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Ethicists explore civil lawsuits as a tool to push for regulation of unproven, direct-to-consumer stem cell therapies

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In the realm of direct-to-consumer marketing for unproven therapies, a staggeringly large number of stem cell interventions have emerged in the United States. A new report from Baylor College of Medicine and Mayo Clinic demonstrates that individual and class action lawsuits from individuals injured by stem cell treatments can be an effective new tool in fighting to crack down on these unproven therapies. The study appears in *npj Regenerative Medicine*.

"Many of the clinics that offer direct-to-consumer stem cell therapies are operating outside of FDA regulations and with no scientific evidence of efficacy, so it has become a patient protection issue," said Claire Horner, assistant professor in the Center for Medical Ethics and Health Policy at Baylor and first author on the paper.

The research team identified nine lawsuits in which patients sued clinics that sold them therapies that either did not work or caused harm. Horner and colleagues drew a comparison between these lawsuits and previous public health litigation, where class action and individual cases generated media attention and encouraged other parties who were harmed to file suit.

"The selling of stem cell therapies has become a significant global public health concern as many patients have been physically harmed, paid large out-of-pocket payments and suffered emotional distress from a botched

stem cell treatment," said Dr. Zubin Master, corresponding author and associate consultant in the Biomedical Ethics Research Program at Mayo Clinic. "Yet it seems that many in the general public believe that clinics providing for-profit stem cell therapies provide innovative medical care or cutting-edge experimental treatment. This is an inaccurate portrayal of the current for-profit stem cell marketplace."

Firstly, Master explains, providers should not be offering an intervention as innovative care or experimental treatment if there is no scientific rationale to do so. Moreover, when patients are offered a stem cell intervention, they need to be informed of the risks, benefits and alternatives so they can make an informed decision on whether they should undertake the procedure. More often than not, for-profit clinics downplay risks, overemphasize benefits and use patient testimonials as demonstration of treatment efficacy.

"While many of these direct-to-consumer therapies are not evidence-based treatments, are not undergoing a peer review process and can be dangerous, this paper isn't focused on the harm these therapies are causing. It's about evaluating litigation as a viable tool to raise awareness and patient advocacy, and increase patient protection," Horner said.

Most importantly, using civil lawsuits as a tool to fight these therapies shows people who have been injured that they are not alone. This approach also may help set legal precedent, reshape the media narrative, stress the need for adequate safety and efficacy standards and encourage authorities to focus their attention on policy reform and enforcement.

"Our analysis demonstrates that this can be a legitimate avenue to encourage stronger FDA enforcement to end unproven, direct-to-consumer stem cell therapies," Horner added.

More information: Claire Horner et al. Can civil lawsuits stem the

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tide of direct-to-consumer marketing of unproven stem cell interventions, *npj Regenerative Medicine* (2018). DOI: 10.1038/s41536-018-0043-6

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