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

PRESS RELEASE

UTMD's Board of Directors Comments on FDA Allegations

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Contact: Paul Richins
(801) 566-1200

Salt Lake City, Utah - Stephen W. Bennett, M.D., MPH&TM, Dr. PH, Barbara A. Payne, Ph.D. and Ernst G. Hoyer, B.S. Engineering, MBA, Utah Medical Products, Inc.'s (Nasdaq: UTMD) independent directors during the full period of time of the Company's disagreement with the Food and Drug Administration (FDA) since 2001, advise shareholders that they have been completely informed and kept current by representatives of management, independent experts and legal counsel as the Company's disagreement with the FDA has evolved.

The directors confirm their full and unanimous support for the position that, it is in UTMD shareholders' best interest to proceed through the Federal Court process because of the fundamental refusal by FDA managers to communicate.

Mr. Hoyer states

> "Since the early 2002 inspection, the Company has never had an opportunity to discuss its differences regarding inspectors' observations with any reviewer or manager in the FDA. We have had no opportunity to reach a reasonable resolution. As a clear example, the Company formally requested non-binding mediation in May 2004, in which the FDA's CDRH Ombudsman had agreed to be mediator, but were rejected by the FDA's Tim Ulatowski.
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> In mediation, the FDA would be expected to say what provisions of the QSR were in dispute and why. Instead, FDA's response was 'Tell us what you've done to get into compliance.' I hope that the paradox is obvious. The Company firmly believes and has believed, consistent with the opinions of its independent experts, that it is in compliance with the QSR."

After three years of conscientious, but futile, efforts to seek a response and dialogue with FDA management regarding the Company's numerous written responses to inspectors' observations, the only alternative FDA offered to the Company is an oppressive Consent Decree that would shut down the Company, destroy all inventory, and literally cede control to FDA personnel whose qualifications/ identity are unknown and who have refused to respond to repeated UTMD requests to meet.

Dr. Bennett, who participated in the sole meeting with agency personnel other than inspectors after 2001, states

> "There was a complete absence of good faith dialogue in the May 2003 meeting with Denver District Director Belinda Collins and Regional Director Dennis Baker, who had requested the meeting. They were not

informed, declined to provide any information of substance, and refused to discuss the most recently concluded inspection. The agenda provided by UTMD could not be implemented, because information was not exchanged. Rather, information continued to flow only in one direction – from UTMD to FDA.

We understand that the Company's position is unusual, and may appear unwise to some shareholders. I assure you that we haven't been provided another reasonable alternative.

FDA's Larry Spears, in recent public statements, has said that FDA has identified persistent QSR violations and has given repeat warnings to the Company. Those statements are false.

Although we would keenly prefer to be in a different situation, and respect the mission of our FDA, the fact is that we also have the obligation in our present extreme circumstances to stand up for the Company's rights, employees' rights and the rights of American citizens under explicit requirements of law and regulation, not to mention common decency. The FDA's position is simply, 'Admit violations (that have not been defined or discussed), and we will let you stay in business, maybe.'

I am also very disappointed that Utah's elected representatives have not yet taken an active interest in investigating this situation, and in trying to keep productive law-abiding citizens in Utah employed. We look forward to more involvement and help from Senator Bob Bennett, Senator Orrin Hatch and Congressman Jim Matheson. I sent a personal letter to Senator Hatch in June 2003 in which I expressed, among other things, 'It is a sad and disturbing thing when a government agency abuses its power particularly when both incivility and incompetence on the part of an inspector, as in this case, is followed by bureaucratic ineptitude and punitive actions… I firmly believe that a part of the FDA is out of control and behaving contrary to its own policies, and a cover-up is in progress.'"

Dr. Payne asks

"How is this litigation by the FDA consistent with the following August 4 campaign speech?

'John Edwards and I are campaigning across the country talking about how we can build an America that is stronger at home and respected in the world, and that means creating a business climate that helps companies succeed and create good paying jobs right here in America,' Senator Kerry said in his prepared remarks.

'Clearly, we can do a better job lowering the cost of doing business in America. That makes us more competitive and it reduces the incentive for somebody to decide to go overseas,' Kerry said.

How is it in the public interest to punish an innovative company making proven safe and effective life-saving devices, ironically because it prefers to manufacture in the U.S. and agrees with the FDA's own December 1997 "Guide to Inspections of Medical Device Manufacturers" which was maintained at least through UTMD's 2003 inspection? The guide, which has a section entitled "The Small Manufacturer," states, 'An investigator should not insist that a manufacturer meet a QS/GMP requirement that does not contribute to its assuring conformance to specifications, simply because it's part of the new regulation.' The guide also states, 'Section 519(a)(4) of the FD&C (Federal Food, Drug and Cosmetic) Act prohibits record keeping requirements that are unduly burdensome to a device

> manufacturer.' The guide states, 'An investigator should realize that a small firm usually does not need the same degree of documentation necessary as required for a large firm to achieve a state of control.' The guide also states, 'Practices may be more brief and less detailed for a small manufacturer of less complicated devices unless the firm is producing non-conforming devices.' Despite the above consideration theoretically given small companies by the FDA, UTMD's experts agree that the Company complies with all provisions of the QSR.
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> During the multiple and burdensome FDA inspections since 2001, one fact is certain – UTMD devices do conform to specifications. UTMD has many years of experience producing and shipping devices supported by objective evidence that these meet specifications using current manufacturing processes. The lawyers representing the government have acknowledged that there is not a risk to public health."

The directors remind shareholders and the public that FDA statements about "violations" must be truthfully qualified. No violation exists until the FDA proves this through supporting evidence in Federal Court proceedings or the accused (UTMD) agrees to make such an admission. UTMD will not be making such an admission because, with the firm support of industry experts, it is confident in its compliance with the QSR. UTMD is proud of its continuing record of providing safe and effective devices manufactured by dedicated and qualified personnel who implement quality systems certified to compliance with the worldwide recognized ISO 13485 standard for medical devices, as further recognized by the FDA.