HEARING BEFORE THE HOUSE ENERGY & COMMERCE HEALTH SUBCOMMITTEE

HEALTHIER AMERICA: LEGISLATIVE PROPOSALS TO IMPROVE PUBLIC HEALTH

TESTIMONY OF RENÉ QUASHIE
VICE PRESIDENT, DIGITAL HEALTH
CONSUMER TECHNOLOGY ASSOCIATION

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Introduction

Chair Griffith, Ranking Member DeGette and Members of the Committee, thank you for the opportunity to testify on legislative proposals to improve public health. Specifically, my testimony will focus on the *Digital Health Screeners Act of 2026* and the promise of health wearables.

The *Digital Health Screeners Act of 2026* addresses a real and growing gap. Health wearables have moved far beyond fitness tracking. They now help detect risk, guide behavior and support disease management. Policy has not kept pace. Congress has an opportunity to update the framework so patients can benefit from tools they already use while preserving strong safety guardrails. This bill is a smart step in that direction.

My name is René Quashie, and I serve as Vice President of Digital Health at the Consumer Technology Association (CTA), the largest tech trade association in North America. CTA represents more than 1200 companies from iconic global brands to early-stage startups – powering innovation across the U.S. economy and supporting more than 17 million American jobs. Eighty percent of CTA companies are small businesses and startups. We produce CES, the world's most powerful tech event, and lead national efforts on policy, market research, and standards development across emerging technologies.

CTA's Health Division includes a diverse array of companies advancing consumer-based, technology-enabled health solutions to improve health outcomes and reduce costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, and health systems. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and chronic disease management, and they are driving the next wave of American innovation in health.

Promise of Health Wearables

To understand the opportunity before Congress, it is useful to look at how far wearables have come. A decade ago, early devices focused primarily on step counting and basic activity tracking and only a quarter of Americans owned a wearable.[1] In 2016, CTA published its first health standard, *"Physical Activity Monitoring for Fitness Wearables: Step Counting,"* establishing a baseline for accuracy and performance in consumer devices. CTA is an American National Standards Institute (ANSI)-accredited standards development organization, and our standards work helps drive industry consensus on data practices, product development and performance criteria.[2] .

At the time, adoption was limited and functionality was narrow. Today, that landscape has changed dramatically. At CES 2026, attendees experienced AI-driven wearables offering personalized health insights – from smart glasses to smart rings to EEG earbuds. The sensor technology in wearables has advanced so that some features now offer clinical-grade information through U.S. Food & Drug Administration (FDA)-cleared functions. This gives consumers health data they once could access only in a clinical setting, and can support:

[1] https://rockhealth.com/insights/digital-health-consumer-adoption-2016/
[2] https://www.cta.tech/resources/?type=standard&topics=Digital+Health

- Earlier screening for disease;
- Better self-management of chronic conditions; and
- More informed conversations with clinicians.

One example is FDA-cleared obstructive sleep apnea (OSA) risk detection. OSA remains an incredibly underdiagnosed condition – according to the American Academy of Sleep Medicine, an estimated 80 percent of cases remain undiagnosed – and it can lead to serious consequences such as heart disease, stroke, diabetes and depression.[3] Undiagnosed cases of sleep apnea cost the system approximately $149.6 billion annually.[4] And this is just one example – CTA member companies are also developing wearable features like hypertension notifications, AFib alert, and stress management.

These tools will not replace clinicians. But they can extend reach, support prevention and help patients and providers act sooner. Now is the time to discuss how regulatory frameworks can evolve to responsibly support the expanding role of wearables in health care.

FDA General Wellness Guidelines

At CES 2026, U.S. Commissioner of Food and Drugs Dr. Marty Makary announced updates to how the FDA plans to regulate wearables and other wellness products. The updated *General Wellness: Policy for Low Risk Devices* states that FDA will now consider devices that collect physiological data as general wellness products as long as manufacturers do not use the data to make medical claims.[5] This updated guidance is an important change for three reasons:

1. It reflects how the line between "wellness" and "medical device" has blurred since Congress last addressed these tools in the *21st Century Cures Act*.
2. It recognizes that consumers now expect richer information from products they already wear and trust.
3. It maintains FDA's core role in safeguarding safety and effectiveness for devices that do make medical claims.

The *Digital Health Screeners Act of 2026* would codify this updated approach. That would:

- Provide clarity and certainty for developers;
- Encourage innovation in low-risk screening and coaching tools; and
- Help avoid case-by-case confusion over whether a device belongs in the wellness or medical category.

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[3] *New national indicator report details importance of prompt sleep apnea diagnosis and treatment*. American Academy of Sleep Medicine. April 2023.
[4] Ibid
[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

Additionally, building off the updated *General Wellness* guidelines, industry groups will play an important role in establishing frameworks and standards for wellness devices that do not require FDA pre-market approval are effective products for consumers. This is where CTA, as an ANSI-accredited SDO, plays a critical role in building this framework. CTA's newest standards working group, *Wearable Performance and Trust*, will define recommendations and best practices for demonstrating outcome-driven verification and validation methods across a variety of wearable technologies. The group will also evaluate where there are the greatest use case specific gaps that should be prioritized for additional standardization. We look forward to keeping the Committee updated on the working group's progress and outputs.

Additional Considerations

While the *Digital Health Screeners Act of 2026* and updated FDA guidance mark real progress, Congress should address several additional priorities:

1. *Health Data Privacy*

Many consumer-facing digital health manufacturers and deployers are not considered covered entities under the *Health Insurance Portability and Accountability Act* (HIPAA) and often are not subject to business associate agreements with a HIPAA covered entity. To help address this gap in health data privacy protections, CTA released *Guiding Principles for the Privacy of Personal Health Data*, a voluntary framework designed to help companies, especially those outside HIPAA's scope, implement responsible data practices.[6] However, both innovators and consumers need a comprehensive and preemptive federal data privacy bill that:

- Protects consumers' personal data, including health-related data;
- Promotes innovation and avoids rules that lock in outdated models;
- Prevents a patchwork of conflicting state laws; and
- Reduces incentives for frivolous lawsuits that do not improve privacy outcomes.

Such a law would give consumers clear, consistent protections and give innovators one predictable set of rules.

2. *Data Interoperability*

As more people use wearables and other personal health devices, we must ensure that the data they generate can flow securely into electronic health records (EHRs) when patients and providers want that connection.

Industry is already working on this. For example, CTA participates in the HL7 FHIR "Caliper" Accelerator**,** which aims to ensure delivery of high-quality, near real-time data from medical devices, including patient-facing tools, into EHRs. [7]

Congress can help by:

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[6] *Guiding Principles for the Privacy of Personal Health Data*. Consumer Technology Association. 2021.
[7] https://blog.hl7.org/hl7-launches-caliper-a-new-fhir-accelerator-advancing-real-time-medical-device-interoperability

- Supporting standards-based interoperability efforts;

- Continuing oversight of information blocking enforcement under the *21st Century Cures Act,* so business practices do not block lawful, patient-directed data sharing; and

- Encouraging alignment across agencies on how device and EHR standards fit together.

Interoperable data will increase the value of wearables for both patients and clinicians and reduce duplicate testing and administrative burden.

3. *Reimbursement*

Coverage drives adoption. CTA research shows that insurance coverage remains one of the most important factors influencing whether consumers adopt health technologies. Many payers, including Medicare, still treat wearables as optional tools rather than essential components of care. That view no longer reflects reality. As these technologies improve, payment policy should evolve so patients and providers can use them at scale. The Centers for Medicare & Medicaid Services (CMS) has begun to address this with the ACCESS model, which tests technology-enabled care approaches. Congress should:

- Monitor and build on models like ACCESS;

- Encourage clear, predictable coverage pathways for technology-enabled care; and

- Support payment rules that recognize when wearables and digital tools help avoid more costly care.

Reimbursement that reflects real-world use will help patients and providers adopt tools that improve outcomes and lower costs.

4. *Additional Regulatory Considerations*

While FDA's updated *General Wellness* guidance, as well as the TEMPO pilot – announced in conjunction with CMS' ACCESS model – are important first steps in helping streamline regulatory approval processes for digital health tools like wearables, developers face a gap between low-risk general wellness products, and Class II regulated medical devices and above.

Some emerging functions fall between these categories. For example, a wearable might use physiological data to alert a consumer that they may be at risk and should seek follow-up with a clinician, without diagnosing disease.

Such tools are not as low-risk as simple wellness features, but they may not warrant the same pathway as higher-risk medical devices. Congress should explore tailored approval or authorization pathways for these intermediate-risk functions. Building on the precedent in the *21st Century Cures Act*, Congress should continue to refine and update regulatory pathways to better align with innovative health devices. A more nuanced framework will support safe, responsible use of advanced screening features and avoid forcing all such tools into one of two extremes.

Conclusion

Health wearables and consumer-facing digital health technologies no longer sit at the margins. They are widely used, increasingly sophisticated and uniquely positioned to expand access to preventive and personalized care. CTA research and CES innovation trends both point to continued rapid growth in this space. Policy frameworks built for an earlier era no longer fit.

The *Digital Health Screeners Act of 2026* is an important step forward. Congress should codify updated regulatory approaches, support interoperability and reimbursement and advance a national privacy framework. These actions will help patients, strengthen innovation and keep the United States at the forefront of digital health.

CTA and its members stand ready to serve as a resource – advancing standards, promoting interoperability and working collaboratively with regulators to ensure that technology continues to improve health outcomes, reduce costs and strengthen the health of all Americans.