

News and Perspectives

From Measurement to Meaning: The Next Decade of the Quantified Self

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Abstract

Consumers are increasingly seeking more interpretation and more guidance from their wearables, making it necessary for the wearables industry to address the gap between data and interpretation—between wellness and medical device—to stay competitive. In this *News and Perspectives* article, JMIR Correspondent Blythe Karow reports on how advances in AI, regulation, and wearable technology are shaping the future of the quantified self.

Key Takeaways:

- The quantified self movement has evolved. We no longer just want data, we want meaningful interpretation of that data.
- Meaningful interpretation is where companies step into regulated medical device territory, so many of them have been dragging their heels.
- It's now time to see them step into the world of regulated medical devices.

Blythe Karow is a MedTech strategist with over 25 years of experience in the wearables space. She is also the founder of The Karow Advisory Group and [The Device Files](#) Substack. This op-ed kicks off her 3-part series on the quantified self and how the wearables space is evolving.

Have you heard of the term “the quantified self”? It describes the practice of understanding ourselves through continuous or periodic self-measurement. We’ve all been doing it for a while now, even if we weren’t paying attention. Your phone will let you know how many steps it thinks you’ve taken today, or maybe you own a wearable like an Apple Watch,

Fitbit, or Oura ring in order to measure even more biosignals. What began decades ago as a niche pursuit has become an ordinary health behavior for a [large share of the US population](#) and, more recently, an [instrument of national health policy](#).

The movement rests on the [premise](#) that measurement drives improvement. Give people visibility into their own physiology and they will probably act on it. For a long time, that was enough to carry the industry forward. The novelty of being able to count your steps and aim for an exercise goal was enough to fuel the industry for almost two decades.

Did You Know?

In 1965, Japanese clockmaker Yamasa released a [pedometer](#) to harness the fitness enthusiasm following the 1964 Tokyo Olympics. But what do you do with a pedometer? Why do we care about counting steps? Yamasa solved that problem by giving customers a target: they named the device the Manpokei, which translates to “10,000-step meter.”

To this day, many people aim to get their 10,000 steps a day, assuming it rests on something clinical. But no, the target was chosen because the Japanese character for 10,000, 万, resembles a walking person, and because a round number is memorable and sold well.

The quantified self movement began less with meaning and more with amusement and good marketing. Until recently, we have been very good at counting things and much less clear on what the counting was for.

The Interpretation Gap

This early promise of consumer wearables does work, to a certain extent. The trick is that people have to know how to use the health data they get from their wearables to course correct.

[Early products](#) focused on the “low-hanging fruit,” where there were options for both easy data collection and a pretty obvious intuitive connection a layperson could make to behavior change. So, of course, we aimed at weight loss. Next came sleep quality, answering the question, “Am I getting decent sleep?”

The problem is that we've moved past that. Any person who has worn a device for months or years will tell you that they don't need to keep measuring their sleep. They get it—it's not great. So, what do they do about it?

I can speak to this directly. I started using a wearable in part because I suspected, entering my mid-forties, that my sleep quality had degraded and that it was dulling my cognitive processing during the day. The device confirmed the suspicion with impressive precision. I do not get enough deep sleep. But, now that we've established this fact, the device has stopped being useful. It does not tell me how to fix it or even just suggest what type of doctor or next step might be able to perform the further diagnostics necessary.

The data is both too much and no longer enough. We live in a world where we are inundated with data all the time. It's exhausting. We don't only want data anymore, we want someone or something to help us crunch that data and figure out what it all means and what to do about it.

That gap, between what we measure and what it means, is where the wearables industry now finds itself stuck—and it's going to be the defining problem of the next decade for the entire industry built around the quantified self movement.

Why the Gap Exists

Many companies have, in fact, avoided closing that gap because it is quite complicated.

Years ago, the complication was in the actual interpretation of the data, but [AI and machine learning algorithms](#) are helping to solve this. Now the hurdle is government regulation. In order to provide the interpretation that customers want, wearable companies need to move into the world of regulated medical devices. That layer of interpretation and guidance turns a consumer wearable into a regulated Software as a Medical Device (SaMD) app.

I write about this intersection often, and there have been a lot of [interesting developments](#) over the last year. One of the most impactful changes recently was the US Food and Drug Administration (FDA) Wellness Guidance released in [January 2026](#), which more clearly defined where the line is between consumer tech and medical device. We now have clear instructions on when a product crosses the line: detecting your heart rate and showing it to you is comfortably inside the wellness lane. Telling you what an abnormal pattern means for your health, and what to do about it, opens up the world of headache that is operating as a medical device.

The Cost

Here's the issue: if a new feature makes your product a medical device, you now need to manufacture to new quality specifications, have further safety and effectiveness testing, and set up ways to monitor and gather any adverse events,

and it all has to be bundled and submitted to the FDA. You then need to wait an average of [155 to 341 days](#), depending on the pathway, to sell that new interface tweak to your end user.

So, naturally, companies hedge. They surround genuinely clinical-grade signals with wellness language, disclaimers, and the familiar refrain that a product is “not intended to diagnose, treat, cure, or prevent any disease.” They deliberately decline to close the gap.

The Clock Has Run Out

For years, medical device and wellness wearables have been slowly but surely converging—biosensing has become more sophisticated and precise, while the machine learning algorithms that can interpret its data have become smarter and more accurate.

But the time is soon approaching when people will give up their wearables if companies stay only in the wellness lane and do not continue to evolve in their offerings. The companies that intend to serve that demand, and to make good on the health claims increasingly attached to their products, will have to cross into medical-device territory, or at least operate to that standard.

And they should want to. Once they do, the opportunity to unlock future value is vast.

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Once wearable platforms do begin to interpret in earnest, holding continuous physiological data, running it through AI, and routing users toward specific care, they stop being accessories and start [becoming the entry point](#) to the health care system itself. They begin to own the first conversation about a person's health, influencing which specialist a user sees and which treatments they consider, a role primary care physicians have traditionally held.

In other words: the interpretation gap is not a dead end but the beginning of a meaningful shift in the future of the quantified self.

Keywords: wearable electronic devices; self-management; personal health records; medical devices; equipment and supplies; US Food and Drug Administration; quantified self

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