Negative: Sandbox FDA

By “Coach Vance” Trefethen

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

Case Summary: The AFF plan : FDA work with Sandbox to "filter" stringent regulations and focus on regulations that actually apply to AI medical devices. “Sandbox” is a scaled down regulatory approval process used to test new devices in a restricted, safe space (sandbox) differently from the normal testing and approval process. AFF may claim that Britain (UK) and Indonesia are using it successfully today, and we have responses to both of those. Scrutinize carefully any foreign evidence and make sure it’s talking about “Sandbox for artificial intelligence medical devices” and not just any kind of Sandbox. Sandbox can also be used for testing of other critical systems, like financial industry software, and some of their solvency evidence may be coming from other industries like that.

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Negative: Sandbox FDA

NEGATIVE DRUG APPROVAL EVIDENCE APPLIES TO AI

“Drug approval” evidence applies to AI devices – they have the same risks and concerns for FDA approval

Pew Charitable Trusts 2021 (non profit health care research organization) “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 31 Jan 2022)

AI algorithms need to be trained on large, diverse datasets to be generalizable across a variety of populations and to ensure that they are not biased in a way that affects their accuracy and reliability. These challenges can resemble those for other health care products. For example, if a drug is tested in a clinical trial population that is not sufficiently representative of the actual populations it will be used in, it will not work as well when implemented in real-world clinical settings. In AI, similarly, any model must be evaluated carefully to ensure that its performance can be applied across a diverse set of patients and settings.

INHERENCY

1. Software Precertification Program

FDA has already begun an expedited 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.

2. Faster methods of thorough testing

Let the Status Quo finish developing faster methods of complete testing instead of trying to find shortcuts

Pratik Shah, Francis Kendall lead authors with 6 other co-authors 2019. (Shah and Kendall are with 1 Massachusetts Institute of Technology, Media Laboratory. Co-authors were: Sean Khozin, Ryan Goosen, Jianying Hu, Jason Laramie, Michael Ringel and Nicholas Schork) Artificial intelligence and machine learning in clinical development: a translational perspective, published 26 July 2019 NATURE PARTNER JOURNALS <https://www.pratiks.info/uploads/s41746-019-0148-3.pdf> (accessed 31 Jan 2022)

Another theme at workshops focused on novel trials designs such as “basket,” “umbrella,” and many adaptive designs have been encouraged by regulatory agencies and can exploit emerging AI and ML techniques. These designs can enroll patients in a trial, profile them (e.g., using DNA sequencing, proteomics, metabolomics, etc.), and then use RWD [Real World Data] for matching drugs considered in the trial to the pathologies identified from the profiling. Strategies for matching drugs to patient profiles in these studies can be based on AI and ML analysis of large relevant data sets. AI and ML can further be used to support an electronic version of study data monitoring, thereby ensuring that data are correct and the patients are safe; thus reducing the need for expensive on-site study monitoring. Furthermore, HER [Electronic Health Records] data can be combined with other RWD types, such as genomics and patientreported concerns, can be mined with AI and ML techniques to create a more comprehensive picture for drug and biomarker discovery. As methods for each of these tasks are determined and refined, computational solutions, including AI and ML, can be implemented to reliably replicate clinical trial activities at scale. These types of clinical trials—which ultimately test intervention “algorithms” such as drug–patient profile matching schemes—are likely to become more pronounced and prevalent in the future, and could be greatly facilitated by leveraging clinical outcomes monitoring and RWD collection.

SOLVENCY

1. A/T “Works in United Kingdom (Great Britain)” – Not so fast.

They don’t have it yet. UK path to health care AI is full of bewilderment, confusion, and unfinished regulations

Andrea Downey 2020. (medical journalist) “Regulatory sandbox for AI needed to test and build systems, NHSX says” 12 Feb 2020 <https://www.digitalhealth.net/2020/02/regulatory-sandbox-for-ai-needed-to-test-and-build-systems-nhsx-says/> (brackets added) (accessed 30 Jan 2022)

“Smart regulation could really help make the UK the best place in the world to develop AI in health. The benefits will be huge if we can find the sweet spot, where we maintain the trust that AI is being used properly and safely, while creating a space in which compliant innovation can flourish,” [British National Health Service executive Matthew] Gould wrote. “We aren’t there yet. There are multiple regulators involved, creating a bewildering array of bodies for innovators to navigate and creating confusion for organisations in the NHS [National Health Service] and social care who want to make the most of these innovations.” Gould said that regulation for machine learning still needed to be ironed out and a clear path for innovators to get regulatory approval for their AI also needed to be established.

UK still needs more study to figure out how to do sandboxes for Health Technology Assessment (HTA)

[Emily Leckenby](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Emily-Leckenby), [Dalia Dawoud](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Dalia-Dawoud), [Jacoline Bouvy](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Jacoline-Bouvy) &  [Páll Jónsson](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-P_ll-J_nsson) 2021. (Leckenby - Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK. Dawoud - Science Policy and Research Programme, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence, London. Bouvy - NICE Scientific Advice, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence. Jonsson - Data and Analytics, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence , Manchester UK) “The Sandbox Approach and its Potential for Use in Health Technology Assessment: A Literature Review” 13 July 2021 <https://link.springer.com/article/10.1007/s40258-021-00665-1> (accessed 30 Jan 2022)

Our review supports establishing such sandboxes by HTA agencies, however, research is needed to understand how to embed these sandboxes in the organisational structure of current HTA agencies, managing the changes that accompany their implementation, and evaluate their benefits.

The UK medical Sandbox was not able to determine best practices for Health Technology Assessment (HTA)

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As digital health technology advances, HTA agencies must adapt to successfully appraise such technologies. NICE has published evidence standards relating to digital health technologies as part of a project funded by NHS UK. The aim of the standards is to improve innovator and commissioner understanding of the levels of evidence required for digital healthcare technologies. While a sandbox has been used to explore regulation of these products in the UK, sandboxes have not been used to determine the best methods for assessing these products from an HTA perspective or the policies and processes that underpin these assessments.

2. A/T “Works in Indonesia” – not so fast

Most recent evidence in the round Dec. 2021: Indonesian medical AI is governed by a 2009 law, not Sandbox, and it needs new legislation to address shortcomings

**Look at the title of the article: “Urgency of designing” new legislation. That means it’s not working now. [Grammatical errors in the text are due to the authors, though highly qualified, being non-native English speakers.]**

Hary Abdul Hakim, Chrisna Praja, Hardianto Djanggih December 2021. (Hakim and Praja are with the faculty of Muhammadiyah Magelang University, Indonesia. Djanggih is with the faculty of Muslim University of Indonesia) THE URGENCY ON DESIGNING THE LEGISLATION FOR THE USE OF ARTIFICIAL INTELLIGENCE IN INDONESIAN MEDICALPRACTICE <https://ejournal.balitbangham.go.id/index.php/dejure/article/download/2046/pdf> (accessed 31 Jan 2022)

Previous discussion mentioned on the use of AI in medical practices, while during its implementation Indonesia faced various significant challenges. Meanwhile, by implementing AI in medicine, Indonesia will have significant good impact especially the future health care services. Furthermore, by the current existing regulation, namely Health Act 2009, states that any development of technology in health care services is allowed. By implementing AI, it is easier for medical professionals to care for a larger number of patients.AI tools help them make better diagnostic decisions, improve treatment outcomes and reduce medical errors. AI could also take part in solving Human Resource issues, such as recruiting and selecting the potential healthcare work force. However, to avoid the misconduct of AI in medicine, and to face various challenges ahead in its implementation such as: human resources challenges, technology challenges and legal liability challenges. In conclusion, the application of AI in medical practice must be accompanied by the establishment of regulations, which aim to avoid all actions or negative impacts arising from the application of AI.

Indonesia sandbox was “tele-medicine” (doctor visits over Zoom) not AI medical devices

JAKARTA POST 2021 (Indonesian newspaper; journalist Thomas Dewaranu) “Opinion | Regulatory Sandbox for Health Technology in Indonesia” 10 Aug 2021 <https://www.cips-indonesia.org/post/opinion-regulatory-sandbox-for-health-technology-in-indonesia> (accessed 31 Jan 2022)

There are only 2 regulations that govern digital health services. Ministry of Health Regulation 20/2019 on Telemedicine Services as part of Health Services Facilities, and National Agency of Drug and Food (BPOM) Control Regulation No. 8 of 2020. To fill the gap, the Indonesian Medical Council (KKI) has also issued Regulation No. 74/2020 on clinical authority and medical practice through telemedicine during the COVID-19 pandemic in Indonesia. Nonetheless, all these regulations provide limited provisions on consumer data protection standards, and this is further worsened by the long dragging debates on Personal Data Protection (PDP). The absence of regulations and standards in this sector means that regulatory sandboxes can play an anticipatory role - to develop regulation alongside technological changes of new products and services. Through this process, telemedicine providers can be given a space to test out current best practices in data management, sharing, and protection. From this, regulators can then be informed about the current technological stage in the industry and how to provide an innovation-supportive regulatory framework for the sector. As a testing ground for innovative startups, regulatory sandboxes for telemedicine can also be applied to advance the interoperability of the platform with different health-related services such as private and public insurance, and e-payment.

If Indonesia’s medical device process was improved, it wasn’t Sandbox. It was adoption of ASEAN (Assoc. of Southeast Asian Nations) standards

Cekindo Business International 2021. (international business consulting firm operating in Indonesia) 2 July 2021 “A Simple Guide to Indonesia Medical Device Registration” <https://www.cekindo.com/blog/medical-product-registration-indonesia> (accessed 31 Jan 2022)

The long and highly bureaucratic market entering process has been, to some extent, facilitated by the harmonization of Indonesian regulations with the rest of ASEAN countries under the [Medical Device Directive (AMDD).](https://asean.org/?static_post=asean-medical-device-directive) In addition, the AMDD has brought changes into the classification of medical products on the basis of the risk they can cause if handled improperly. The former three categories have been replaced by a four grade-evaluation system.

3. No working models with product innovation

UK Study finds: Health Technology Assessment (HTA) sandbox experience is very limited and doesn’t include product development

[Emily Leckenby](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Emily-Leckenby), [Dalia Dawoud](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Dalia-Dawoud), [Jacoline Bouvy](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Jacoline-Bouvy) &  [Páll Jónsson](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-P_ll-J_nsson) 2021. (Leckenby - Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK. Dawoud - Science Policy and Research Programme, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence, London. Bouvy - NICE Scientific Advice, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence. Jonsson - Data and Analytics, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence , Manchester UK) “The Sandbox Approach and its Potential for Use in Health Technology Assessment: A Literature Review” 13 July 2021 <https://link.springer.com/article/10.1007/s40258-021-00665-1> (accessed 31 Jan 2022)

Focusing on HTA policy and methods: there is limited activity within this area, as many sandboxes currently focus on regulatory issues only, and do not include HTA within the product development pathway. A HTA sandbox would therefore complement already established regulatory sandbox programmes.

4. More study needed first before we change the pre-market review for AI 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.

5. FDA cannot successfully implement Sandbox AI approach

Link: UK Study says we need 6 elements for a Sandbox approach to succeed in health care, and we must have ALL 6.

[Emily Leckenby](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Emily-Leckenby), [Dalia Dawoud](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Dalia-Dawoud), [Jacoline Bouvy](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-Jacoline-Bouvy) &  [Páll Jónsson](https://link.springer.com/article/10.1007/s40258-021-00665-1#auth-P_ll-J_nsson) 2021. (Leckenby - Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK. Dawoud - Science Policy and Research Programme, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence, London. Bouvy - NICE Scientific Advice, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence. Jonsson - Data and Analytics, Science, Evidence and Analytics Directorate, National Institute for Health and Care Excellence , Manchester UK) “The Sandbox Approach and its Potential for Use in Health Technology Assessment: A Literature Review” 13 July 2021 <https://link.springer.com/article/10.1007/s40258-021-00665-1> (accessed 30 Jan 2022)

A range of mechanisms are being adopted by regulators to support innovation while also delivering appropriate regulatory oversight, through what is referred to as “anticipatory regulation”, where regulation is seen as a support tool for safeguarding responsible innovation, rather than a barrier . One such mechanism is live-testing environments such as ‘sandboxes’.   
**END QUOTE.   
That’s what the Affirmative is advocating. Later in the same article they go on to explain the 6 requirements, all of which must be present to succeed. THEY WRITE QUOTE:**  
Anticipatory regulatory approaches can also be described according to six key principles: inclusive and collaborative, future-facing, proactive, iterative, outcomes-based and experimental. For a sandbox to truly be anticipatory in its approach, it must consider all these principles within its intended activity and outcomes.

Failure: FDA fails at outcome-based evaluation. Example: Accelerated approval of the drug “eteplirsen” showed lack of outcome analysis and follow-up

Anna Kaltenboeck, Amanda Mehlman and Dr. Steven D. Pearson 2021. (Kaltenboeck - MA, MBA Program Director and Senior Health Economist, Center for Health Policy and Outcomes Memorial Sloan Kettering Cancer Center. Mehlman - Director of Strategic Partnerships Institute for Clinical and Economic Review. Pearson - MD, MSc President Institute for Clinical and Economic Review) <https://icer.org/wp-content/uploads/2021/04/Strengthening-the-Accelerated-Approval-Pathway-_-ICER-White-Paper-_-April-2021.pdf> (accessed 31 Jan 2022)

The FDA granted authorization to Sarepta Therapeutics in 2016 to market this treatment as the first for Duchenne Muscular Dystrophy (DMD). The excitement in the patient community was palpable, but the approval came despite sharp and unusually public internal disagreement within the FDA over whether the drug had met the bar for demonstrating reasonable likelihood of clinical benefit. [**END QUOTE**] Following its approval, some private payers deemed the evidence inadequate for coverage and balked at paying for eteplirsen, although coverage denials were routinely overturned on appeal. The annual cost of the drug in real-world practice rose to over $1 million per patient, and the drug quickly became a source of blockbuster revenue for Sarepta. To many, the capstone of this saga has been the drug maker’s failure to follow through on its post-marketing evidence requirement. [**THEY CONTINUE LATER IN THE SAME CONTEXT QUOTE:]** As part of the accelerated approval of eteplirsen, the FDA required Sarepta to conduct studies to characterize the treatment’s effects by 2018 and to confirm benefits of treatment by 2021. The company launched no studies until late in 2019 and, at the time of this paper, more than four years after eteplirsen’s accelerated approval, no additional evidence of the drug’s efficacy or safety has been made publicly available. The FDA, for its part, has taken no action against Sarepta and, in fact, granted accelerate approvals to its second and third DMD drugs in 2019 and 2021, respectively.

6. Missing Standards

FDA has yet to develop the basic standards for any type of AI health care approvals (sandbox or otherwise)

Pew Charitable Trusts 2021 (non profit health care research organization) “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 31 Jan 2022)

Especially as the use of AI products in health care proliferates, FDA and other stakeholders will need to develop clear guidelines on the clinical evidence necessary to demonstrate the safety and effectiveness of such products and the extent to which product labels need to specify limitations on their performance and generalizability. As part of this effort, the agency could consider requiring developers to provide public information about the data used to validate and test AI devices so that end users can better understand their benefits and risks.

7. Captured by industry

Link: FDA has been captured by industry. They’ll approve anything industry tells them (or pays them) to approve

NEW YORK TIMES 2021 (journalist Farad Manjoo) 2 Sept 2021 “America Desperately Needs a Much Better F.D.A.” <https://www.nytimes.com/2021/09/02/opinion/fda-drug-approval-trust.html> (accessed 30 Jan 2022)

Why do regulators approve so many potentially dangerous drugs, when many provide only minor improvements on existing drugs? Part of the story may be the conflicts of interest baked into the structure of the F.D.A. In 1992, Congress [allowed the agency to collect fees](https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments) from the industry it oversees to pay for the high costs of drug approvals. These fees [pay for much](https://jamanetwork.com/journals/jama/article-abstract/2758605) of the salaries of F.D.A. review workers responsible for the approval of new drugs. [The F.D.A.’s critics say](https://www.vox.com/2015/9/18/9333639/female-pink-viagra-fda-approved) the fees have turned the agency into more of a partner of the industry than an overseer. The fees are set [by negotiation](https://www.pogo.org/investigation/2016/12/fda-depends-on-industry-funding-money-comes-with-strings-attached/) between the agency and the drug industry; negotiations set the amount the industry pays the agency and also set certain [“performance goals”](https://www.fda.gov/media/99140/download) the agency must adhere to, among them commitments on the speed of its reviews.

Impact: Failure. Canada example proves - Industry capture means sandbox failure.

Marianne Apostolides 2021 (award-winning author of seven books. She is currently a fellow in Global Journalism at the Dalla Lana School of Public Health, University of Toronto) 4 Nov 2021 “Health Canada’s controversial ‘regulatory sandbox’: Enabling innovation or lowering the bar for safety?” <https://healthydebate.ca/2021/11/topic/health-canadas-regulatory-sandbox/> (accessed 31 Jan 2022) (brackets added)

The first pilot project in the sandbox will be launched in the coming months. Asked whether he has confidence in Health Canada’s ability to strike the right balance between innovation and patient health, [Director of Dalhousie University’s Health Law Institute, Matthew] Herder laughs, then carefully constructs his response. “That depends on who’s driving this process: Is it going to be Health Canada – and are they going to staff it with scientific expertise? Or is it going to continue to be informed by the industry they’re trying to regulate? “I think that’s the question we need to keep asking.”

8. Many other blocking factors unsolved

Multiple factors block AI medical innovation, way beyond the scope of AFF plan

Pratik Shah, Francis Kendall lead authors with 6 other co-authors 2019. (Shah and Kendall are with 1 Massachusetts Institute of Technology, Media Laboratory. Co-authors were: Sean Khozin, Ryan Goosen, Jianying Hu, Jason Laramie, Michael Ringel and Nicholas Schork) Artificial intelligence and machine learning in clinical development: a translational perspective, published 26 July 2019 NATURE PARTNER JOURNALS <https://www.pratiks.info/uploads/s41746-019-0148-3.pdf> (accessed 31 Jan 2022)

Despite these propositions for the use of ML to accelerate medical research, very few successful use cases have emerged. These limited successes have been attributed to, among other things, insufficient time elapsing since the introduction of relevant technologies and deficiency of current computer science deep learning and related ML models to generalize more complex and realistic medical data sets and tasks. Other important factors that impede the adoption of AI/ML techniques in therapeutic development include the paucity of large numbers of high-quality labeled data, nascent regulations, and ethical and legal concerns about data sharing. Alternative learning systems that leverage human brain and its neocortex and learn from fewer examples have been proposed as alternatives to deep learning, but have not been widely adopted.

DISADVANTAGES

1. Weakens public trust

Link: Public knows “sandbox” means they haven’t been tested fully, and they lose trust in government agencies.

Joshua Burd 2021. (JD candidate, Univ. of Penn.Law School) 27 July 2021 “Regulatory Sandboxes Slowed the Spread of COVID-19” <https://www.theregreview.org/2021/07/27/burd-regulatory-sandboxes-slowed-spread-covid-19/> (accessed 30 Jan 2022) (brackets added)

Even if the COVID-19 EUAs can be considered regulatory sandboxes, [Prof. Jacob] Sherkow [Univ. of Illinois College of Law] [worries](https://poseidon01.ssrn.com/delivery.php?ID=318115065115117127013068069000017087017069064045069066075090112069073003022123120018022103030104056120001028126081089006116080117022094008013004029022106125113014112065073085001075009019001115008090085095104071108076019111116114101031009110006087067074&EXT=pdf#page=37) that the unique circumstances of the pandemic limit how useful the experience will be for the implementation of future regulatory sandboxes. Sherkow [argues](https://poseidon01.ssrn.com/delivery.php?ID=372020070024100116013086075075030011030078052092059006029091118011022081031083009113102061051016000116101116093127004067084099001072061051050075073100091127006089102039002079119113072015084080113086067086087120108080127103029004010024103071009018064089&EXT=pdf&INDEX=TRUE#page=37) that regulatory sandboxes, including the COVID-19 EUAs, can diminish public trust in government agencies. He [reported](https://poseidon01.ssrn.com/delivery.php?ID=318115065115117127013068069000017087017069064045069066075090112069073003022123120018022103030104056120001028126081089006116080117022094008013004029022106125113014112065073085001075009019001115008090085095104071108076019111116114101031009110006087067074&EXT=pdf#page=37) that polling data suggests that Americans are both skeptical of the vaccines and less confident in FDA because of perceptions about the transparency of vaccine data.

Link: FDA shortcuts fuel public mistrust

HARVARD PUBLIC HEALTH REVIEW 2021. An Institutional Solution to Build Trust in Pandemic Vaccines” <http://casandbox.com/2021/05/25/31-article-heled/> (accessed 30 Jan 2022)

While the causes of vaccine mistrust are highly heterogenous (Palamenghi, 2020), mistrust in governmental agencies has long been acknowledged as a contributing factor (Miyachi, 2020). This mistrust has grown substantially during the COVID-19 pandemic, especially in the case of the FDA, which is widely perceived as having departed from its usual data-driven review processes in response to external pressures demanding the quick review and authorization of COVID-19 treatments (Baden et al., 2020).

Brink: Public trust is severely compromised right now. Not a good time to be reducing it more.

Ryan Cross 2021. (journalist) CHEMICAL & ENGINEERING NEWS 25 Jan 2021 “Will public trust in science survive the pandemic?” <https://cen.acs.org/policy/global-health/Will-public-trust-in-science-survive-the-pandemic/99/i3> (accessed 30 Jan 2022)

“It is just extraordinary what we’ve been through in the past year,” says Eric Topol, founder and director of the Scripps Research Translational Institute. “If you were to write a script about how to destroy the credibility of science, we just saw it. It couldn’t have been more of a comprehensive, systematic takedown, because it happened at every level.”

Impact: Human health. Human health improvement depends on trust in government health agencies

[Sarah D. Kowitt](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kowitt%20SD%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), [Allison M. Schmidt](https://www.ncbi.nlm.nih.gov/pubmed/?term=Schmidt%20AM%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), [Anika Hannan](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hannan%20A%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), and [Adam O. Goldstein](https://www.ncbi.nlm.nih.gov/pubmed/?term=Goldstein%20AO%5BAuthor%5D&cauthor=true&cauthor_uid=28520750) 2017 (Kowitt and Schmidt are with Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill. Hannan and Goldstein are with Lineberger Comprehensive Cancer Center, UNC-Chapel Hill. Go Tarheels!) 16 May 2017 “Awareness and trust of the FDA and CDC: Results from a national sample of US adults and adolescents” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5433718/> (accessed 30 Jan 2022)

A growing body of research has shown associations between trust in government and health-related behaviors and outcomes. For instance, in a study of HIV-positive adults, individuals with higher trust in government reported greater use of health care services, increased use of antiretroviral medications, fewer emergency room visits, and improved mental and physical health. Other studies have demonstrated the importance of governmental trust with vaccination intentions and uptake. From these studies, trust in the government and the health information it communicates can positively impact health outcomes.

Impact: Public health. Key public health issues of our time depend on credibility

[Sarah D. Kowitt](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kowitt%20SD%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), [Allison M. Schmidt](https://www.ncbi.nlm.nih.gov/pubmed/?term=Schmidt%20AM%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), [Anika Hannan](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hannan%20A%5BAuthor%5D&cauthor=true&cauthor_uid=28520750), and [Adam O. Goldstein](https://www.ncbi.nlm.nih.gov/pubmed/?term=Goldstein%20AO%5BAuthor%5D&cauthor=true&cauthor_uid=28520750) 2017 (Kowitt and Schmidt are with Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill. Hannan and Goldstein are with Lineberger Comprehensive Cancer Center, UNC-Chapel Hill. Go Tarheels!) 16 May 2017 “Awareness and trust of the FDA and CDC: Results from a national sample of US adults and adolescents” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5433718/> (accessed 30 Jan 2022)

Some of the key public health issues of our time—vaccines, medical devices, pharmaceutical access and uptake, food safety, bioterrorism, tobacco use—are all issues for which trust in the sources of messages about these issues is important. Without trust in the government or federal agencies, public confidence in government communication about the above issues may be diminished.

2. Abandoning Pre-Cert

Link: Cross-apply Inherency evidence about the existence of FDA Pre-Certification program

Link: Mutually exclusive or else not topical.

If Pre-Cert is the same as AFF plan, then AFF plan is untopical (not substantial reform) and wasteful (paying money to set up a duplicate of an existing program). If Pre-Cert is different from the AFF plan, then you would have to abandon Pre-Cert in order to do their plan. There would be no advantages to putting new AI devices through both Pre-Cert and Sandbox. That would just slow things down even further.  
  
In order to be topical, the Affirmative must advocate abandoning the FDA Pre-Cert program.

Link: Pre-Cert is effective because it uses a Total Product Life Cycle (TPLC) approach

**And this evidence is key because the FDA is the agency AFF is using for their plan. They can’t say FDA doesn’t know what they’re doing and then turn around and use them to run their plan. But if FDA knows what they’re doing, and FDA says Pre-Cert solves everything, then AFF MUST concede that we have an effective system today.**

Food & Drug Administration 2019. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) – Based Software as a Medical Device (SaMD) <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf> (accessed 31 Jan 2022)

As envisioned in the Software Pre-Cert Program, applying a TPLC approach to the regulation of software products is particularly important for AI/ML-based SaMD [Software as a Medical Device] due to its ability to adapt and improve from real-world use. In the Pre-Cert TPLC approach, FDA will assess the culture of quality and organizational excellence of a particular company and have reasonable assurance of the high quality of their software development, testing, and performance monitoring of their products. This approach would provide reasonable assurance of safety and effectiveness throughout the lifecycle of the organization and products so that patients, caregivers, healthcare professionals, and other users have assurance of the safety and quality of those products. This TPLC approach enables the evaluation and monitoring of a software product from its premarket development to postmarket performance, along with continued demonstration of the organization’s excellence (Figure 2).

Successfully tried: Pre-Cert has successfully been used on some diagnostic products in the U.S. already (unlike Sandbox, which has no success examples in the US)

Food & Drug Administration 2019. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) – Based Software as a Medical Device (SaMD) <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf> (accessed 31 Jan 2022)

This framework gives manufacturers the option to submit a plan for modifications during the initial premarket review of an AI/ML-based SaMD. FDA’s premarket review and determination regarding the acceptability of such plans would provide reasonable assurance of safety and effectiveness and would include review of the SaMD’s performance, the manufacturer’s plan for modifications, and the ability of the manufacturer to manage and control resultant risks of the modifications. FDA has successfully explored this voluntary approach to review device modification plans in certain recent De Novo classifications regarding several in-vitro diagnostic next generation sequencing products.

Link: Pre-Cert is better than Sandbox. Canada adopted Sandbox in 2019… and hasn’t approved a single thing yet. Their Sandbox administrator says Canada needs to learn from FDA’s Precertification!

Mark McCarty 2020 (journalist) 21 Sept 2020 “Health Canada making use of ‘regulatory sandbox’ to address AI” BIOWORLD <https://www.bioworld.com/articles/498030-health-canada-making-use-of-regulatory-sandbox-to-address-ai> (accessed 31 Jan 2022)

The field of artificial intelligence (AI) is stretching the boundaries of conventional med-tech regulation, and several regulatory agencies are working to cut that Gordian knot. Marc Lamoureaux, director of digital health at Health Canada’s (HC) medical device directorate, said on a Sept. 21 webinar that legislation passed in 2019 gives the agency a “regulatory sandbox” in which to experiment with AI regulation, a mechanism he said may bring these algorithms to market much more rapidly than would otherwise be the case.  
**END QUOTE. HE GOES ON LATER IN THE CONTEXT TO SAY QUOTE:**  
However, HC has not granted marketing authorization for a legitimately adaptive algorithm to date, and Lamoureaux said HC sees the FDA pre-certification mechanism for software as a medical device as instructive. The Canadian statute requires that significant device modifications must be taken up as a new regulatory filing, something he said is a barrier for innovation in this space. This is a barrier for regulators as well, Lamoureaux said, because “it inundates us with decisions” about how to regulate these algorithms.

Impact: Turn the AFF case. Their impacts get worse with an Affirmative ballot.

Abandoning the time, personnel and money we have invested in a system we know works for one that is unproven and unready is guaranteed to set back the goals of the Affirmative case and make things worse, not better.