

Who pays for personalized medicine?

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While researchers are busy identifying new biomarkers to detect disease and tailor treatments to individual needs, legal battles have been waged all the way up to the Supreme Court, trying to sort out whether a private company can own the rights to a particular biomarker.

In a new Perspective piece published today in the New England Journal of Medicine, Jason Karlawish, MD, professor of Medicine, Medical Ethics and Health Policy in the Perelman School of Medicine at the University of Pennsylvania, and co-author Aaron S. Kesselheim, MD, JD, MPH, from Brigham and Women's Hospital and Harvard Medical School, delve into a series of high profile court cases testing the limits of patent protection.

In the months since a US Supreme Court ruling unanimously "rendered invalid two patents covering a method for determining proper drug dosage," as Nature reports, discussions have swirled about how to pay for <u>personalized medicine</u>. The NEJM co-authors report that "a patentable process now needs to involve an inventive and novel application of a law of nature beyond well-understood, routine, conventional activity, previously engaged in by those in the field."

Without patents protecting such medical discoveries, some have argued that there is no way to recoup the costs of biomarker innovation. To that end, Supreme Court Justice Breyer suggested whether special market-exclusivity protection was warranted.

Instead, the authors suggest that enhanced public funding, public-private



partnerships, and open-source consortia may improve biomarker discovery and development, more than a private model. According to the NEJM piece, "the Supreme Court's move to free the fundamental processes of medical diagnosis from private ownership...could ultimately enhance the public health."

As biomarkers become more and more prevalent -- helping diagnose diseases, and pairing with treatments targeted to individual needs -- there will need to be solutions to balance the needs of ensuring access to this useful information and paying for personalized medicine.

Provided by University of Pennsylvania School of Medicine

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