Negative: Autonomous Radiology Standards

By “Coach Vance” Trefethen

***Resolved: The United States federal government substantially reform the use of Artificial Intelligence technology***

Case Summary: The AFF plan sets higher standards for FDA approval of AI autonomous radiology cancer screening, under the theory that status quo FDA approves them too quickly before they are accurate enough.

Note that all the Bradley Thompson evidence, even if it doesn’t specifically mention radiology in the quote text, is in an article specifically on that topic. The title of his article tells you this clearly in the source citation.

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 Negative: Autonomous Radiology Standards

TOPICALITY

1. The most mixed up case you will hear this year

The Affirmative is advocating Status Quo and the Negative is advocating change

Since there is no autonomous AI radiology in use today, the entire premise of the Affirmative’s case is that they want to preserve it that way for the foreseeable future. They’re advocating enacting barriers that would slow down or block technological change.

By contrast, the Negative advocates leaving Status Quo policies alone because they are rapidly changing for the better. In a few years, if left to itself, the changes happening in current technology trends will give us a better world. If the Affirmative doesn’t get in the way, that is.

Violation: Only the Negative upholds their topical burden in the round

The Negative denies the resolution because we believe the federal government should do exactly nothing, just let current trends continue. That’s exactly what Negatives can and should do. By contrast, the Affirmative wants to freeze the Status Quo. No one is using autonomous AI radiology today, and no one will be using it the day after their plan is enacted, and for a long time thereafter. But there’s no way an Affirmative can advocate maintaining the Status Quo and hope to win a team policy debate round.|

Impact: Negative ballot

If we’re the only ones upholding our topical burden, we deserve to win the round. Both teams are denying significant federal reform of the use of AI, just denying it in different ways. If there are 2 Negative teams in the round, then no matter who wins, you should write Negative on the ballot.

INHERENCY

1. Not being used

There are no autonomous AI radiology algorithms on the market today

Dr. Howard B. Fleishon MD and Dr Bruce G. Haffty MD 2020. (Fleishon is with American College of Radiology. Haffty is with Radiological Society of North America) 30 June 2020 “Subject: (Docket No. FDA-2019-N-5592) “Public Workshop – Evolving Role of Artificial Intelligence in Radiological Imaging;” Comments of the American College of Radiology <https://www.acr.org/-/media/ACR/NOINDEX/Advocacy/acr_rsna_comments_fda-ai-evolvingrole-ws_6-30-2020.pdf> (accessed 13 Jan 2022)



AI is only used in radiology for research purposes, not in treating patients as of today



2. Status Quo regulations solve

Status Quo FDA policy is: No AI devices can go on the market unless they first prove benefits outweigh the risks

Pew Charitable Trusts 2021. (non-profit research organization) 5 Aug 2021 “How FDA Regulates Artificial Intelligence in Medical Products “ <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> (accessed 14 Jan 2022)

Several AI-driven devices currently on the market—such as IDx-DR, OsteoDetect, and ContaCT (see the text box, “Examples of FDA Cleared or Approved AI-Enabled Products”)—are Class II devices that were reviewed through the De Novo pathway. Class III devices pose the highest risk. They include products that are life-supporting, life-sustaining, or substantially important in preventing impairment of human health. These devices must undergo the full premarket approval process, and developers must submit clinical evidence that the benefits of the product outweigh the risks. The continuous glucose monitoring system, Guardian Connect system, was approved through a premarket approval.

Status Quo FDA regulations on AI approval are very strict (maybe even too strict)

Stan Benjamens, Pranavsingh Dhunnoo and Bertalan Mesdo 2020. (Benjamens - Medical Imaging Center, University Medical Center Groningen, Netherlands. Dhunnoo & Mesko - The Medical Futurist Institute, Budapest, Hungary. ) The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database 11 Sept 2020 <https://www.nature.com/articles/s41746-020-00324-0> (accessed 14 Jan 2022)

Because of the high-risk nature of these medical devices and the unknown consequences of using AI/ML for medical decision-making and data analysis, the FDA has stringent regulatory requirements for medical device licensing. Developers of AI/ML-based medical devices and algorithms have to go through rigorous processes that are time and resource consuming. This can be considered pivotal as a barrier for the introduction of AI/ML in medicine.

3. New approval standards already underway

FDA recently published a new Action Plan for developing new methods to evaluate AI algorithm

Pew Charitable Trusts 2021. (non-profit research organization) 5 Aug 2021 “How FDA Regulates Artificial Intelligence in Medical Products “ <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> (accessed 14 Jan 2022)

Most recently, the agency published the “Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan,” outlining its intended next steps. These include updating its proposed framework and issuing draft guidance on the predetermined change control plan, encouraging harmonization among technology developers on the development of GMLP, and holding a public workshop on medical device labeling to support transparency to end users. In addition, the agency will support efforts to develop methods for the evaluation and improvement of ML algorithms, including how to identify and eliminate bias, and to work with stakeholders to advance real-world performance monitoring pilots.

MINOR REPAIR – Post-release auditing instead of blocking pre-release approval (and cross-apply to Solvency #3 – we need to do this M.R. before the AFF plan)

There are some risks, but extra auditing of AI radiology after release would be enough to mitigate them

Casey Ross 2020 (technology journalist) 28 Feb 2020 “AI has arrived in medical imaging. Now the FDA needs to monitor its impact on patients” <https://www.statnews.com/2020/02/28/ai-medical-imaging-fda-monitor-impact-patients/> (accessed 14 Jan 2022) (brackets added)

But seizing that benefit requires careful monitoring to track the impact of AI systems as they are deployed in communities with different patient populations and varying levels of resources and clinical expertise, specialists said. One danger is that once doctors start using AI systems to interpret images, they could begin to lean too heavily on the machines and fail to exercise appropriate oversight. Another is that a lack of diversity in data used to train and validate a product could result in inaccurate readings when they are deployed in certain settings.  [Director of Radiology at Mass. General Hospital, Constance] Lehman said those risks could be offset by using existing performance checks in breast imaging and other specialities. “We do have the benefit of required audits, and I think we have an opportunity to leverage that and really look at what the performance is as centers are integrating AI into their programs,” she said. “We might even consider a higher bar for performance reporting if AI is used autonomously.”

FDA endorses the Minor Repair: They recommended not increasing pre-release testing but have more oversight after it goes to market

Bradley M. Thompson 2020 (J.D.; medical industry attorney) 9 Apr 2020 “New Developments in FDA Regulation of AI” <https://www.mddionline.com/regulatory-quality/new-developments-fda-regulation-ai> (accessed 14 Jan 2022)

Three years ago FDA launched an initiative to develop a Precertification Program that would shift the regulatory focus from the product to the developer. FDA reasoned that if it had confidence in health software developers and believed them to have a culture of quality and organizational excellence, FDA could allow the software onto the market with an abbreviated review, so long as the company agreed to submit to much greater FDA oversight during the postmarket phase.

HARMS / SIGNIFICANCE

1. Doctor oversight

Doctors know the limitations of AI and don’t use it autonomously. They either use it for research or have physician review for diagnosis

Dr. Howard B. Fleishon MD and Dr Bruce G. Haffty MD 2020. (Fleishon is with American College of Radiology. Haffty is with Radiological Society of North America) 30 June 2020 “Subject: (Docket No. FDA-2019-N-5592) “Public Workshop – Evolving Role of Artificial Intelligence in Radiological Imaging;” Comments of the American College of Radiology <https://www.acr.org/-/media/ACR/NOINDEX/Advocacy/acr_rsna_comments_fda-ai-evolvingrole-ws_6-30-2020.pdf> (accessed 13 Jan 2022)



2. Biased sources

Critics of autonomous AI radiology are biased against it because they think they’ll lose their jobs

Prof. Emre Pakdemirli 2019 (associate prof. of radiology, University of Health Sciences, Ankara, Turkey) Feb 2019 Acta Radiologica Open (open peer-reviewed journal online) “Artificial intelligence in radiology: friend or foe? Where are we now and where are we heading?” <https://www.researchgate.net/publication/331256297_Artificial_intelligence_in_radiology_friend_or_foe_Where_are_we_now_and_where_are_we_heading> (accessed 13 Jan 2022)



SOLVENCY

1. FDA incompetence and lack of capacity

FDA doesn’t have the skills nor the manpower to manage massive increase in AI regulation

Bradley M. Thompson 2020 (General Counsel, AI Startups in Health Coalition ) 25 Mar 2020 Re: Comments on Public Workshop – Evolving Role of Artificial Intelligence in Radiological Imaging <https://www.regulations.gov/comment/FDA-2019-N-5592-0012> (accessed 13 Jan 2022)

Over the next 10 years, companies deploying AI in healthcare will ramp up the data they collect postmarket by enormous amounts. We won’t try to project here exactly how much, but hopefully everyone agrees it’ll be a huge number. If FDA asks companies to start turning over to the agency even a small portion of that data, it will overwhelm the agency. We understand that FDA presently suffers from human resource constraints, particularly those with an AI software background. The agency is frankly not set up with either the manpower or information systems to read and interpret data transmitted to it on an ongoing basis postmarket. Though, conceivably, FDA could staff up or purchase and deploy its own AI system specific to this task, the expenditures are beyond FDA’s current financial resources, and supplemental appropriations for this task would likely be years in the future.

2. Impossible standards

It’s silly to expect AI to achieve 98% success before it can be used. By that standard, all human radiologists should be fired

Casey Ross 2020 (technology journalist) 28 Feb 2020 “AI has arrived in medical imaging. Now the FDA needs to monitor its impact on patients” <https://www.statnews.com/2020/02/28/ai-medical-imaging-fda-monitor-impact-patients/> (accessed 14 Jan 2022) (brackets added)

She [Constance Lehman, director of breast imaging at Massachusetts General Hospital] also pointed out, however, that the potential for newer and more powerful AI models should be considered in the context of current human performance, which is widely variable in breast imaging. “You could go to a center where the radiologist who interprets your mammogram has a sensitivity of 40%, missing 60% of all cancers that come through for that individual,” Lehman said. “Or you could go to a center where the radiologist has a very consistent sensitivity of 95%, only missing 5% of cancers.”  Artificial intelligence could help reduce such variation by giving radiologists more consistent and precise information in assessing the risks facing their patients.

3. More study needed first before we change the pre-market review for AI medical devices

Need to do the Minor Repair (approve quickly / more audits afterwards) first for a few years, to get the information needed to modify pre-market AI review process

Pew Charitable Trusts 2021. (non-profit research organization) 5 Aug 2021 “How FDA Regulates Artificial Intelligence in Medical Products “ <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> (accessed 14 Jan 2022) (our Minor Repair is to “fully implement” the streamline review/audit afterwards pilot project and let it finish before deciding on anything like the AFF plan)

In 2019, the agency began piloting an oversight framework called the Software Precertification Program, which, if fully implemented, would be a significant departure from its normal review process. Rather than reviewing devices individually, FDA would first evaluate the developer. If the organization meets certain qualifications and demonstrates it has rigorous processes to develop safe, effective devices, it would be able to undergo a significantly streamlined review process and make changes or even introduce products without going through premarket review. Nine companies participated in this pilot program. The lessons learned may help inform the development of a future regulatory model for software-based medical devices.

FDA needs more time to study the AI medical device approval process. Can’t decide quickly because it’s very complex

Pew Charitable Trusts 2021. (non-profit research organization) 5 Aug 2021 “How FDA Regulates Artificial Intelligence in Medical Products “ <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> (accessed 14 Jan 2022)

The regulatory framework governing these tools is complex. FDA regulates some—but not all—AI-enabled products used in health care, and the agency plays an important role in ensuring the safety and effectiveness of those products under its jurisdiction. The agency is currently considering how to adapt its review process for AI-enabled medical devices that have the ability to evolve rapidly in response to new data, sometimes in ways that are difficult to foresee.

4. Vagueness and Gaps not solved

AFF claims Status Quo FDA regulations are vague, but the plan doesn’t address 5 remaining gaps, so it will still be vague post-plan

Pew Charitable Trusts 2021. (non-profit research organization) 5 Aug 2021 “How FDA Regulates Artificial Intelligence in Medical Products “ <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> (accessed 14 Jan 2022)

FDA’s recent SaMD Action Plan is a good step forward, but the agency will still need to clarify other key issues, including:

1. When a modification to SaMD or an adaptive ML device requires premarket review. The draft guidance on the predetermined change control plan could be a critical part of this policy.

2. Whether and how the Software Precertification Program can be extended beyond the pilot phase.

3. The distinction between software regulated by FDA and exempt software, which will turn heavily on the difference between informing clinical decisions and driving them.

4. How GMLP, when they are developed, will intersect with the current quality system regulations that apply to all devices.

5. How software updates and potential impacts on performance will be communicated to end users.

DISADVANTAGES

1. Blocks technological innovation

Link: Innovation blocked. Increased FDA regulation would make it more difficult for startups to innovate important medical AI radiology apps

Bradley M. Thompson 2020 (General Counsel, AI Startups in Health Coalition ) 25 Mar 2020 Re: Comments on Public Workshop – Evolving Role of Artificial Intelligence in Radiological Imaging <https://www.regulations.gov/comment/FDA-2019-N-5592-0012> (accessed 13 Jan 2022)

A small company simply could not operate with FDA peppering it with questions on a daily basis. This level of micromanagement by the agency would be devastating to operations. The net effect of that devastation would be the company’s inability to dedicate sufficient resources to its operations including quality assurance. It is the patient, then, that would suffer from the company’s distraction. Further, the amount of data that FDA would require of companies would require the company to expend additional (and likely, human) resources to satisfy FDA’s requests. While large companies can more easily absorb this additional headcount, smaller companies, and especially startups, cannot. Long-term, this would make it more difficult for startups to innovate important

new FDA-regulated AI.

Impact: Health and money. More AI innovation means better health for patients at lower cost

[PETER MEATH 2019 (CO-HEAD OF HEALTHCARE AND LIFE SCIENCES, MIDDLE MARKET, J.P. MORGAN COMMERCIAL BANKING](PETER%20MEATH%202019%20%28CO-HEAD%20OF%20HEALTHCARE%20AND%20LIFE%20SCIENCES%2C%20MIDDLE%20MARKET%2C%20J.P.%20MORGAN%20COMMERCIAL%20BANKING)) 13 Mar 2019 “3 Ways Artificial Intelligence Can Help Medtech Save Lives” <https://www.jpmorgan.com/commercial-banking/insights/ai-medtech-save-lives> (accessed 14 Jan 2022)

Pathologists can draw on AI’s ability to cross-reference hundreds of thousands of comparable slides and data sets to both predict and evaluate different diagnoses. Cancers can be identified more accurately and efficiently, and at earlier stages of progression—ultimately leading to better treatment protocols and patient outcomes. Like pathology, medical imaging is an aspect of healthcare that has traditionally relied on human interpretation alone, but the immense volume of imaging presents an opportunity for more efficient analysis. Medical imaging—such as MRIs and CTs—essentially provide a tool for radiologists to identify underlying patterns. Since pattern analysis and recognition sit at the core of how AI is built, AI can be used by doctors in all facets of the decision process—from detection and diagnosis to decision analysis and treatment. AI can simply cross-compare and analyze a more complete data set than humans can assess by themselves. This can improve both the quality and speed of the analysis, benefiting the efficiency and cost for doctors and the health system as a whole.

2. Deaths from missing treatment

Link: AFF reduces / slows the availability of AI scanning technology

If not, then it doesn’t accomplish anything.

Problem: The choice isn’t between imperfect AI scans and better human scans. It’s between AI scans and NO scans because there is a shortage of qualified radiological analysts. And the impact is people die from heart attacks

Dr. Ha Hong 2020 (PhD; Investigator/Co-founder Caption Health, Inc. ) PUBLIC WORKSHOP - EVOLVING ROLE OF ARTIFICIAL INTELLIGENCE IN RADIOLOGICAL IMAGING DAY 2 FINAL (003) FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH , PUBLIC WORKSHOP - EVOLVING ROLE OF ARTIFICIAL INTELLIGENCE IN RADIOLOGICAL IMAGING , February 26, 2020 <https://www.regulations.gov/document/FDA-2019-N-5592-0010> (accessed 14 Jan 2022)

Heart disease can be accurately diagnosed with echocardiography or heart ultrasound scanning, but this often happens too late. Let's suppose that you wake up in the middle of the night with severe chest pain and shortness of breath, symptoms consistent with heart disease. You are in severe pain and brought to the ER, the emergency room doctor performs physical exam on you using plain old stethoscope, but the doctor does not perform ultrasound on you. In fact, the doctor cannot. Although they clearly know all the benefits and advantages of using ultrasound in this particular case, there are not that many people who can scan. This bottleneck, CDR bottlenecking, image acquisition causes delay in diagnosis and treatment, costing you a life. So why this is such a bottleneck? Why aren't more people able to scan? The problem is that ultrasound is so difficult, it's very difficult to use, especially in cardiac space. It is an unnatural hand-eye coordination problem, a tiny movement in hand positioning can dramatically change the image on the screen and the images themselves are very unintuitive. You do not know where you are, where the target is, how to navigate, and even if you hit the target, you do not know whether that is good enough or not. And to compound this problem, everyone is really different. Obesity, pathology and implanted devices can introduce significant variations on the images and also, simply everyone has different heart shapes . So that's the reason why there's a bottleneck., It takes years and years to master this and to become an ultrasound imaging professional.

Backup evidence: Speed matters: 1) for emergency situations 2) for underserved areas with no access to radiological technology

Dr. BRIAN GARRA, M.D. 2020. (Physician, Division of Imaging Diagnostics and Software Reliability, Office of Science and Engineering Laboratories – FDA) PUBLIC WORKSHOP - EVOLVING ROLE OF ARTIFICIAL INTELLIGENCE IN RADIOLOGICAL IMAGING DAY 2 FINAL (003) FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH , PUBLIC WORKSHOP - EVOLVING ROLE OF ARTIFICIAL INTELLIGENCE IN RADIOLOGICAL IMAGING , February 26, 2020 <https://www.regulations.gov/document/FDA-2019-N-5592-0010> (accessed 14 Jan 2022)

Faster is helpful in an emergency situation, for example. More access is helpful in a rural environment, for example, where people have no imaging capability whatsoever. Even in the U.S., in Appalachia, for instance, people have no access to imaging and there's a lot of potential for us to fix the third-world part of the United States by having more access and more skilled access in places where there's not much skill.