

# UTAH MEDICAL PRODUCTS, INC.



CORPORATE HEADQUARTERS  
7043 South 300 West  
Midvale, Utah 84047  
Telephone: 801-566-1200  
FAX: 801-566-2062  
NASDAQ Symbol: UTMD  
[www.utahmed.com](http://www.utahmed.com)

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## PRESS RELEASE

### Utah Medical Products' Claim Denied by HHS

Contact: Kevin L. Cornwell

February 15, 2006

Salt Lake City, Utah - On July 15, 2005, Utah Medical Products, Inc. (UTMD) filed an administrative claim with the Department of Health and Human Services (HHS), the parent of the U.S. Food & Drug Administration (FDA), under the Federal Tort Claims Act (FTCA), alleging abuse of process in relation to the negligence and wrongful acts of FDA employees while acting within the scope of their employment during the inspections, review and subsequent enforcement actions taken and/or attempted, including public statements, during the period of 2001 through 2005.

On February 14, 2006, UTMD received a letter from HHS dated February 10, 2006,

“This letter constitutes the notice of final determination on this claim, as required by 28 U.S.C. '1346(b). Your client's [UTMD's] claim is not cognizable under the FTCA. Accordingly, the claim of Utah Medical Products, Inc, is hereby denied.”

The claim that UTMD filed is now available to the public on UTMD's website [www.utahmed.com](http://www.utahmed.com), or by contacting Kevin Cornwell.

It remains UTMD's conviction that the claim is valid. The very misleading August 10, 2004 press release which appeared on the official FDA website is a good example. The Company believes that it has proof of fraudulent reports by inspectors, reviewers and other FDA employees which led to an ordeal in which the Company prevailed, but was significantly damaged.

According to Judge Bruce S. Jenkins, in the “Memorandum Opinion & Order” dated October 21, 2005,

“The court has been impressed as well by Utah Medical's design of product, its record-keeping of each step along the way, the acceptance in the market of its products, the Company's uniform processing of complaints, and the manner in which change is made in practice and procedure as a result of complaint handling.”

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“It makes no sense for the court to order Utah Medical to do something they are already doing.”

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According to CEO Kevin Cornwell,

“We were hoping that independent and objective representatives of the executive branch of government would have been assigned to investigate this claim, and be willing to discuss a constructive settlement with UTMD. Such a settlement would include restoring our reputation for manufacturing high quality products, rectifying a permanent public record that is incorrectly disparaging of UTMD, actually conducting the UTMD requested investigation in which FDA claimed it found no evidence of inspector bias but has been proven never to have happened, and repaying UTMD’s totally unnecessary costs of litigation that resulted because no one in FDA wanted to open a dialogue regarding UTMD’s responses to predetermined inspectional observations. It continues to be disappointing that officials in our government prefer to hide than to admit any wrongdoing. It’s not hard, with an effective quality system, to do the right thing necessary to take corrective actions, and appropriate preventive actions for the future.

There is much more of a story here of systemic corruption than has been publicly disclosed to date. Fraud, which according to a dictionary is “deliberate deception for unfair gain,” is not included in the discretionary function privilege of the government.”

UTMD now is free to file suit against the FDA in the federal district court, or file a request for reconsideration, before August 10, 2006. The Company will carefully consider all of its options.

Utah Medical Products, Inc., with particular interest in health care for women and their babies, develops, manufactures, assembles and markets a broad range of well-established disposable and reusable specialty medical devices designed for better health outcomes for patients and their care-providers. For more information about Utah Medical Products, Inc., visit UTMD’s website at [www.utahmed.com](http://www.utahmed.com).