effectiveness" under "its conditions of use". However, in both verbal and written (See Section IV.B for specific quotes) statements, the most qualified experts at the FDA have repeatedly stated that:

- The dose-reduction results produced by the LCD-CT tool are too high to be clinically reliable; and
- The tool was never intended to provide clinically valid outcomes to assure safety and effectiveness.

If the FDA's own experts cannot make the conclusion required by the regulation, then the statutory standard is not met. Yet the CHO-calculated percentages continued to be embedded in the FDA-cleared device labeling.

Second, Dr. ___ has made repeated formal requests for the Agency to specifically assess the compliance to this regulation and justify the validity of the CHO. In response, the Center's formal decision, dated Mar. 31, 2023, avoided both requests. Instead, it responded with an assertion that the CHO is "valid" because there are "peer-reviewed, scientific publications validating the CHO model", while avoiding the key issue: in these self-identified validation

[13] 21 CFR § 860.7(c)(2)

studies, **what claims were validated?** Further, when asked to evaluate compliance to 21 CFR 860.7(c)(2), the Center simply stated that "the information provided… is not sufficient to conclude that regulatory violations exist," offering no analysis, no legal reasoning, and no engagement with the evidence submitted.

On appeal, in the Agency decision letter dated July 17, 2023, the Agency upheld the Center's position not by providing its own justification, but by deferring to the Center's determination that the CHO is a "valid" methodology. The Agency stated the Center's conclusion "*that the 'information provided' by Dr. ___ did not establish a 'regulatory violation' appears to flow from that determination.*" This reduces regulatory requirements into a language game: because there are studies self-identify as validation studies, so the CHO is valid; and because it is valid, it does not violate the Valid Scientific Evidence regulation.

Finally, the CHO fails the regulatory standard at a more fundamental level: it makes no testable or falsifiable claims about how its outputs can assure "safety and effectiveness of a device under its conditions of use". As a result, no one—inside or outside the Agency—has ever tested whether the numerical results produced by the CHO can assure "safety and effectiveness of a device under its conditions of use." Thus no one would have the evidence to draw the type of conclusions required by this regulation.

B. Executive Order Governing Scientific Integrity

On May 23, 2025, President Donald J. Trump issued an Executive Order entitled "Restoring Gold Standard Science" which stipulates that federal agency science is: "structured for falsifiability of hypotheses." [14] Falsifiability—the idea that a scientific method must be open to testing and capable of being proven wrong—is a foundational principle in the Philosophy of Science, introduced by Karl Popper to distinguish science from pseudoscience or non-science.

The key technology in the LCD-CT tool, the CHO, is the signature contribution of a former FDA scientific director and member of the National Academy of Engineering. First proposed in 1985, the CHO method has been extensively researched for nearly four decades, both inside and outside the FDA, mostly funded by FDA and NIH.

First, the tool is unfalsifiable in both basic science and applied science domain. In the basic science domain, the CHO is described as an anthropomorphic observer—a mathematical model that borrows the concept of "channels" from vision science to approximate human visual perception. However, the underlying mechanisms of these so-called "channels" are not quantitatively understood, nor is there demonstrable link between the CHO outputs and human signal detection performance that would allow for prospective prediction. Thus, despite its elegant mathematical formulation, there is no scientific basis for the CHO to make scientifically valid claims about human observers in empirically meaningful settings. Most published research using the CHO focuses on retrospective fitting: tuning parameters to make the CHO "track" or fit existing human observer data after the fact. These studies typically lack statistical measures of goodness-of-fit, and fail to establish prospective predictive power.

[14] EO 14303 Sec. 3(vi)

Lacking established empirical content in the basic science domain – that is, demonstrable agreement between theory and prediction, the CHO was nonetheless applied in an applied science context as the core technology in the LCD-CT tool for evaluating CT dose reduction. Yet without a sound foundation in basic scientific research, the CHO could not, and still cannot, make any specific, testable claims of practical relevance, including clinical relevance—regardless of the sophistication of its computational modeling.

Effectively, the CHO makes the following claims and disclaims:

- The CHO is an anthropomorphic (i.e., human-like) observer, though it is never claimed to predict human observers in any prospectively meaningful way.
- The CHO can be used to support the FDA clearance of CT dose-reduction percentages, though it is never claimed that the resulting percentages have clinical relevance.

As shown, these positions are structured to be unfalsifiable and irrefutable—because no matter what uncomfortable evidence is presented, the Agency can always respond: "We never made that claim!"

Second, the intent to apply the CHO while evading falsifiable scientific claims is evident in the language used on the FDA's LCD-CT tool webpage[15]. The phrasing is presented with scientific terminology while explicitly disclaiming any meaningful connection to real-world outcomes, rendering the tool precluding empirical testing—and thus unfalsifiable:

- *"The LCD-CT tool can help assess the image quality improvements of…"*
  This statement offers no claim that such image quality improvements affect clinical safety or effectiveness.

- *"The tool can also help assess quantitative dose reduction potential…"*
  Again, no claim is made about clinical relevance. This phrasing is as analogous to saying, "garlic and rat poison can help treat cancer"—technically true only if one avoids any connection to safety, effectiveness or any measurable or perceivable real-world consequences.

- *"Intended users are CT device developers, CT image reconstruction developers, and image denoising and processing software developers."*
  This omits any reference to clinicians or patient outcomes, implicitly removing clinical accountability.

- *"Users should be aware that a radiation dose reduction level established with the [tool]… does not transfer directly to clinical tasks on specific patients."*
  This disclaimer explicitly severs any connection to clinical relevance—undermining not only the tool's utility, but also the FDA's core mission. The phrase "specific patients" may create the impression that the tool outcomes are potentially valid at the population level. Yet the tool has never been validated for any population, and the Agency has never claimed otherwise.

[15] https://cdrh-rst.fda.gov/lcd-ct-low-contrast-detectability-lcd-test-assessing-advanced-nonlinear-ct-image-reconstruction-and

Third, the FDA's own public and internal positions confirm the unfalsifiable nature of these claims. Over the past several years, Dr. __ has repeatedly requested that the Agency either allow "a small internal scientific seminar" or clearly state the CHO tool's scientific claim – namely: "What is the claim of the CHO?" This is the most basic question of any scientific tool. To date, no answer has been provided and no seminar permitted. Instead, the Agency has issued written statements that further reinforce the tool's lack of falsifiability:

- *"We always knew [the CHO study] would give optimistic numbers..."*
  This admission came from the former FDA scientific director, who originally developed the CHO, after being presented with evidence that the CHO's dose-reduction percentages in cleared labeling were too high—i.e., "optimistic"—to be clinically safe.

- *"[The method] is not meant to indicate clinical levels of performance..."*
  This statement, given as a Director's Rebuttal during formal dispute resolution, directly contradicts the FDA's statutory obligation.

- *"..the estimates of dose reduction that [the CHO study] generates may not necessarily be fully achievable in true clinical practice."*
  This claim, published by FDA scientists in a journal article promoting the tool[16], is a disclaimer which tacitly acknowledges that the tool's reported percentages are too high to be considered clinically valid or achievable.

- *"CHO methodology has limitations, and dose reductions, as evaluated by CHO, do not necessarily correlate with clinical dose reduction ..."*
  This statement, taken from the Center's official decision letter during formal dispute resolution, concedes the tool's lack of validity in regulatory use—but frames this failure as mere "limitations."

Thus, the Agency's position is circular: 1) because the CHO makes no clinical claim, the FDA asserts it has no obligation to validate it clinically—even though it uses the CHO-generated values to justify device clearance, the very process intended to ensure clinical safety and effectiveness. 2) because the CHO makes no clinical claim, no post-market data can falsify a claim that it never made. Thus, the FDA can continue recommending the tool in clearing new CT dose reduction devices.

HHS Secretary, Robert F. Kennedy Jr., and FDA Commissioner Dr. Martin Makary have publicly committed to restoring "Gold-standard Science" in regulatory practice. Unfalsifiable practice is not Gold-standard science. According to foundational principles articulated by Karl Popper, methods that evade falsifiable claims do not meet the criteria of legitimate science and may be classified as pseudoscientific. Even flawed science is much preferable than pseudoscience, for flawed science is open to criticism and refutation. We urge Secretary Kennedy and Commissioner Makary to address the problem of unfalsifiability in regulatory science and to implement policy changes accordingly.

[16] https://pubmed.ncbi.nlm.nih.gov/24989382/

C. Federal Laws and Regulations Governing Device Labeling

21 CFR § 801.109 is the regulation which governs adequate device labeling for prescription devices. In pertinent part, it provides –

> 21 CFR § 801.109(c)
> **"Labeling** on or within the package from which the device is to be dispensed bears information for use, **including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions** under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but **only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device**. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso."
>
> 21 CFR § 801.109(d)
> "Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains **adequate information for such use**, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, **under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented.** This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information."

The provisions of 21 CFR § 801.109(c) apply to labeling on or within the package, and the provisions of 21 CFR § 801.109(d) apply to any labeling. Both subsections require that labeling contain adequate information for safe and intended use. The dose-reduction percentage labeling cleared with the CHO fails to meet this standard. The FDA has acknowledged that these percentages are not clinically safe and are not intended to indicate clinical performance (see Section IV.B for specific quotes), and the labeling provides no instructions for safe application of these percentages, nor any warning that using such unvalidated dose reductions may compromise diagnostic accuracy.

In the Dispute Resolution Appeal, Dr.___ stated "*From my read of Section I.3 (of the center decision letter), it appears the 'limitations' of CHO are: its outcome is so invalid, that the best thing users can do is to ignore the FDA-cleared labeling…If this is not the case, I request the Center to come up with specific labeling languages to explain how to "correctly" use the numerical number of dose reduction in cleared labeling to accomplish something, anything!*" This request was not granted. The Agency also failed to provide a regulatory counsel assessment of these labeling violations.

Moreover, the exemption under § 801.109(c)—allowing omission of such information where it is "commonly known"—does not apply. The CHO is not well understood by practitioners.

Therefore, the inclusion of these percentages in labeling without corresponding instructions or warnings constitutes a regulatory violation under both 21 CFR § 801.109(c) and (d).

The U.S. Code section (21 U.S.C. § 352)that defines misbranded devices in pertinent part provides –

> "A drug or device shall be deemed to be misbranded—
> (f)Directions for use and warnings on label
> Unless its labeling bears **(1) adequate directions for use; and (2) such adequate warnings** against use in those pathological conditions or by children where its use may be dangerous to health**, or against unsafe dosage** or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users**,** except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.
> **(j)**Health-endangering when used as prescribed
> If it is dangerous to health **when used in the dosage** or manner, or with the frequency or duration prescribed, recommended, or **suggested in the labeling** thereof." (emphasis added)

Under 21 U.S.C. § 352(f), a device is deemed misbranded if its labeling lacks "adequate directions for use" and "adequate warnings... against unsafe dosage or methods..." For the same reasons stated above, the device labeling as a result of using the CHO violates this provision.

Additionally, under 21 U.S.C. § 352(j), a device is misbranded if it is "dangerous to health when used in the dosage ... suggested in the labeling..." Because the labeling suggests dose levels that the FDA has internally acknowledged pose a risk of misdiagnosis, this provision is also violated. Together, these omissions render the labeling misleading and the devices misbranded under federal law.

D. Challenged Material Does Not Meet the Higher Standards of Influential Information

For influential information, the HHS Guidelines require its agencies to employ "a high degree of transparency about the data, sources, methods, measures, assumptions and limitations used to develop the information in order to facilitate reproducibility by qualified third parties"[17]. In other words, for influential information the FDA is held to a higher standard of transparency and reproducibility.

As explained above, the Agency's opaque and circular claims fall well short of the high degree of integrity and utility required of influential information. Further, the Agency's continued reluctance to subject the LCD-CT tool to scientific scrutiny reflects a regulatory thinking that may extend beyond the LCD-CT tool. On the homepage of the Catalog, which

[17] HHS Guidelines Part 1 D (f)

currently houses 77 tools, the Agency states: "*..the FDA has not evaluated the suitability of these tools within any specific context of use.*" [18] This raises serious concerns:

1. How can the FDA assert that a regulatory science tool has not been evaluated within any specific context of use, while that tool has already been used in a specific regulatory context to clear specific devices?
2. Are there other tools in the Catalog that, like the CHO, are unfalsifiable—i.e., tools that make no testable claims linking their outputs to clinical safety or effectiveness, and thus escape validation, while still being recommended to support regulatory decisions?

V. Challenged Materials Present a Public Health Threat

The FDA is legally obligated to assure that medical devices are reasonably safe and effective *in clinical use*. However, because the LCD-CT tool makes no clinical claims, it is shielded from clinical validation —thus evading the very requirements that govern tools used in regulatory process. In this case, the Agency failed to meet this basic obligation.

In 2018, a major hospital reported an adverse event (AE) to the FDA. A CT scanner was using up to 75% dose reduction setting by default. The hospital staff did not realize it was active, because the setting was not clearly disclosed to users. As a result, one patient's abnormality was not detected. Fixing the setting was so complex that only two medical physicists at the hospital knew how to do it.

Notably, the adverse event was ultimately dismissed by the Agency, without acknowledging the existence of the device feature that was alleged to have caused the adverse event.

Multiple independent studies have all found that safe dose reductions were below 25%. (These studies were collected in 2018 after the adverse event was reported to the FDA. The literature review included papers that used clinical or realistic images, human observers and diagnostic accuracy related endpoints.)

1. Schindera ST, Odedra D, Raza SA, Kim TK, Jang HJ, Szucs-Farkas Z, Rogalla P. Iterative reconstruction algorithm for CT: can radiation dose be decreased while low-contrast detectability is preserved? Radiology. 2013;269(2):511–518. doi:10.1148/radiol.13122349
2. Schindera ST, Odedra D, Mercer D, Thipphavong S, Chou P, Szucs-Farkas Z, Rogalla P. Hybrid iterative reconstruction technique for abdominal CT protocols in obese patients: assessment of image quality, radiation dose, and low-contrast detectability in a phantom. AJR Am J Roentgenol. 2014;202(2):W146–W152
3. Solomon J, Marin D, Roy-Choudhury K, Patel B, Samei E. Effect of radiation dose reduction and reconstruction algorithm on image noise, contrast, resolution, and detectability of subtle hypoattenuating liver lesions at multidetector CT: Filtered back projection versus a commercial model-based iterative reconstruction algorithm. Radiology. 2017;284(3):777–787. doi:10.1148/radiol.2017161736
4. Goenka AH, Herts BR, Obuchowski NA, Primak AN, Dong F, Karim W, Baker ME. Effect of reduced radiation exposure and iterative reconstruction on detection of low-contrast low-attenuation lesions in an anthropomorphic liver phantom: an 18-reader study. Radiology. 2014;272(1):154–163. doi:10.1148/radiol.14131928
5. Fletcher JG, Yu L, Li Z, Manduca A, Blezek DJ, Hough DM, Venkatesh SK, Brickner GC, Cernigliaro JC, Hara AK, Fidler JL, Lake DS, Shiung M, Lewis D, Leng S, Augustine KE, Carter RE, Holmes DR

[18] Regulatory Science Tools Catalog | Center for Devices and Radiological Health

3rd, McCollough CH. Observer performance in the detection and classification of malignant hepatic nodules and masses with CT image-space denoising and iterative reconstruction. Radiology. 2015;276(2):465–478. doi:10.1148/radiol.2015141991

Citing this evidence, Dr.___ has repeatedly requested that the Agency's research division undertake a broader, systematic literature review to either confirm or refute these findings. To date, the FDA has never disputed Dr. ___'s findings, nor has it, based on all available information, conducted the requested literature review.

Nonetheless, the FDA had already approved devices with reductions ranging from 50% to 82%. At this level, 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. More concerning, the Agency contends that it is not accountable for negative post-market outcomes of using the tool because it never claimed the tool assures safety and effectiveness.

Despite its known scientific invalidity, the tool continues to be used to support the clearance of new CT dose reduction devices.

There is growing concern that CT scans may increase cancer risk[19], creating an urgent need to reduce radiation dose while still maintaining the diagnostic value of these scans. Achieving this balance requires two distinct scientific understandings: (1) how radiation dose correlates with cancer risk, and (2) how radiation dose correlates with diagnostic accuracy. While the first is relatively well-established, the second remains poorly understood—even among FDA experts. Unfortunately, the Agency's reliance on unfalsifiable methods has impeded the kind of scientific inquiry necessary to advance this second area of knowledge. For years, Dr. ___ formally requested the opportunity to present an internal seminar within the Agency to discuss theoretical foundations and preliminary evidence related to dose-dependent diagnostic accuracy. To date, such a seminar has not been permitted.

VI. Demand for Prompt Correction

As outlined above, the LCD-CT tool does not meet the Information Quality Act's standards for integrity and utility. Thus, the tool should be removed from the Catalog.

On its website, the FDA declares that it "recognizes that public access to high quality information is critical to achieving this mission and public input, in turn, improves the quality of the information we disseminate." The FDA can validate that recognition by taking the corrective actions that we request. Specifically, we respectfully request that the Agency:

1) Remove LCD-CT from the Catalog.
2) Publicly acknowledge that the tool is not "structured for falsifiability of hypotheses."
3) Consider recall devices that are related to this complaint or justify why the devices should not be recalled.
4) Review all diagnostic imaging tools for falsifiability and publish results.
5) Conduct an internal seminar examining the systemic failures evidenced by this case.

[19] Just 1 Year of CT Scans Could Lead to Over 100,000 Cancer Diagnoses, Study Finds_____

6) Log the 2018 adverse event into the Manufacturer and User Facility Device Experience (MAUDE) Database:
   The 2018 adverse event should be formally logged as a Medical Device Report (MDR) in the MAUDE database, which serves as the FDA's public repository for adverse events involving medical devices. At present, the event is categorized as a private trade complaint, which is inappropriate for a documented adverse event. The MDR entry must explicitly include the correct name of the device feature or software module alleged to have caused the event, to ensure transparency, accountability, and traceability within the FDA's post-market surveillance system.
7) Disclose Dispute Resolution documents to the public: Make the following documents publicly available (excluding appendices or attachments) to promote transparency and public trust:
   - Dr. ___'s dispute resolution initiation memo
   - The Center's decision letter
   - Dr. ___'s formal appeal memo to the Agency
   - The Agency's final decision letter

   These documents reflect the internal handling of a matter involving potential regulatory noncompliance and public safety risk, and their disclosure is in the public interest.

We look forward to receiving your response at the contact information heading this stationery within 60 days, as specified within the FDA Information Quality Guidelines[20], if not sooner, given the adverse public health consequences stemming from this issue.

Thank you in advance for your prompt attention to this complaint.

Sincerely,

____ , Ph.D.
Biomedical Engineer
Food and Drug Administration

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