



April 20, 2007

Cell Therapeutics to Pay \$10.5 Million to Settle Allegations of Illegal Sales and Marketing Activities

On April 17, 2007, Cell Therapeutics, Inc. (“CTI” or “the Company”), announced it had agreed to pay \$10.5 million to the United States to settle civil claims concerning the marketing, promotion, and sale of Trisenox®. The settlement stems from a *qui tam* suit filed by a former employee who alleged that the Company improperly promoted the drug for off-label uses. Under the settlement with the U.S. Department of Justice (DOJ) and the Office of the Inspector General, U.S. Department of Health and Human Services (HHS-OIG), the company denied that it engaged in wrongdoing.

General Alleged Misconduct

The Relator’s complaint alleged that CTI knowingly and unlawfully promoted Trisenox for off-label uses and offered improper inducements to physicians to prescribe the drug. The conduct covered by the settlement occurred between September 2000 (when Trisenox was first approved by the U.S. Food and Drug Administration) and June 2005. According to the government, the company’s improper conduct included the following:

- **Off-Label Promotion:** Trisenox was promoted for the treatment of Acute Myelocytic Leukemia, Chronic Lymphocytic Leukemia, Chronic Myeloid Leukemia, Liver Cancer, Multiple Myeloma, and Myelodysplastic Syndromes when it had only been approved for refractory or relapsed Acute Promyelocytic Leukemia. Sales representatives led doctors and Medicare intermediaries to believe that Trisenox was medically accepted for these off-label indications and thus eligible for Medicare reimbursement. This includes marketing to physicians who rarely, if ever, treated APL patients.
- **Anti-Kickback Statue:** Both off-label promotion and unlawful inducements, including allegations that the company provided doctors and others with food, gifts, grants, and other items of value to induce them to prescribe the company’s products.

For more information, contact:

John T. Bentivoglio
202.626.5591
jbentivoglio@kslaw.com

Jennifer Bragg
202.626.5596
jbragg@kslaw.com

Mark Jensen
202.626.5526
mjensen@kslaw.com

J. Sedwick Sollers
202.626.5612
wsollers@kslaw.com

Chris Wray
202.626.5570
cwright@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Suite 200
Washington, D.C. 20006
Phone: 202.737.0500
Fax: 202.626.3737

www.kslaw.com



FDA/Healthcare & Government Investigations Practices

- Clinical Trials: In funding clinical studies to investigate possible off-label uses of Trisenox, Cell Therapeutics failed to provide investigators with study drug at no cost or at their cost of production as required by law. Investigators were then required to acquire the drug by commercial means, including submitting false claims to Medicare.

Specific Allegations

The complaints filed by the Relator and U.S. Attorneys' Office allege that Cell Therapeutics knowingly and/or recklessly engaged in unlawful promotion of Trisenox to expand revenue beyond a very limited on-label market. The settlement agreement describes the following activities in support of its allegations:

- Consultant Agreements: The Company paid doctors to attend presentations about off-label usage and characterized these payments as consulting agreements. Similarly, CTI is alleged to have paid between to \$500 and \$1000 each to attend consultant meetings despite the fact no advice was sought, reviewed or acted upon. According to the government, the purpose of these meetings was solely to promote Trisenox off-label.
- Advisory Boards: The DOJ alleged that Cell Therapeutics attempted to circumvent laws that prohibit off-label promotion by establishing Advisory Board meetings to function as "independent continuing medical education" (CME) seminars. At least one Advisory Board meeting, hosted at a resort facility, emphasized Trisenox's potential off-label uses. The event, attended by physicians, involved minimal information exchange and participant feedback. Participants were paid \$1,000 each and encouraged to spend most of the time utilizing the resort's golf, tennis and spa facilities.
- Return on Investment (ROI) Analysis: The DOJ alleged that CTI executives conducted ROI on several Ad Boards, Consultant Meetings, and CME programs.
- Speaker Fees: The DOJ alleged that many speaker fees and honoraria were simply rewards for past and future off-label prescribing by doctors and recommend Trisenox for similar purposes to other physicians.
- CME: Two Medical Communications companies were named in the Relator's complaint; the government's intervention did not include these parties but alleged that they served as conduits through which the company funneled money to hand-picked speakers who then presented content entirely controlled by the company. Money given as grants, (although allegedly to fund clinical studies), was pulled from Cell Therapeutics' marketing budget. The physicians on the receiving end rarely generated a significant clinical work product; they often merely collated or reported on existing data or records.



FDA/Healthcare & Government Investigations Practices

Settlement Provisions

The settlement contains CTI's assertion that, if any false or misleading statements were made about Medicare coverage of the company's product, such statements were the consequence of negligent advice provided by a third party (which appears to be a well-known reimbursement consulting firm). CTI currently is engaged in litigation against that consulting firm. The settlement amount, \$10.5 million plus interest accrued since December 2006, absolves CTI of liability for the alleged activity but releases no individuals from further legal action.

Corporate Integrity Agreement (CIA)

As Cell Therapeutics no longer markets any commercial products, the settlement does not include a CIA. However, if the company develops or acquires a marketed product within the next five years, the settlement requires CTI to notify the HHS- OIG and enter into a CIA.

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If you have questions about the Cell Therapeutics settlement, or would like more information about King & Spalding's experience in government investigations of pharmaceutical manufacturers, please do not hesitate to contact:

John T. Bentivoglio	jbentivoglio@kslaw.com	202.626.5591
Jennifer Bragg	jbragg@kslaw.com	202.626.5596
Mark Jensen	jensen@kslaw.com	202.626.5526
J. Sedwick Sollers	wsollers@kslaw.com	202.626.5612
Chris Wray	cwray@kslaw.com	202.626.5570

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