Wearables, the FDA and patient advice: What physicians should know

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The Food and Drug Administration (FDA) has basic rules for regulating wearable devices and other digital health tools, but those rules may change as rapid innovation continues and the agency creates new pathways to ensure the safety and efficacy of new consumer-facing products. AMA experts outlined this and other need-to-know facts for physicians counseling patients who are increasingly looking to the wearable as a health tool.

Attorney Shannon Curtis, AMA assistant director for federal affairs, said during a recent education session that there are three important things for physicians to keep in mind when counseling patients about wearables or mobile health (mHealth) apps.

Be aware of an app or device's regulatory status before recommending it to patients. "You want to be mindful of what's being approved and what's not, and be aware that, a year from now, we can have a very different set of rules," said Curtis, pictured here.

Alert patients to data privacy issues. "Help patients understand that their data might not just stay with their wearable or their physicians, and they need to know where their data is going. These apps and wearables are big data mines for companies that make them."

Help patients understand the information they receive. "A patient may tell you, 'My watch told me I'm having a heart attack, what do I do?'" Curtis said. Also, physicians should be ready to answer the questions and for the volume of questions that will come with the new technology—especially direct-to-consumer genetic tests.

On FDA regulation, the rule—for now, at least—is clear: Any device that is "intended for use in the diagnosis of disease of other conditions, or in the cure, mitigation, treatment, or prevention of disease" requires FDA approval, Curtis said. This goes for devices meant for humans and animals, as the FDA regulates both.

The scrutiny a new product receives is stratified by three levels of risk with products such as syringes and gauze at the first level and devices such as pacemakers in the third.

Wearable devices—mostly in the form of watches, bracelets, vests or glasses—are not regulated if they are intended for general wellness uses, which include maintaining or encouraging a general state of health or activity, or reducing the risk or impact of chronic disease. If a device that performs these same tasks is implanted rather than worn, then the FDA will regulate it, Curtis said.

mHealth apps are regulatorily treated in a similar fashion. Apps that purport to do the following get a light touch:

- Help users self-manage diseases or conditions without offering specific treatment suggestions.
- Provide information related to conditions and treatment.
- Organize and track patient health information.
- Automate physician tasks.

If, however, an app is making specific recommendations or a diagnosis, the FDA is going to take a look at it, Curtis said.

"It's probably going to change a lot more in the not-so-distant future, just because the innovation in this space is so quick," she added. "It's a new area for the FDA and it requires a lot of staff with very new expertise. Innovation is coming fast and furious."

There already has been some splintering to this approach. Last September, the FDA approved functions on the Apple Watch 4 that produce an electrocardiogram to detect the presence of atrial fibrillation (AF) and to analyze the wearer's pulse rate to identify irregular heart rhythms suggestive of AF and notify the user.

"This does not mean Apple Watch as a whole is FDA approved," Curtis explained. "It's only those functions. The FDA is not looking at anything else the Apple Watch does."

"Wild, wild West"

AMA research has found that physician enthusiasm for technology "is directly tied to a solution's ability to help them take better care of patients," said Meg Barron, AMA digital health strategy vice president. Curtis and Barron co-presented the education session at the 2019 AMA Annual Meeting.

"It can feel like the wild, wild West right now," Barron said. But one of the ways the AMA is helping is by leading Xcertia, a multistakeholder organization developing industry-vetted guidelines focused on improving the quality, safety and effectiveness of mHealth apps' ability to improve care.

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