



STEM CELL INDUSTRY
2007
FALL
UPDATE

By

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3rd Annual
STEM CELL
S U M M I T
New York • February 26, 2008

The Most Comprehensive Stem Cell Meeting is in New York on February 26.

The pace of development in this family of technologies we loosely call “Stem Cells” is accelerating. More labs, more scientists, more clinical researchers, more physicians, and more patients are using, studying, and reporting on the therapeutic effects of stem cells than ever before.

The 3rd Annual Stem Cell Summit promises to be the largest yet with **over 50 of the world’s leading stem cell companies, 3 scientific panels to review 2007 publications** and a **panel of patients who’ve recently received stem cell therapies.**

As always, the Stem Cell Summit is where to go to receive the most comprehensive overview of the stem cell industry. No company, physician or investor in any of the following disciplines can afford to miss the 3rd Annual Stem Cell Summit:

Cardiovascular
Immunology
Musculoskeletal
Neuroscience
Oncology
Urology

REGISTER AT
www.stemcellsummit.com

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Introduction

Twenty-five years of watching the birth, struggle, early adoption, and eventual widespread use of medical technologies has left me believing as much in chaos theory as in the best-laid plans of entrepreneurs and scientists.

When the subject is biology, humans in pain, money, ego and the market bending influences of the FDA, no path is straight or predictable. In the case of stem cells, two other factors are in play – politics and a powerful, new and partially understood biological mechanism of action.

The rules of the stem cell game are new. Even the simple and reliable rule of scientific method, which still operates and works, is struggling against the reality that most hypothesis offered up for testing remain rooted in old ways of thinking. What scientists think they know, they find that they do not. Linear thinking is as useful in the world of the stem cell as gravity in Alice's Wonderland.

Although some scientists say we are decades from commercializing stem cells, living, breathing people—some who would have otherwise died—are being treated with stem cells in government-licensed clinics in Germany, military hospitals in China, or in clinical studies throughout the United States. These people seem to be popping out of the woodwork. They are Parkinson's patients whose tremors have reportedly stopped. They are heart patients who have traded in their \$85,000 pacemakers for \$600 autologous stem cell transplants and are back at work. They are spine trauma victims whose neural pathways seem to be healing. And they are talking to anyone who will listen—including the news media and television viewers everywhere.

There are wars between the embryonic stem cell adherents and the adult stem cell adherents, which strike us as stunningly irrelevant in the face of the revolution unfolding.

I've maintained for the past couple of years that the pace of development of this family of technologies we loosely call "Stem Cells" is accelerating. More labs, more scientists, more clinical researchers, more physicians, and more patients are using, studying, and reporting on the therapeutic effects of stem cells than ever before.

The stem cell train has left the station. Patients are asking for and receiving stem cell treatments—in FDA-approved studies and in unapproved protocols outside their respective countries.

Commercially available stem cell therapies (all allogenic at the moment) notched sales of \$10 million in the United States in the first half of 2007. The march toward FDA approval of the first phase III stem cell drug continues, and that eventuality can be counted in months, not years.

Other FDA-approved products that render stem cell therapies legal and demonstrably useful are likewise months from market.

And the basic science that underlies sourcing, understanding, deploying and, yes, manipulating stem cells took several important leaps forward in the past 9 months alone.



Thus far, 2007 may have been as eventful as any full year preceding it. We just finished a review of the first nine months of 2007, and out of hundreds of key events, we selected 80 announcements that had significant bearing on the development of this nascent industry.

Compiling all of this information reinforces our view that we are witnessing the birth of a major new medical industry. In terms of scope and impact, the stem cell industry may be the largest of this or the next generation.

Like a river seeking its own path, stem cell commercialization is creating its own channel through the medical community. In this new environment, charlatans are emerging, it is true. But it is also true, that legitimate treatments are being performed outside the bounds of the FDA or European regulatory framework and are producing salutatory results for some of the most desperate patients.

This trickle of patients, we suspect, will grow significantly. Autologous stem cell treatment is affordable (\$25,000 to \$50,000—the price of a new car) and its impact—not cures, but noticeable, even life-altering changes—is substantial enough that others will find the courage to journey to Germany, China, or India for medicine’s version of the “hail Mary” pass.

Physicians and scientists can smell the change coming. The number of physicians who’ve now employed stem cells is reaching the hundreds, and these individuals know, they really know, that stem cells represent a new future—not so much for what these cells can regenerate into but rather for the ways in which they change the organism itself.

Perhaps the most interesting and significant event of the first three quarters of 2007 was the growing realization that stem cells may be the single most effective tool medicine has encountered to combat autoimmune disease. In that massive arena of maladies, stem cells may be the new penicillin, the new sulfa drug.