

## A PARADIGM SHIFT

Stem cell research and cloning are not only issues of morality and religion, they represent a huge economic power base within the business and scientific community. Technology can be of true benefit to humankind but it is also a vehicle for enormous profit that brings the power brokers, with amoral attitudes, to reap economic and power gains regardless of what may or may not be the right thing to do. Important science is often forsaken if it does not comply with the socio-political economic agenda of the power structure. Science that represents a paradigm shift that is not in compliance or suggests a change that causes economic and political shifts is sure to cause intense efforts to suppress it.

Such is the case of Thomas Ronald Theodore, M.D. who is currently incarcerated in a federal prison, for what many believe to be a discovery of a true paradigm shift in cell culture technology that has been patented by the U.S. government and several other countries. Dr. Theodore discovered that a commonly used buffer in many cell cultures, which has been used for years, in fact, was an active compound that has now been patented as a biological response modifier (BRM). The compound (HEPES) and its related compounds called zwitterions have demonstrated significant effects on many cell systems in the body and appear to work alone and in synergism with many existing therapies, increasing their efficacy. It is of great importance that the zwitterions appear to have the ability to stimulate the production of stem cells and cause the adult body to produce stem cells and other blood cells in the same way they are made embryonically. The effects of HEPES on the various organ systems of the body and on diseases such as cancer and damaged organs are significant. Stem cells, which are often grown in HEPES, are used to help fight disease and repair damaged tissue. The paradigm came when it was discovered that the HEPES buffer which the stem cells were grown in, in fact, could cause the same effects. Current medical literature is already starting to validate the effects. Whether HEPES causes the body's own cells to start the repair process or the damaged or diseased cells respond in some way to the zwitterions effects is still not clear. Also it should be noted that much of the past research data involving cell cultures was performed with HEPES in culture. The concentration of HEPES is also apparently important.

The FDA was notified of the biological response modifier effects of HEPES and the U.S. patents that had been issued. As HEPES is used as a "buffer" in some medicines and in cell culture processes, the FDA should have been immediately concerned and started a review. Walter Reed Army Research Center had notified Dr. Theodore that they were starting to evaluate the effects that were reported. International medical literature was and is still reporting that the effects are real. Then one day all communication stopped with Walter Reed Army Research Center.

Several months later, Dr. Theodore was indicted for mail fraud and FDA violations related to a company that he was a consultant to five years previously. The company was using gross cell culture supernatants to treat cancer and was violating FDA regulations in shipping and manufacturing. The work of the company was actually promising. A dispute with the FDA and the justice department was eventually quieted when a U.S. Congressional House Commerce Subcommittee and the FDA agreed to allow shipments of the product despite the violations because of the promise of the cell cultures based on early results. The company apparently closed because of lack of funding. Then five years later, just several months after the FDA was notified of the discovery of HEPES being a true biological response modifier, the indictment came. Neither the company, its directors, or its officers were charged with a felony. Only Dr. Theodore was so charged. The Chairman and CEO pled to three FDA misdemeanors and received a year's probation. Dr. Theodore, the consultant, was charged with nine felonies. He was sent to trial, against his and his lawyer's objection, with an elderly ill attorney who had never tried a case in federal court. The court would not let the government FDA investigators testify. The FDA administrators, who were subpoenaed, failed to respond to the subpoena. In fact, no witnesses responded to federal subpoena. Dr. Theodore was sentenced to ten years in prison and ordered to pay \$1.6 million in restitution. The FDA now wants to debar him from doing research. Also, his sentence was five years in excess of the statutory maximum allowed by law. He has lost his home and been declared indigent by the court. His court appointed appeals lawyer apparently has little interest in his case.

It is clear that the powers that be will stop at nothing to accomplish their goals. Dr. Theodore's work is too big a paradigm shift. For sure, adult stem cells can likely be made to act as embryonically derived cells. There is a reasonable chance that embryo derived stem cell lines can be avoided. However that would mean no business for many biotech companies or an expensive shift in costs and resources.

**Sometimes you can be too right.** That's what appears to have happened. If President Bush means what he says about avoiding embryo research, he should have someone look into the plight of one who opposed the establishment totally inadvertently. Hopefully, Senator Brownback and his committee reviewing stem cell research, will do the same.

Dr. Thomas R. Theodore, M.D.