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PRESS RELEASE

UTMD Updates Status of FDA Lawsuit

Contact: Kevin L. Cornwell January 26, 2005

Salt Lake City, Utah - Utah Medical Products, Inc. (UTMD) is a defendant in a lawsuit filed more than five months ago by the Food and Drug Administration (FDA or Agency) in the U.S. District Court in Salt Lake City, alleging violations of the Quality System Regulation (QSR). The objective of the QSR is "to ensure that finished devices will be safe and effective…"

On November 16, 2004, UTMD announced the admissions made under oath by the FDA designated enforcement official that the FDA is not claiming that UTMD's devices are unsafe, ineffective, defective or causing any harm to patients. UTMD was pleased with this FDA confirmation of UTMD's history of quality service to the health care community, but remains saddened and puzzled by FDA's motivation.

Two more months have passed in the discovery process since that announcement. UTMD provides this update to shareholders, clinicians, and other interested constituents with respect to the litigation progress. During this time, as part of the discovery process, a number of FDA and Center for Devices and Radiological Health ("CDRH") documents including expert reports have been obtained, and additional depositions of FDA officials have been taken by UTMD's lawyers. Also, UTMD's independent experts have filed their reports.

According to an expert report filed on January 10 on behalf of UTMD by a respected 28-year FDA compliance veteran, and former FDA District Director, "It is my opinion that UTMD is in substantial compliance with all requirements of the QSR." This position directly contradicts the FDA's.

Another expert report filed by a 30-year professor in plastics materials engineering at a major university, who previously taught FDA inspectors, expressed that, "The FDA fundamentally misconstrues and misunderstands the nature and principles of plastics parts manufacturing, such as injection molding and extrusion… Utah Medical's procedures and guidelines related to extrusion and injection molding operations and process control are superior."

UTMD CEO Kevin Cornwell states,

> "Our belief that some personnel within the FDA have abused their authority and the concept of due process is strengthened by disclosure of documents that are being discovered only because of the benefit of the judicial process. Expert reports filed on behalf of the FDA rely on information provided by the FDA rather than the on-site

manufacturing facility audit that was performed by UTMD's independent experts. Regrettably, FDA documents contain a very subjective and negative characterization of UTMD, its employees and representatives.

The CDRH official considered the Agency's 'expert' decision-maker regarding the QSR, in an internal e-mail to other reviewers within the Agency prior to the completion of a 2003 inspection directed, 'This [FDA Form] 483 is going to have to be dead on, for me to support an observation with all the issues surrounding the inspections. I will not be able to massage it for the complaint [for injunction] like some cases…' 'Massage'? So much for honesty, due process and simple fair play. We were told by the FDA District Director that this was a routine inspection, and were never advised that the purpose of the inspection was to prepare an injunction lawsuit. So much for the independent and objective review of supposedly factual observations by inspectors.

The only explanation for this that I can offer is that UTMD's well-educated and experienced technical people apparently offended enforcement personnel expressing views about, or questioning, our special products and processes that differed from those opinions of the FDA personnel. Publicly, the FDA invites questions and disagreement. Yet, in our experience, when one disagrees, the observation massage machinery is set in motion, and dialogue with, and feedback from, FDA personnel is cut off.

There have been a few documentation errors identified in thousands of pages of UTMD documents, spanning a decade or more, that FDA inspectors reviewed during hundreds of hours of multiple inspections since 2001, and some isolated examples where a UTMD employee failed to follow a written procedure. But significantly, there is nothing of consequence that has affected the safety or effectiveness of UTMD's devices.

The FDA, as a scientific law enforcement agency, must take actions based on fact, not emotion. The facts do not support the FDA's characterization of UTMD in its lawsuit. UTMD has dedicated, well-trained personnel who understand the importance of accuracy and following procedures. Yet, in the course of manufacturing millions of specially hand-assembled devices, mistakes happen. The identification of these and subsequent training and other corrective actions are evidence that UTMD's Quality System works, and provides valuable continuous movement toward perfection."

UTMD respects and recognizes the important responsibility of the FDA, but it also believes in the right it has to ask questions and understand the basis for any FDA concerns. This is what UTMD has heard from FDA representatives in the public forum, and we believe the effort to encourage dialogue is helpful.

'When you stand for your liberty, we will stand with you.'
…. President George W. Bush, Inauguration Address, January 2005

UTMD asks its elected representatives to support the President's statement, starting here at home. UTMD has accepted this challenge because we believe, at a personal level, that honesty and truth should prevail, particularly when it regards U.S. government officials who claim to be protecting the

public; and at a practical level, because of our small size, we are not able to simply “appease them to go away” as some are wont to do. Presently, it appears the only avenue available for FDA enforcement oversight is through the expensive and time-consuming judicial process.

Congress passed the Sarbanes-Oxley Act to protect public shareholders by addressing ethical break-downs in companies like Enron and WorldCom. Since the value of UTMD’s investors’ holdings have been significantly unfairly damaged by the FDA, we believe that responsible legislators will expect similar mandated ethical standards for Federal law enforcement officials.

UTMD continues to manufacture and distribute all of its safe and effective products worldwide without any regulatory restriction, because the FDA ultimately must prove its allegations. UTMD affirms its belief in previous statements in press releases about its conscientious compliance with the QSR, as well as significant deficiencies in the FDA’s performance, which appear to be increasingly supported by the evidence in discovery to date.

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, proven safe and effective, disposable and reusable specialty medical devices.