

# 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

### UTMD Announces Filing a Request for Reconsideration with HHS

Contact: Kevin L. Cornwell

August 7, 2006

Salt Lake City, Utah - On July 15, 2005, Utah Medical Products, Inc. (Nasdaq: 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.

On February 15, 2006, as part of informing public shareholders of the HHS denial, UTMD indicated that it had an August 9, 2006 deadline to file suit against the FDA in the federal district court, or file a request for reconsideration. In order to disseminate an answer to shareholder follow-up questions fairly, the Company is announcing that it filed a request for reconsideration with HHS on July 12, 2006. The request for reconsideration 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 request for reconsideration includes the following:

#### **REQUEST FOR REMEDIES**

Utah Medical believes that the Company, its employees, shareholders, suppliers and customers, along with all other taxpaying and non-taxpaying U.S. citizens, are entitled to expect that the federal government will act in good faith to carry out its responsibilities, and not waste dear taxpayer resources for an improper purpose. Utah Medical respectfully seeks the following administrative remedies:

- 1) removal of the August 10, 2004 FDA press release which remains posted on the FDA's website;

- 2) (acknowledging the irreparable harm that has been done to UTMD's reputation for manufacturing high quality products) posting of a public press release from the FDA (in manner and form similar to the August 10, 2004 press release posted on the FDA's website) acknowledging that Utah Medical's quality system is and has been in compliance with the QSR (per the U.S. Court's judgment);
- 3) a public declaratory statement from the Secretary of HHS that FDA must comply with its own regulations, and that unethical conduct that violates the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635) will not be tolerated;
- 4) that the FDA inspectors and reviewers complicit in the 2001- 2003 Utah Medical inspections, and ensuing improper treatment of Utah Medical, be barred from any future involvement with Utah Medical;
- 5) the purging of the FDA's administrative file of all FDA-483s, EIRs, CDRH memos, interoffice e-mail, other fraudulent memoranda related to the 2001 through 2004 inspections and recommendations for permanent injunction (or at least a cover letter to all documents subject to the FOIA that states, "Despite the contents of these documents, Utah Medical was found to be in full compliance with the QSR by an independent Court. Therefore, the veracity of any of these documents cannot be relied on or verified.");
- 6) a commitment from HHS, or some suitable government entity independent of the FDA, to conduct and document the results of a formal investigation of FDA actions in this case, to publicly disclose the results and to retrain, reprimand, reassign and/or dishonorably discharge FDA personnel who violated government rules and regulations; and
- 7) provide recovery of pecuniary damages incurred by Utah Medical as the result of the conduct of the FDA.

In recent criticism, Rep. Henry A. Waxman, D-Calif., stated that "the FDA can't do its job when its enforcement arm is tied behind its back." In response, David Elder, Director of the FDA Office of Enforcement, was quoted in the August 2006 issue of the "Guide to Medical Device Regulation," as follows:

"FDA enforcement cannot be properly judged by counting the number of actions taken by the agency," he [Elder] said. "FDA has increasingly used an enforcement strategy based on efficient risk management principles that focuses on combating the greatest public health risks and maximizing our deterrent effect against potential violators. **As a result of FDA's focus on those firms and those violations that present the highest risk to consumers and public health, the agency has taken prompt, targeted and aggressive action against firms that are in violation of law.**" (emphasis added)

According to UTMD CEO Kevin Cornwell,

"I agree with Mr. Elder that the number of administrative Warning Letters issued by FDA has no correlation with the quality of medical devices being manufactured by industry. I also agree that FDA should be allocating its limited enforcement resources based on risk to the public health. But that's where my agreement with Mr. Elder ends.

I question the basis for Mr. Elder's statements, because his representation about FDA using efficient risk management principles does not comport with UTMD's experience with the FDA. To my knowledge, the lawsuit brought by FDA in 2004 seeking an injunction to shut down UTMD's operations because of alleged violations of the Quality System Regulation (QSR) has been the only such action litigated through trial on behalf of the FDA in the ten years since promulgation of the QSR. After three years of intensive and extensive inspections of UTMD and "review" by so-called agency experts, the federal court decided unequivocally against the FDA. Utah Medical was in compliance with the QSR!

In contrast to Mr. Elder's statement, the FDA's action was neither prompt nor based on any risk to the public. The fact that no risk assessment was ever done by the FDA was a travesty. There were no FDA allegations that UTMD's devices were defective, or not safe or not effective. The agency never investigated whether UTMD's finished devices met specifications, and never challenged the soundness of the risk assessments that we had performed."

The FDA's published mission statement states, in part,

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Mr. Cornwell further states,

"The FDA has the power to destroy public institutions and people's careers and lives. That power should be used carefully and judiciously. If there's not a risk to public health, FDA should not be capriciously using its power to punish people. It's a direct contradiction to their mission.

The FDA needs to use the principles of quality assurance to learn from this UTMD experience, and respond responsibly to our request for remedies. I do not understand how the leadership of the FDA can reconcile the fact that it is a significant violation of the Quality System Regulation (QSR) when companies do not follow their written procedures, but when employees of the FDA, which is charged with the enforcement of the QSR, do not follow important agency procedures, it is simply ignored."

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).