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NEWS FOR IMMEDIATE RELEASE

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Attorney General Kaul Joins Multistate Letter Urging FDA to Address Concerns about Dangerous Pulse Oximeter Inaccuracies Impacting Communities of Color

MADISON, Wis. – Attorney General Josh Kaul joined a multistate coalition of 25 attorneys general in submitting a letter to urge the U.S. Food and Drug Administration (FDA) to strengthen guidance and provide clear warning labels regarding incorrect pulse oximeter readings for patients of color. This letter comes on the heels of the one-year anniversary of the first public convening of the FDA's Medical Devices Advisory Committee to address concerns related to pulse oximeters' race and color bias.

"We are urging the FDA to take additional steps to prevent inequities in health care resulting from the use of pulse oximeters," said Attorney General Josh Kaul. "This issue highlights the importance of identifying disparities in the health care system and acting promptly to eliminate those disparities."

Pulse oximeters are routinely used to measure blood oxygen levels, which shape medical care for illnesses including heart failure, sleep apnea, and respiratory conditions. First invented in the 1980s and developed primarily based on tests involving a predominantly white population, pulse oximeters are now widely used throughout the healthcare system because they are the only rapid, noninvasive method of measuring oxygen saturation. Recent studies have indicated that inaccurate results from pulse oximeters are more likely when used to monitor patients of color, particularly patients with darker skin. The medical device's inaccuracies may lead to delays in treatment and hospital admissions, which can lead to severe or life-threatening consequences and contribute to lower quality healthcare.

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In the letter, the coalition calls for the FDA to issue guidance and new warning labels regarding the risks of skin tone-based bias in use of pulse oximeters.

Pulse oximeter use dramatically increased during the COVID-19 pandemic, when the readings were sometimes the only objective measure for determining what kind of treatment a COVID patient would get. When healthcare resources were stretched thin and subject to rationing, a patient's pulse oximeter reading could mean the difference between being allowed to come into the hospital for treatment versus monitoring symptoms at home or getting access to a lifesaving medication. Researchers have known for decades that darker skin tones could reduce a pulse oximeter's accuracy, but the COVID pandemic led to a significant increase in evidence and wider awareness of the implications of this bias.

In the letter, the coalition commends the FDA's implementation of safety communication about pulse oximeter accuracy and the convening of the Medical Devices Advisory Committee to further address the negative impacts of this device to patients of color. However, the FDA has yet to indicate clear warning labels or provide additional guidance to protect individuals from harm as pulse oximeters are currently sold over-the-counter and used in hospitals and clinics.

In the letter, the attorneys general request that the FDA take the following steps, including:

- Requiring manufacturers and vendors of pulse oximeters to include warning labels to all users about the device's effectiveness based on skin tones.
- Calling for inclusion of similar warnings in other medical devices that incorporate pulse oximeter readings, such as medical device software used for diagnosis or treatment of medical conditions.
- Issuing guidance to healthcare providers about the risks and reduced efficacy of pulse oximeters for patients of color.
- Implementing an expedited timeline for FDA to swiftly review the Medical Devices Advisory Committee's recommendations.

In filing the letter, Attorney General Kaul joins the attorneys general of Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and the District of Columbia.

A copy of the letter is available here.

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