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News We're Watching: AGs Push For Pulse Ox Warnings. VP Harris Announces AI Initiatives; FDA Looks At Digital Health And Diabetes

by Brian Bossetta

This week, 25 state attorneys general pressed FDA Commissioner Robert Califf to improve pulse oximeter safety warnings; MDIC extended the deadline on an industry cybersecurity benchmark study; and more guilty pleas and settlements were entered in Medicare fraud cases.

25 State Attorneys General Urge Pulse Oximeter Warning Labels

Labeling for pulse oximeters should carry warning labels alerting users the equipment may be less reliable in individuals with a darker skin tone, 25 state attorneys general said in a *1 November letter* to US Food and Drug Administration commissioner Robert Califf.

"It is imperative that the FDA act now to prevent additional severe illness and mortalities among darker skinned people resulting from inaccurate or misleading pulse oximeter readings as well as inadequate diagnostic and treatment protocols and procedures. This is particularly critical as the nation moves from a declared coronavirus public health emergency to a still-dangerous endemic phase," the letter states.

Specifically, the letter asks the FDA to require warnings on pulse oximeters and devices that incorporate pulse oximeter readings; issue an updated comprehensive safety alert; send a letter to health care providers about the issue; and accelerate review and release of the recommendations of a November 2022 advisory panel meeting on pulse oximeters. (Also see "*FDA Advisory Panel Agrees Pulse Oximeter Skin Pigment Discrepancies Pose Clinical Threat*" - Medtech Insight, 3 Nov, 2022.)

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The letter was signed by state attorneys in Arizona, California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington and Wisconsin.

Harris Announces White House Initiatives To Advance 'Safe And Responsible' AI

During her recent visit to the UK, Vice-President Kamala Harris delivered a speech at the US Embassy in London announcing a series of *steps* the US is taking to promote the use of safe and responsible artificial intelligence.

Harris also spoke of the dangers irresponsible AI poses to democracy and furthering inequality.

The vice president's address comes on the heels of a comprehensive *executive order* President Joe Biden signed last month on AI development. (Also see "*Former ONC Head of Policy: AI Executive Order Is Surprisingly Comprehensive*" - Medtech Insight, 1 Nov, 2023.)

The AI initiatives Harris announced include the establishment of the United States AI Safety Institute (US AISI), which will be housed in the National Institute of Standards and Technology (NIST). US AISI will create "guidelines, tools, benchmarks, and best practices" for evaluating and mitigating dangerous capabilities and conducting evaluations to identify and mitigate AI risk.

The White House is also releasing a draft policy guidance on US government use of AI through the Office of Management and Budget, which will be available for public comment. The guidance outlines concrete steps to advance responsible AI innovation in government, increase transparency and accountability, protect federal workers, and manage risks from sensitive uses of AI.

Harris also announced that 31 nations have joined the US in endorsing the "Political Declaration on the Responsible Military Use of Artificial Intelligence and Autonomy" — which establishes a set of norms for "responsible development, deployment, and use" of military AI capabilities that can help responsible states around the globe harness the benefits of AI capabilities in a responsible and lawful manner.

Industry Cybersecurity Benchmark Assessment Deadline Extended

The Medical Device Innovation Consortium (MDIC) has extended its deadline for its annual Medical Device Cybersecurity Maturity Survey to November 24.

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The original deadline for the survey was 20 October. It is intended to measure the cybersecurity readiness of medical device manufacturers by following the framework set out in the Medical Device and Health IT Joint Security Plan's (JSP). Previous use of JSP is not a requirement for participation in the survey. (Also see "*News We're Watching: New Branding For J&J, FDA Device Safety Report, LimFlow System Approval*" - Medtech Insight, 15 Sep, 2023.)

Last year, the survey only garnered 17 responses from MDMs, but many experts viewed the results as an accurate reflection of the industry's cybersecurity preparedness, which was low. (Also see "*MDIC Cybersecurity Benchmarking Maturity Report: An 'Honest Reflection' Of The Industry*" - Medtech Insight, 24 Jan, 2023.)

An updated JSP 2 is in the works and will be informed by the results of the survey.

FDA Seeks Public Comment On Diabetes Digital Health Technologies

The FDA's Center for Devices and Radiological Health has opened a public comment period on the potential use of digital health technologies to detect early warning signs of diabetes and prediabetes.

Among other issues, CDRH is looking for information on public health groups working to prevent diabetes; subpopulations that might benefit the most from remote detection tools; ways to use machine learning to identify at-risk patients through available medical records; and how biomarkers could be integrated into clinical decision software.

The comment period is open though 31 January 2024 at *regulations.gov*.

More Guilty Pleas In False Claims Act Cases As Enforcement Surge Continues

The US Department of Justice continued its apparent focus on health care fraud cases in recent weeks, with defendants in three separate cases pleading guilty. The cases involved a total of almost $15m in claims for durable medical equipment and genetic testing that was not medically necessary.

Two of the individuals were health care providers, while the third co-owned a DME vendor. Specifically:

- Nurse practitioner *Kristen Bolling* of Sheridan, WY, pleaded guilty to conspiracy to commit health care fraud. Bolling worked with multiple companies to generate orders for DME and genomic testing and was paid $15-$30 per appointment, ultimately collecting around

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$200,000. In total, Medicare paid more than $6.1m for the unnecessary products. Her sentencing is scheduled for 9 January.

- Physician *Alex Glotser* of Metairie, LA, also pleaded guilty to conspiracy to commit health care fraud. Glotser, who was charged earlier in October, reportedly signed prescriptions for medically unnecessary DME and laboratory tests for Medicare beneficiaries he never saw or even spoke to. (Also see "*Surge In US Enforcement Actions Shows Focus On Diagnostics*" - Medtech Insight, 11 Oct, 2023.)

- *Julian Latty* of Suffolk, VA, pleaded guilty to conspiring to defraud health insurance programs of more than $2m through fraudulent claims for braces and other medical equipment. Latty was a co-owner of Virginia Beach-based Beach Medical Suppliers LLC. He and his co-conspirator paid doctors to sign prescriptions for equipment that beneficiaries did not request or need, ultimately submitting $4m in fraudulent claims between 2018 and 2020.

Additionally, clinical laboratory *Genesis Reference Laboratories LLC* of Orlando, FL, has agreed to pay almost $1.2m to resolve False Claims Act allegations that its marketers paid illegal kickbacks to health care providers. The government says that Genesis paid three marketing companies to encourage healthcare providers in Missouri and Texas to order Genesis' laboratory tests. The marketing companies then, with Genesis' knowledge, directed some of the funds to providers as kickbacks.

Brown University Releases Biological Emergency 'Playbook'

Accurate and timely testing is crucial to a successful response to the next pandemic or other biological emergency, the Brown University Pandemic Center says in its new *Testing Playbook for Biological Emergencies*. The 50-page manual provides recommendations on best practices for public health laboratories, hospitals, health care providers and government agencies during each of the six phases of the emergency, which range from the initial detection of a pathogen outside the United States through the spread of infections, high levels of cases, and eventually bringing the pandemic under control.

The playbook addresses diagnostic testing for individuals, public health testing, and even wastewater surveillance. It recommends the development of flexible tests that could be quickly modified to detect a specific pathogen, allowing for the launch of diagnostics as soon as one week after the novel disease is identified.

"The purpose of this Testing Playbook is to provide executive leaders with a guide to easy-to-use information that will inform their planning on how equitable access to accurate testing can quickly be provided to all communities during an emerging biological event involving an

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unexpected, contagious pathogen and how the data from testing can inform emergency decisions at each stage of a crisis," the document explains.

The authors also stressed that the playbook is intended as a "living document" that will be continuously revised in response to scientific developments and feedback from stakeholders.

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