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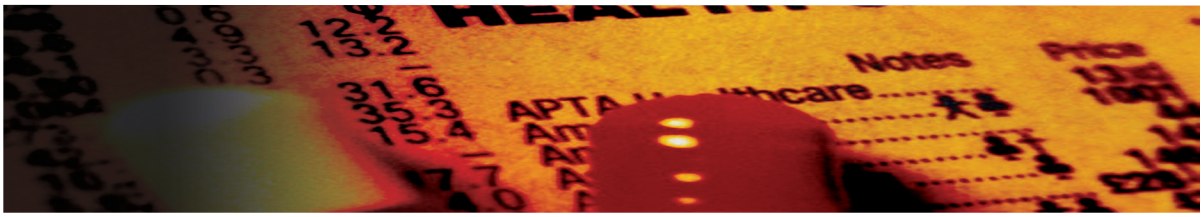
Issue 1



MARCH 2015

IN THIS ISSUE

The articles "Professional Athletes and Unproven Stem Cell Treatments" and "U.S. National Football League Athletes Seeking Unproven Stem Cell Treatments," co-authored by Kirstin R.W. Matthews, Ph.D., and Maude Cuchiara, Ph.D., appeared in *Texas CEO Magazine* (November 2014) and *Stem Cells and Development* (December 2014). Matthews is a fellow in science and technology policy at Rice University's Baker Institute for Public Policy. Cuchiara is a Baker Institute scholar for science and technology policy.

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HEALTH POLICY research

Rice University's Baker Institute for Public Policy-Baylor College of Medicine
Joint Program in Health Policy Research

Should ads featuring athletes promoting unproven stem cell treatments at for-profit clinics be subject to oversight?

"Yes," says Kirstin Matthews, Ph.D., co-author of two recent articles on the subject. "Athletes have an outsize influence on the promotion of products. When they receive these types of therapies, the public regards them as both safe and effective."

In recent years, many prominent U.S. athletes have turned to stem cell treatments for orthopedic injuries. The athletes have publicly credited stem cells for their speedy recovery and swift return to the playing field, though most treatments have not undergone rigorous clinical trials to determine their safety and effectiveness. Nevertheless, clinics offering stem cell treatments routinely use professional athletes as spokespersons and imply clinical benefits despite the absence of robust data to support the claims.

High-profile athletes who have received stem treatments for injuries include U.S. National Football League stars Peyton Manning and Terrell Owens, as well as Major League Baseball pitcher Bartolo Colón. The treatments are proprietary and vary slightly from clinic to clinic. In general, tissue (typically from fat or bone marrow) is first extracted from the patient. Cells are then isolated and injected back into the patient systemically or at the injury or disease site. These therapies should be subject to clinical trials or regulated by the Food and Drug Administration (FDA), but are not because they are considered same-day procedures and the cells are "minimally manipulated."

More complex treatments are now prohibited by the FDA — the result of a federal court case, affirmed in 2014, involving two clinics, Regenexx in Colorado and CellTex in Texas. The clinics were conducting therapies where patients were injected with cells that had been grown in the lab for several days after isolation prior to treatment. The FDA determined that these treatments require oversight because the culture of cells in the lab went beyond "minimal manipulation." The courts agreed, and CellTex and Regenexx moved these specific treatments to Mexico and the Cayman Islands.

Even with this setback, stem cell clinics continue to promote their therapies online. However, most clinic websites use patient testimonials rather than scientific data to support their therapeutic claims. The data, if included at all, is often buried in the "frequently asked questions" sections of the websites, and some of the cited work is research conducted by the clinic itself that was not peer-reviewed. In some cases where for-profit clinics use professional athletes to endorse their treatments online, it is unclear if the athlete ever received the therapy. The public should be wary of unsupported marketing claims and the endorsements of celebrities they may trust.

Stem cells hold great promise for future cures and therapies. However, clinics promoting unverified stem cell procedures risk undermining future stem cell therapies, especially if patients experience negative results. A traditional clinical trial setting could help to optimize and validate these therapies. In the future, regulators should oversee the clinics' promotional campaigns to ensure the validity of the claims, as well as the safety of consumers.

Texas CEO. Nov. 29, 2014.
Stem Cells Devel. 2014: 23: Sup 1

HEALTH POLICY research presents a summary of findings on current health policy issues. It is provided by Vivian Ho, Ph.D., James A. Baker III Institute Chair in Health Economics and Director of the Health Policy Forum at Rice University's Baker Institute, in collaboration with Laura Petersen, M.D., M.P.H., chief of the Section of Health Services Research in the Department of Medicine at Baylor College of Medicine.

This publication aims to make research results accessible to regional and national health policymakers. The views expressed herein are those of the study authors and do not necessarily represent those of the Baker Institute or of Baylor College of Medicine.

The Baker Institute and Baylor College of Medicine's Section of Health Services Research work with scholars from across Rice University and Baylor College of Medicine to address issues of health care — access, financing, organization, delivery and outcomes. Special emphasis is given to issues of health care quality and cost.

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