Unsettled Liability Issues for “Prediagnostic” Wearables and Health-Related Products

Many people currently use various wearable or other health-related technologies known as general wellness products—sometimes without (adequate) regulation or enforcement by Congress and the Food and Drug Administration (FDA)—that disclaim diagnostic functions but may nevertheless be used by patients and physicians for diagnostic purposes. These products (referred to in this Viewpoint as “prediagnostics”) include well-known wearables such as the Fitbit, but also less-familiar technologies. Hyfe is a smartphone application that ambiently tracks user coughing patterns over time and analyzes cough frequency and intensity. The SeizAlarm smartphone application tracks movements and heart rate to detect seizurere alike activity and alert emergency contacts. Lumen is a stand-alone product that uses breath to measure and track metabolism. Patients may use these products and applications for the initial stages of assessing their health; sometimes they might rely on them to identify a disease or condition. Patients may also provide their data to a physician to incorporate into an evaluation or a treatment. As these products proliferate, physicians could even recommend some of these prediagnostics and health-related technologies to their patients.

Although these products may help many patients and physicians improve care, they occupy a legal gray area. Who is responsible if a product fails to detect a seizure? Who is liable if a user or physician relies on a product to detect asthmatic events but it fails to do so? Physicians may be concerned that advising some patients to use these products and not advising others to do so could subject them to malpractice claims. Because product liability for these devices is somewhat unsettled, patients and their lawyers may turn to medical malpractice theories of litigation in hopes of recovering damages. Although some of these issues have not yet been litigated, liability claims for wearable and other health-related consumer products is likely to arise more often as technology improves and proliferates. This Viewpoint examines the murky legal treatment of these products for patients, physicians, and manufacturers and recommends solutions.

Ability to Sue
Unbeknownst to many patients (or even physicians), most of the prediagnostic products available to consumers are not regulated by the FDA. The FDA has authority to regulate “devices,” but by statutory definition (21 USC §321[h][1][B]) these are products “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.” This means that manufacturers can advertise prediagnostics without FDA regulation as long as their “intended use” falls outside that definition’s scope. It also means that prediagnostic products will generally fall outside the device regulatory pathways unless the manufacturer objectively intends the product to be used in the “diagnosis of disease or other conditions”—something that can be inferred from the functionality of the device as well as the manufacturer’s marketing of it.

This also has an important implication for liability. When the FDA evaluates a device through the most stringent premarket approval or even a less stringent 510(k) clearance, lawsuits claiming the product is defective under state law may be preempted (ie, barred by federal law). But because the same federal law does not apply to prediagnostic technologies that have not undergone FDA review, individuals harmed by these products can attempt to sue manufacturers under state law. But it also means that if the FDA exercises jurisdiction over a manufacturer of a product that has not undergone FDA review but could be classified as a device, the manufacturer could face liability under both state tort and federal law. To date, the FDA has determined that some products marked as prediagnostics are actually devices that must undergo FDA review, such as the Owlet Dream Sock, designed to monitor blood oxygen saturation and pulse rate in infants, but there has been little tort-based litigation thus far.

Liability Under Tort and Contract Law
Under US tort law, manufacturers are liable for injuries caused by defective products. Products can be defective because of defects in their manufacture, design, or marketing (ie, failure to provide adequate instructions on how to safely use the device and any reasonable warnings of the risk of doing so). To win a case, an injured party must show that they used the defective product that injured them in a manner that is reasonably foreseeable or, in some jurisdictions, in a manner that a reasonable consumer would expect. Under contract law, a manufacturer is liable if the product caused the injury...
during an intended use, one to which the product is ordinarily put or one to which the producer knows it will be put.4

Courts have not resolved these issues for prediagnostics and health-related technologies. SeizAlarm, for example, claims to be the “#1 rated seizure detection mobile app” but also notes on its website that “SeizAlarm does not convert your iPhone or Apple Watch into a medical device and is not intended to be used in the diagnosis, monitoring, prevention, or treatment of disease.”5 If a person uses this product thinking it will provide diagnostic-type information about when a user is likely to experience a seizure and is injured when it fails to detect one, use may be foreseeable, the person’s expectations may be reasonable, or the use was an intended use. Although relevant, these kinds of disclaimers do not by themselves insulate companies from liability or FDA enforcement. For example, state tort law may look to how consumers actually use the product to determine liability.

Physicians also may encounter unresolved (liability) questions when a patient brings them information from a prediagnostic product, particularly when the device or application uses artificial intelligence or other opaque technology. It will be difficult for most physicians to interpret the meaning of a particular cough pattern, biodata, or a (seizurelike) movement pattern recorded by a prediagnostic product without knowing more about the methods and reliability of how the product collects data or transforms those data into outputs.6 This concern is most pronounced for physicians in the acute care setting but also exists for any physician using the information.

Concerns about data quality also will be raised in litigation by manufacturers and physicians as a defense to tort and contract claims, often focusing on the role of the user in generating data. For example, Hyle requires users to initiate a session and then ambiently collects data whenever the application is running, which may include environments ill suited for accurate data collection. Manufacturers may argue that the user was at fault because they incorrectly collected or inputted data. When physicians are involved in interpreting information from prediagnostic products, manufacturers may claim that it was the physician who made a mistake. The physician, however, may argue that the prediagnostic product was not reliable enough to be used in treatment determinations, creating a liability morass from which the plaintiff may emerge without compensation.

Potential Solutions

There are several ways to address these issues, each with limitations. For instance, states could make a series of legislative changes. Legislatures could carve out safe harbors for physicians whose patients provide them with data from prediagnostic products, just as some states have limited liability for emergency medical technicians, or even risks presented by certain activities operated by important state industries (such as skiing in Utah).7,8 However, it may be difficult to crisply define “prediagnostics” as a statutory category.

A related but perhaps more feasible solution would be for states to adopt language specifying that, for liability purposes, physicians who receive data from a prediagnostic product should treat that information like any other patient self-reported symptom in the scope of their diagnostic work. State legislatures could also adopt a presumption against physician liability when relying on a prediagnostic wearable or other health-related product or a presumption against allowing the data from the prediagnostic product into evidence in cases alleging that physicians inappropriately relied on that data. Such a presumption could be overcome by providing evidence showing the product is reliable when used consistently with the way the injured person used it. However, it may be difficult for plaintiffs to overcome that presumption if the information needed is tightly controlled by the product manufacturer. More generally, it may be difficult to get state legislatures to act in this area.

Beyond legislative intervention, because courts often look to custom as evidence of the standard of care—and sometimes as determinative of it for physicians—best practices developed by physicians could help shape liability determinations when they inevitably arise in the courts. For example, courts could incorporate statements of best practices on the use of prediagnostic information developed by physician organizations to help establish the appropriate legal standard governing physician conduct.

Additionally, public regulators such as the Federal Trade Commission and states’ attorneys general could vigorously enforce existing laws against manufacturers of prediagnostic products that advertise in a misleading manner or otherwise violate state unfair and deceptive trade practices laws. Although potentially useful, this approach may be limited by the First Amendment’s protection of advertising as “commercial speech.”9,10 Also, a market-based approach, such as Consumer Reports, is also possible. However, prediagnostic manufacturers may not want such third-party evaluation and might also be concerned it would invite closer scrutiny from regulators.

Prediagnostic products and other health-related applications are bringing exciting technologies directly to consumers and mesh well with the goal of meeting patients “where they live,” sometimes literally. But these products also present a context that is rife with legal uncertainty. For these products to achieve their full potential, the legal system and physician leaders must start filling some of these gaps related to the use of these products, especially when it comes to liability.

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