EXHIBIT A.

## REQUEST FOR RECONSIDERATION

Pursuant to 28 C.F.R. §14.9(b), Utah Medical Products, Inc. ("Utah Medical" or the "Company") hereby requests that the Department of Health and Human Services ("DHHS") reconsider its February 10, 2006 final determination denying Utah Medical's claim submitted July 15, 2005 that employees of the Food and Drug Administration ("FDA") committed tortious acts constituting an abuse of process in connection with various inspections of Utah Medical. A copy of Utah Medical's claim designated DHHS Claim No. 05-0317 and of the DHHS letter denying the claim are attached hereto as Exhibit R1, and are hereby incorporated by reference as though fully set forth herein. In its February 10, 2006 letter denying Utah Medical's claim, the DHHS simply stated that the claim was denied on the basis of the bald conclusion that Utah Medical's "claim is not cognizable under the FTCA" without providing any substantiation or reasoning for that position. It is respectfully submitted that that determination is wrong and that DHHS should reconsider its denial.

## OVERVIEW OF THE FACTS

Utah Medical was organized and incorporated in the State of Utah in 1978 to develop, manufacture and market innovative medical devices that improve healthcare. The Company has been remarkably successful in achieving that objective, attested to by the broad clinical acceptance of its products, a number of which have been in dominant use for more than a decade. The Company owns or licenses 54 patents, several of which have now expired and have been incorporated by many other medical device manufacturers into their products. Utah Medical currently employs about 206 people. Employees who work in its manufacturing operations in Utah, Oregon and Athlone, Ireland average ten years tenure with the Company. Utah Medical has paid more than fifty million dollars in Federal corporate income taxes since 1987.

In 1993, Utah Medical first established the quality system under which it operates today after years of continuing refinement. Utah Medical's manufacturing processes have been consistently producing products that perform as intended and meet specifications to a high degree of assurance, almost the same way for well over a decade, except for continuous improvements and operational upgrades. As noted by Dan Jarcho, lead trial counsel for Utah Medical, published in the FDLI Update 2006, Issue 2, [2]

> "FDA criticized the means of compliance without assessing the end result. The consequence was a trial in which the undisputed evidence showed that the quality system was consistently meeting its objective of ensuring safe and effective high-quality products, and a trial in which FDA simply tried to second-guess the

methods used, without presenting evidence that the Company's chosen methods were inadequate to meet their objective.

The evidence showed that Utah Medical's full range of product and process testing, comprehensive procedures, and skilled engineers establish a carefully controlled component manufacturing process that consistently meets specifications at an extraordinarily high rate – more than 99.7% of the time. The agency's witnesses admitted that even a 95% probability of meeting specifications constituted a 'high degree of assurance.' And FDA did not contest the company's evidence that it consistently meets specifications more than 99.7% of the time. In fact, the agency's witnesses conceded that they had *never even analyzed* whether the company consistently meets specifications." [2]

In 1994, Utah Medical became one of the earliest U.S. medical device companies to achieve certification of its quality system under ISO 9001 EN 46001, the subsection specific to medical device design controls. According to The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, compiled by Kimberly A. Trautman, GMP/Quality Systems Expert, Office of Compliance, CDRH, FDA ("Trautman") and published in 1997 by ASQ Quality Press, Milwaukee, WI,

"In 1992 the Global Harmonization Task Force (GHTF) was formed in an effort to harmonize regulatory requirements for the medical device industry. There appears to be consensus that quality system requirements should incorporate the principles of ISO 9001 plus additional requirements specific to the medical device sector."

In 2003, Utah Medical upgraded its quality system certification to the more stringent ISO 13485 medical device standard. The FDA regulatory requirements intended to ensure that *finished* (emphasis added) medical devices will be safe and effective [1], 21 CFR 820 Quality System Regulation ("QSR"), were published in the Federal Register in October 1996 and became effective on June 1, 1997.

"Because the QSR governs such disparate manufacturing processes, FDA repeatedly has emphasized that the QSR is a flexible 'umbrella' regulation that permits a wide variety of methods to achieve compliance. The regulations preamble explains that by following an 'umbrella' approach, the QSR establishes *what* must be done without defining *how* it must be done" [2].

In 1998, Utah Medical received its first comprehensive FDA inspection of its Utah facility under the QSR, "initiated as a GMP inspection per CP 7382.830, Inspection of

1 See 21 CFR §820.1 Scope.
2 See "United States v. Utah Medical Products, Inc.: FDA Violates Its Own QSR Policy" attached as Exhibit R2.

Medical Device Manufacturers".[3] The 1998 FDA Establishment Inspection Report ("EIR") states,

> "No FDA-483, Inspectional Observations was issued and no samples were collected during this inspection."

The following inspection of Utah Medical's Midvale facility occurred in 2001. According to the EIR [4],

> "Inspection of this medical device manufacturer was conducted as a routine DEN-DO, FY-01 work plan assignment in accordance with C.P. 7382.845, Inspection of Medical Device Manufacturers."

At the conclusion of the 2001 inspection on June 8, a two page Form FDA-483 "Inspectional Observations" ("FDA-483") was issued. The Company responded with a June 27, 2001 letter containing 9 Exhibits, with a concluding section,

> "In summary, UTMD (Utah Medical) has addressed all of the observations of the inspector and is committed to making necessary changes in its quality system within a short period of time. Respectfully, I hope you agree that these observations do not warrant a QSIT Warning Letter which might mislead medical practitioners who trust our products in high risk situations into concluding that UTMD's products aren't the safest choices available, which is the basis for UTMD's survival in the marketplace.
>
> I would like to reserve the opportunity to provide more details to augment these responses, if after review, the FDA (Denver) District Compliance Office is not completely satisfied that the observations have been properly addressed. Please do not hesitate to call me directly at (xxx) xxx-xxxx (number deleted)."

Instead of responding to the Company's request for the opportunity to provide additional details that would accomplish a constructive resolution, the compliance reviewer in the FDA's Denver District Office ("DDO"), Regina Barrell ("Barrell"), crafted a Warning Letter which was issued on September 4, 2001. The letter was signed by Howard Manresa ("Manresa"), Acting for the District Director. This Warning Letter triggered a prolonged unnecessary enforcement action including denial of Certificates to Foreign Governments ("CFGs") for two and a half years while Utah Medical was lawfully distributing its products in the U.S. without any restriction, three DDO injunction recommendations after three additional increasingly intensive "inspections" over a three year period of time in 2002, 2003 and 2004, which were followed by written

---

3 FDA Establishment Inspection Report ("EIR") for the inspection conducted at the Midvale, Utah facility on September 11-16, 1998 by James E. Moore, CSO, DEN-DO, SLC-RP.

4 FDA Establishment Inspection Report ("EIR") for the inspection conducted at the Midvale, Utah facility on June 4-8, 2001 by Thai Duong, Investigator

.

Company responses never responded to by the FDA, and ultimately a lawsuit filed in August 2004 by the Department of Justice ("DOJ") seeking to shut down Utah Medical's operations, coupled with a public press release designed to scare hospital administrators and others into stopping use of Utah Medical's products. The press release [5] which is still displayed on the FDA website and circumvented due process, states

> "'FDA will not tolerate manufacturing practices that can potentially put patients at risk,' said FDA Acting Commissioner Dr. Lester M. Crawford. 'Patients have a right to expect that the medical devices used to treat them are safe and effective.'"

Incredibly, the FDA never undertook a risk assessment of Utah Medical's finished devices or tried to demonstrate that Utah Medical's quality system had failed. Lacking any substance related to finished products not meeting specifications, the FDA allegations became focused on the issue of validation of injection molding and extrusion of components according to "industry standards," for which there are no documented industry standards.

> "The court never reached the question whether any industry standards even existed, because it concluded that any such standards would not be incorporated into the QSR. The court stated that '[t]he regulations were promulgated in 1997 with no express incorporation of industry standards,' and held that 'it is fundamental that the regulations state the applicable law.'"

There was never an FDA allegation of any problems with unsafe, ineffective or defective devices. [6]

Notably, the 2001 FDA-483 observations which had to be the basis for allegations of QSR violations in the Warning Letter which started the enforcement action were not included as part of the FDA allegations presented at trial. In the 2001 Warning Letter, Barrell attempted to require Utah Medical to retain a consultant to certify Utah Medical's compliance with the QSR[7]. Surprised with the content of the Warning Letter, Utah Medical called Barrell, the designated FDA contact, and requested a meeting. In answering Utah Medical's question prior to the meeting as to why a consultant's certification was requested, she responded "because you're recidivist" meaning "a string

---

5 Attached as Exhibit R3.

6 See Utah Medical press release dated 11-16-04 attached as Exhibit R4 with excerpts from the 11-9-04 30(b)6 deposition of the FDA.

7 Prior to the DOJ filing of the injunction lawsuit in 2004 and the U.S. Court's confirmation of Utah Medical's compliance with the QSR in 2005, the Company's expert QSR consultants in 2003, both of whom were previously FDA District Directors, Ed McDonnell, Boston District, and John Scharmann, Denver District, after reviewing the same documents that Barrell had reviewed, concluded that there was not a basis for issuing a 2001 Warning Letter. This information was made available to the FDA District Director B. Collins and Regional Director D. Baker in May 2003, but was ignored.

of bad inspections." (Recall that in the prior inspection, Utah Medical's first under the QSR, no FDA-483 was issued.) [8]

During and subsequent to Utah Medical's December 2001 meeting with Barrell and her supervisor Manresa, no disagreement was expressed by the FDA representatives with Utah Medical's exhaustive explanation of the 2001 FDA-483 observations and responses to Warning Letter statements. This meeting was Utah Medical's only face-to-face meeting [9] with FDA reviewers throughout the four year long ordeal where dialogue regarding the substance of FDA-483 observations was allowed. The meeting was cordial, as deposition testimony of Barrell and Manresa confirms.

A chronology of events known to Utah Medical prior to receipt of FDA documents and depositions obtained in discovery is appended as Exhibit R5.

Barrell, and later other FDA officials, rebuffed all Utah Medical efforts to engage in any discussion of the issues after 2001, and embarked on a concerted scheme and conspiracy to punish Utah Medical and two of its executives for declining to hire a consultant [10]. The FDA did so even though it had no legal authority or factual justification to impose such a requirement, and despite the FDA's written assurance to the industry that "[y]ou have a right to disagree with any agency decision, action or operation without fear of retaliation."

After Utah Medical declined to hire a consultant in 2001, Barrell embarked on a coordinated mission to punish Utah Medical by shutting down its business. The FDA engaged in improper pre-filing discovery with respect to an injunction lawsuit that the FDA intended to file against Utah Medical beginning in 2002. Exhibit R8, a more complete written account of the inspection history of Utah Medical from 1995 through 2004, is hereby incorporated by reference as though fully set forth herein. The history record was prepared for the benefit of newly appointed Associate Commissioner for

---

8 Utah Medical received a Warning Letter after a 1995 inspection, under the prior GMP regulation. In 1995, FDA DDO Director Scharmann accepted the Company's responses and in 1998, FDA inspector Moore verified that all promised corrections had been made.

9 A second meeting at the Company with DDO Director B. Collins, Regional Director D. Baker and Associate Chief Counsel P. Kaeding occurred in May 2003, but the FDA officials refused to discuss the details of inspections, despite a prior agreement to discuss Utah Medical's agenda. In discovery, FDA e-mails were obtained that described the proposed meeting as a "listening only" meeting.

10 After first learning of the government's "sign or sue" letter in October 2003, the Company did accede to Barrell's demand that it hire a consultant to certify its quality system. UTMD hired former FDA District Director and 28-year FDA enforcement veteran Ed McDonnell, a recognized QSR expert, who provided the "Declaration of Edward J. McDonnell" dated November 3, 2003 attached as Exhibit R6, and the "Opinion on the Compliance of UTMD with the FDA's Quality System Regulation" dated January 7, 2005 attached as Exhibit R7. However, the FDA chose to ignore Mr. McDonnell's opinions.

Regulatory Affairs, Margaret O'K. Glavin, in August 2005, who apparently chose to ignore it.

In early 2002, Barrell sent [11] a new inspector, Ricki Chase-Off ("Chase"), who, on the third day of a five day inspection wrote in an e-mail to her Denver supervisor and Barrell, "Are we going to look at injunctive action?" Despite the objective as a "limited follow-up inspection," the FDA-483 generated by Chase was six pages long with mostly new observations, only two of which were related, according to the FDA, to allegations made at trial. Utah Medical believes that even those two were unrelated to issues brought to trial. The primary observation on the 2002 FDA-483 (items are listed in order of most serious first), regarded lack of sterilization validation, which was patently wrong, but for which Utah Medical's detailed written responses were again ignored. In the following scripted (by CDRH) and pretextual inspection in 2003, in which national medical device expert and sterilization specialist Karen Coleman ("Coleman") joined Chase, Coleman spent two full weeks focusing on reviewing sterilization records and concluded that there was no evidence of sterilization validation. In the 2003 EIR, Coleman wrote "The overall validity of the firm sterilization validation is questionable because of the problems noted with the firm's comparative resistance studies [CRS], see discussion on FDA 483 item 1A 1, FDA 483 1A 2, and supporting evidence." [12] This allegation never made it to trial, because Monica Wilkins, the second of three FDA national medical device experts and sterilization specialist, concluded in her 2004 inspection of the same documents reviewed by Coleman and other information available to Coleman, in addition to 2002 and 2003 written responses from Utah Medical to Barrell, reviewed and supported by CDRH

11 Per the Chase-Off 2002 EIR, p.1, "This was a limited, follow-up inspection, QSIT Level III, conducted at the request of Denver District Compliance."

12 In response to Coleman's opinions expressed during the 2003 inspection that Utah Medical's independent microbiology consultants, Nelson Laboratories, did not have proper validation test protocols, Utah Medical agreed to perform another validation using a comparison of both methods. Coleman knew that the results of the revalidation proved her opinions wrong before finalizing the 2003 FDA-483, but included her erroneous observations anyway, listed in Observation #1, supposedly because a formal test report had not been written by Nelson as yet. In the FDA-483 discussion, she encouraged Utah Medical "to take your time" in providing the test report, knowing that a new injunction recommendation would be rushed through DDO compliance and CDRH with lack of sterilization validation as a primary justification. Dr. Nelson himself wrote two personal letters included in Utah Medical's April 11, 2003 response to the March 12, 2003 FDA-483, one of which responded in detail to each Coleman/Chase FDA-483 observation regarding sterilization. Dr. Nelson stated, "The comparative resistance studies and validations performed were and are valid and Utah Medical['s] products were and are sterile and properly validated." This response was obviously ignored by both Barrell and Trautman. Barrell submitted her 2003 injunction recommendation on March 27, not waiting for the Company's written response. Larry Spears signed the 2003 supporting CDRH Memo dated August 20, 2003 for Trautman, which was based significantly (first 8 pages out of a 21 page memo) on alleged lack of sterilization validation. Again, there was no FDA response to Utah Medical's written 2003 FDA-483 response. It took Wilkins, in the ensuing pretextual 2004 inspection for an improper purpose, to "resolve" the sterilization validation issue. Note: The FDA's "independent outside" expert, Anita Thibeault, submitted a written opinion on March 19, 2003 in which the number one example supporting lack of process validation stated "There was no evidence that UMPI performed gamma sterilization or EO sterilization according to accepted industry standards or that they provided proof of an equivalent method validation the sterilization process."

personnel including sterilization expert Patrick Weixel as violations, that Utah Medical's sterilization processes were indeed properly validated.

On the fourth day of the 2002 inspection, after scheduling presentation of the FDA-483, Chase told Utah Medical representatives, "You are going to disagree with me, but I've had extensive discussions with Denver and they will be in concurrence with my observations. So. You're welcome to make your objections, but they won't make any difference and I think I already know what they will be." Unknown to Utah Medical, Barrell indeed submitted her first injunction recommendation to CDRH following the 2002 inspection, ignoring Utah Medical's requests to provide more information to satisfy any discrepancies identified by Barrell and for dialogue that would resolve Utah Medical's compliance, and falsely telling Utah Medical that she was a still reviewing the inspection file long after she had in fact submitted her injunction recommendation to CDRH. The June 12, 2002 injunction recommendation, which contained numerous key fraudulent statements [13] as justification for the recommended action, was followed the next day, prior to CDRH receipt and review, by an "upfront loading" telephone conference call from Barrell and Manresa with a number of CDRH representatives including Trautman. The oral demonization[14] of Utah Medical by Barrell was the seminal event which initiated the Barrell/ Trautman conspiracy to hijack FDA's deliberative process. In a subsequent e-mail from Trautman to Paul Tilton, et al, dated July 17, 2002, Trautman states, "Utah Medical Injunction is a significant and fairly difficult GMP case." Questioned about this e-mail during her deposition taken by Utah Medical's counsel on April 26, 2005,

Q. Do you remember believing that this would be a fairly difficult GMP case to prove on the merits as of July of 2002?

A. Like I said, I don't think I had the merits of the case in front of me yet, so I couldn't have made that assessment.

Q. If you didn't have the merits of the case in front of you, why was it that you talked in your e-mail about a continuing history of noncompliance with the GMPs?

A. Because it's typical, like I explained in the upfront loading for the district to give you the compliance history.

Q. And you were relying at that point on what the district (Barrell) had told you then?

A. Yes, sir.

---

13 See Exhibit R8, "Food and Drug Administration Inspections of Utah Medical Products, Inc. 1995 – 2004," pgs 11-17 for a detailed breakdown of Barrell's first injunction recommendation. This was part of a letter sent by Larry Pilot to Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, on September 15, 2005. (A first version of the letter was sent to Ms. Glavin on August 4, 2005. )

14 See Paul Tilton, CDRH, hand written notes of the June 13, 2002 telephone conference obtained in discovery, Defendant's Exhibit 22. Kimberly Trautman states in the telephone call, prior to reviewing any documentation, "We have an OAI situation, but things are untidy."

Q. And you didn't have any reason to question that, correct?
A. No, sir.

Despite her misrepresentations to the contrary, Trautman, the FDA's only internal witness at trial, purportedly an independent reviewer, was heavily involved since June 2002 in attempting to build a case to shut down Utah Medical. The following is in a November 14, 2002 e-mail from Trautman to Eric Blumberg, Office of Chief Counsel:

> "Rick:
> CDRH has an injunction package against the firm Utah Medical (DEN-DO) who is being represented by Larry Pilot. CDRH is approving this injunction. The charge is section 501(h). I have reviewed the deficiencies and determined it is a situation one.
>
> We would like to forward the case as approved but have already planned an update inspection for several reasons. First the amount of time that has past. Second, we would like to get a device expert or senior device investigator involved because of the very adversarial circumstances that occurred during the last inspection. Pilot made the inspection extremely difficult and was an obstructionist for the investigator. In addition, Pilot audio taped the FDA 483 close out meeting and has since attempted to refute every word the investigator said. The re-inspection is scheduled for mid-January 03, as discussed with the district.
>
> The firm has not been forthright in providing documents and we would like to obtain several more documents only to further establish deficiencies which are already approvable.
>
> The district has only documented the one most significant device in all the deficiencies. We believe the form has system issues which will cut across the board into all devices. The district is willing to go further and document the deficiencies for all devices. OC has already prepared inspectional guidance for the reinspection."

There are a number of misleading statements, including intentional misrepresentations, identified by this Trautman e-mail. No deficiencies in any of Utah Medical's devices were alleged by FDA in its action! CDRH did not approve the injunction recommendation until January 13, 2003. Trautman admitted in her deposition that, at this juncture in November 2002, she had not completed her review. Larry Pilot did not participate in the 2002 inspection, except to listen in and ask questions by telephone during the FDA-483 close out discussion. That 2002 FDA-483 discussion was tape recorded, so whether or not Pilot was acting properly with his questions in that meeting can be easily determined independently. At its initiative, the Company audio-taped the meeting, not Mr. Pilot. Trautman's statement that "the firm has not been

forthright in providing documents" is egregiously false, as Trautman well knew. That statement is representative of numerous other misrepresentations capriciously passed along by Trautman to senior FDA managers. Trautman had no first-hand knowledge, and no interest in verifying the damaging statements being made about Utah Medical by Barrell, or she simply made it up on her own. A tape recorded July 2002 telephone conversation with Barrell, for example, provides significant evidence, along with other documents in the record, that the Company was forthcoming in offering and providing many important documents (that later were accepted as "resolving" issues) that were simply (and perhaps conveniently) ignored by Barrell/ Trautman at the time, in addition to repeatedly pleading with Barrell after the 2002 inspection (to no avail) to provide whatever else she might need to reach a favorable conclusion about its compliance. The well-documented fact is that the FDA was only interested in shutting down Utah Medical by finding documents that could be twisted into allegations of noncompliance, and had no interest in the substantial evidence of Utah Medical's compliance with the QSR. Trautman's representation that "The district is willing to go further and document the deficiencies for all devices" demonstrates that the intent was to get the Company, not to constructively resolve differences of opinion and help the company achieve compliance. This is at odds with the mission of the FDA, and an abuse of process. Her further statement that "OC has already prepared inspectional guidance for reinspection" proves that the inspectors were told what to find, and later through daily (documented e-mail) conversations with Barrell/ Trautman et al during the inspection, told what to write in their FDA-483. [15]

The 2003 FDA-483 was a sham, comprised of 14 pages with 19 major observation item numbers with 53 total discrete sub-items. The inspectors did not report what they saw. They reported what they were told to see, or what Barrell/ Trautman worded for them to be included in the FDA-483. The following Trautman e-mail to Weixel, Latish, Tilton, with copy to Barrell, on Friday March 7, 2003 illustrates the point. (Chase/Coleman had told the Company on March 6 that the FDA-483 would be issued on March 7.)

> "I thought we had already arranged to review it (the FDA-483) before it was issued! Why can't Ricki (Chase) issue it Monday? If it is issued today without my review, I do not want any complaints if I do not support something because of the way it was written. This 483 is going to have to be dead on, for me to support an observation with all of the issues surrounding the inspections. I will not be able to massage it for the complaint like some cases because Pilot will kill us in court.

15 See DFI Field Alert #19: Investigator Authority and Responsibilities with Issuing the FDA-483, attached as Exhibit R9. "The FDA-483 under the Act, is the "judgment" of the FDA Investigator actually conducting the inspection who actually observed the "conditions or practices" which have caused or may cause the regulated product to be adulterated."

I am willing to review it right now if I can get it electronically!"

Apparently Trautman's request was honored, because the presentation of the 2003 FDA-483 was postponed, and at 10:00 p.m. on Sunday night March 9 at 10:05 p.m., Utah Medical received an e-mail from Chase, "Here is a list of items we need before we close out on Monday (March 10)," requesting some 30 additional documents. The presentation of the FDA-483 was delayed until Wednesday, March 12 so the "massaging" could take place.

On Monday, March10, Patricia Lefler, Coleman's supervisor, wrote an e-mail to four FDA officials, as follows:

> Subject: Utah Medical – Update
> Spoke with Karen Coleman. The FDA-483 issuance has been delayed until Wed 3-12-03. They are finalizing the FDA-483 today and tomorrow. They received feedback from CDRH as well as others which they believe strengthens the FDA-483 and as such will be making those types of corrections."

Of the 53 discrete jointly fabricated items on the 2003 FDA-483, 46 were found to be "resolved" or "corrected" by a fresh team of inspectors in 2004 by simply reviewing preexisting documents and a further response by Utah Medical to the 2003 FDA-483 that was prepared during the 2004 inspection. Only five of 53 items in the 2003 FDA-483, according to the DOJ, related to allegations brought to trial. Validation of injection molding and extrusion, admitted by FDA/DOJ as the most significant issue at trial, came up as a FDA-483 inspectional observation under the QSR for the <u>first time</u> in 2003. (Inadequate validation of injection molding - not extrusion - was listed on the 1995 FDA-483, under the prior GMP regulation, but DDO accepted Utah Medical's response at that time without the Company making any changes. This 2003 observation was a transparent attempt by Barrell/ Trautman to create "a pattern of violations" which didn't exist.)

In summary, over the ensuing three years since the December 2001 meeting, the FDA conducted biased and pretextual investigations of Utah Medical, generating false, misleading, one-sided and biased FDA-483s and EIRs, **<u>not</u>** for the purpose of legitimately ensuring that Utah Medical was complying with the QSR, but for the purpose of punishing Utah Medical by effectively shutting the company down and destroying its business. The FDA-483s and EIRs were the "factual basis" for the FDA's claims of QSR violations in its August 2004 lawsuit. [17] The FDA Regulatory Procedures Manual March 2004 states

> "Rarely in injunction cases will issuance of the FDA 483 constitute adequate notice, in the absence of further notice from agency compliance officials or senior managers."

Except for contact with inspectors, who (with the exception of Wilkins) were not interested in a dialogue that supported its compliance, Utah Medical had no dialogue, feedback or notice from FDA compliance officials or FDA senior managers after 2001. Beginning in 2003, Utah Medical followed the prescribed appeals process to no avail. No inspectors or other FDA representatives with first-hand knowledge of Utah Medical's quality system testified at trial, which is at least an irresponsible use of litigation by the government.[16] And, as a matter of interest, the only (non-lawyer) representatives of the FDA who attended the trial were Trautman and Barrell.

Barrell and Trautman, and numerous other FDA officials by their complicity, attempted in vain to find some pretextual basis for destroying Utah Medical. The investigators in 2003 promised at the outset of the inspection that they would bring objectionable conditions which would be listed on an FDA-483 to Utah Medical's attention as they were observed. They did not honor this promise, apparently in large part because others were crafting the observations, as the FDA-483 presentation was full of surprises. The close-out discussion of the 2003 FDA-483 was also tape recorded. The record speaks for itself. In its April 11, 2003 written response (which should have at least definitively resolved the sterilization validation issue), the Company requested that Barrell provide the feedback that inspectors declined to give.

> "Please provide us with the references as requested, which appear in the transcript provided as Exhibit A.
>
> Upon completion of your review of this response and the requested receipt of applicable guidance documents, I welcome the opportunity to address any concerns, consistent with offers we have repeatedly made in the past."

The request was again ignored. Another injunction recommendation was submitted by Barrell after the pretextual 2003 inspection by Ricki Chase-Off and Karen Coleman, this time supported by Office of Chief Counsel, which was the basis for a DOJ "sign or sue" letter in October 2003, which required the Company to shut down its operations and destroy all of its inventory. After the FDA declined to accept Utah Medical's counter-proposal, which was simply to have FDA identify what changes it wished Utah Medical to make to its quality system coupled with a commitment from Utah Medical to make those changes, the FDA's Office of Chief Counsel and DOJ decided to conduct another pretextual inspection of Utah Medical in early 2004 by Lori Medina, Ralph Jerndal and Monica Wilkins to attempt to perfect a basis for its injunction lawsuit that it had already decided to file.

---

16 Id. "it is the CSO's responsibility to be able to attest in a legal forum that he/she personally observed the (FDA-483) observations and the supporting evidence."

On March 16, 2004, Utah Medical provided a written response to the DDO Director for the 2004 FDA-483 issued on March 3, which began

Re; Form FDA 483 (7/00), Inspectional Observations, Issued 3/3/04
Monica Wilkins, Lori Medina and Ralph Jerndal, Inspectors

Dear Ms. Collins:

This letter responds to the FDA-483 issued to Utah Medical Products, Inc. (UTMD) on March 3, 2004 by Inspectors Monica Wilkins, Lori Medina and Ralph Jerndal. UTMD's responses and the attached Exhibits each contain confidential information that is not disclosable to the public under the Freedom of Information Act. The following responses are a detailed, but not necessarily fully exhaustive, discussion of the issues. UTMD requests a dialogue with appropriate Food and Drug Administration (FDA) personnel as to any issues for which the following responses are deemed inadequate, so that an exhaustive discussion can occur.

We have carefully reviewed and subsequently investigated all of the observations to determine if the inspectors' observations were indicative of an isolated situation or suggestive of a systemic issue. For years, UTMD has maintained to the FDA that it is in compliance with a reasonable interpretation of the Good Manufacturing Practice (GMP)/Quality System Regulation (QSR) and that it has been and is functioning in a state of control. None of the limited inspectional observations developed after a five (5) week period of inspection are adequate to contradict our position. Frankly, the pervasive intensity of this inspection by three (3) inspectors contradicts most of the prior observations made by Ms. Ricki Chase-Off and Ms. Karen Coleman.

UTMD believes that its conduct and interaction with the inspectors during the period of inspection confirms representations we have repeatedly expressed to your office and others in the FDA about the quality of our performance and the devices we manufacture and distribute. We have nonetheless been denied Certificates to Foreign Government (CFGs). These FDA denials have been harmful to our ability to export devices that are clearly safe and effective for their intended uses, and for which foreign purchasers are being denied benefits that have been and continue to be available to U.S. health care practitioners and their patients. Consequently, we request that you expedite your review of our response and agree to the issuance of requested CFGs because it is the right thing to do.

Where the inspectors made suggestions which are not requirements under the QSR, UTMD has reviewed them with its expert consultants for applicability in its quality system.

> Transcript of the 2004 FDA-483 Discussion with Management on 3-3-04
> The transcript is attached as Exhibit 1. References to discussion in the transcript will be indicated as (T-page no. in Exhibit 1).
>
> **What the inspectors found was a comprehensive and well-established and implemented quality system where adequate procedures existed, and were being followed with required documentation being maintained and disclosed in a timely manner.** UTMD's records indicate that more than 1,000 documents and support data comprised of 10,000 pages as identified below were reviewed by the inspectors:

After receiving no FDA response whatsoever, on May 13 Utah Medical formally requested nonbinding mediation, with the CDRH Ombudsman volunteering to act as mediator. On June 9, 2004, Tim Ulatowski responded to the Company's counsel that he had discussed the request for mediation with agency personnel, including the General Counsel's office, and it was the agency's position that it was not in position to commit to a mediation at this time. Ulatowski stated that FDA "prefers to keep their options open." In other words, the FDA preferred to pursue a frivolous lawsuit for permanent injunction rather than open dialogue that might lead to a constructive resolution of differences. This was in direct violation of agency policy. [17] All three conditions listed in the FDA Regulatory Procedures Manual Section 6-2-5 as requirements for adequate notice were not met, or were violated.

On August 9, 2004, the FDA filed a lawsuit against Utah Medical and two of its executives seeking permanent injunctive relief that would have effectively closed Utah Medical down and destroyed its business, even though the FDA was unable to allege or claim that Utah Medical had manufactured or distributed any unsafe, defective or ineffective finished medical devices. The FDA's case was based on pure speculation on what might happen if the stars aligned in some imagined way. From 2001, Barrell/ Trautman had no evidence of violations of the QSR and simply believed that if they kept looking they would be able to fabricate something that could be used to force Utah Medical into submission, or be destroyed. After the lawsuit was filed on August 10, 2004, Tara Boland, FDA Associate Chief Counsel wrote a letter to Larry Pilot, Utah Medical's attorney, in which she said

> "as you are aware, the Department of Justice ("DOJ") has begun litigation to obtain an injunction against Utah Medical. However, both the agency and DOJ remain open to the possibility of settling this matter through a consent decree, *with terms acceptable to the government*, (emphasis added) at any point during the litigation. We hope that Utah Medical will

17 See "Regulatory Procedures Manual March 2004," Chapter 6 Judicial Actions, Section 6-2-5 Adequate Notice Preceding Injunction Actions.

> agree to a consent decree so that we can work together to help Utah Medical achieve compliance with the QS regulation."

The consent decree that had been offered Utah Medical in October 2003 required that Utah Medical shut down operations, destroy all of its inventory and hire a consultant to certify its quality system, after which it could reopen its business after acceptance solely by FDA (no doubt, in the person of Trautman) of the consultant's certification. As this draconian offer was tantamount to destruction of Utah Medical's business, it was not a feasible option. To Utah Medical, it certainly didn't make sense to destroy millions of dollars of inventory when no devices had been identified that did not meet specifications. Still not knowing what it was violating, Utah Medical provided its counterproposal that if the FDA would identify what specific quality system changes they wished to be implemented, Utah Medical would commit to a date certain that they would be done without arguing whether or not they were requirements. The government's response to that counterproposal was negative, "We are not going to tell you what you are violating. You tell us what you are going to do to get into compliance." The paradox should be clear. It was clear to Utah Medical from the response to its counterproposal and the lack of past constructive dialogue since the December 2001 meeting that there weren't any "terms acceptable to the government" other than the destruction of the Company. It wasn't until the government had to identify its claims with specificity in pretrial hearings in 2005 that Utah Medical learned of what the FDA finally decided to present as violations. If the changes required were so minor as represented by DOJ to the judge during the trial, then why did the FDA refuse Utah Medical's counterproposal in 2003?

Utah Medical had received no feedback from the FDA since the December 2001 meeting in Denver with Barrell and Manresa, in which it appeared that all issues regarding the content of the Warning Letter had been addressed. In court, the DOJ speciously contended that the inspectors and the FDA-483s provided all the feedback that Utah Medical needed.[17]

Since Utah Medical filed its original claim with DHHS in July 2005, and after two years of litigation (initial litigation started in 2003 as a result of the FDA's refusal to provide Certificates to Foreign Governments) and the expenditure of millions of dollars in attorneys' fees and costs in defending the FDA's baseless QSR violation charges, the United States District Court for the District of Utah, after an exhaustive examination of the technical facts, rejected the FDA's claims in their entirety, ruling that Utah Medical was and is in full compliance with the QSR, and denied the FDA's request for a permanent injunction. [18] From the date the government filed its lawsuit to the date of the

18 The government never sought a temporary injunction.

Court's decision, fourteen months elapsed during which time Utah Medical distributed more than one million finished devices for use in the U.S. with no restrictions.

The tortious, willful, fraudulent, and bad faith conduct of the FDA officials in pursuing the meritless litigation against Utah Medical for the purpose of punishing and obtaining revenge against Utah Medical's failure to hire a consultant at the time of the 2001 Warning Letter caused Utah Medical significant damage to its reputation for providing high quality medical devices and pecuniary damages in the amount of at least $7,327,688.80, including lost profits, lost executive time and attorneys' fees, costs and consultant and expert witness fees and costs, all as set forth in Utah Medical's original claim. The FDA officials involved in the inspections violated numerous provisions of the FDA's Investigations Operations Manual ("IOM") which the FDA has stated "is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors." [http://www.fda.gov/ora/inspect-ref/iom/] Numerous FDA officials violated the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635) [http://www.usoge.gov], the Regulatory Procedures Manual, Chapter 6 Judicial Actions, as well as other U.S. government policies and procedures.

**The 2001 Inspection**

During June 2001, Utah Medical was inspected by an investigator from the FDA's DDO. Several observations were conveyed to Utah Medical on a FDA-483 dated June 8, 2001. On June 27, 2001, Utah Medical promptly responded in writing in detail to each observation, including nine exhibits. At the end of the cover letter, Utah Medical wrote

> "In summary, UTMD has addressed all of the observations of the inspector and is committed to making necessary changes in its quality system within a short period of time. Respectfully, I hope you agree that these observations do not warrant a QSIT Warning Letter which might mislead medical practitioners who trust our products in high risk situations into concluding that UTMD's products aren't the safest choices available, which is the basis for UTMD's survival in the marketplace.
>
> I would like to reserve the opportunity to provide more details to augment these responses, if after review, the FDA District Compliance Office is not completely satisfied that the observations have been properly addressed. Please do not hesitate to call me directly at (xxx) xxx-xxxx (number deleted)."

Utah Medical had no further communication from the FDA until September 4, 2001 when the DDO sent Utah Medical a surprising multiple page Warning Letter authored by Barrell taking the position that Utah Medical was in violation of the QSR in various respects, and requesting that Utah Medical obtain the services of an independent consultant to certify the compliance of its quality system with the QSR. When Utah Medical's CEO, Kevin Cornwell, asked Barrell for an explanation as to why the FDA was requesting that a consultant be hired, Barrell stated that it was because Utah Medical was

a "recidivist." This statement was false. The FDA had conducted an inspection of Utah Medical in 1995 under the prior 1978 Good Manufacturing Practice ("GMP") regulation, and had been issued a warning letter on August 15, 1995. Utah Medical responded on August 31, 1995 and on September 11, 1995, then DDO Director, John Scharmann, sent a letter to Utah Medical advising acceptance of the written response by Utah Medical. In 1998, an FDA inspector from the FDA Salt Lake City Resident Post completed a comprehensive inspection of Utah Medical under the QSR, confirmed that the company had made all corrections as promised in 1995, and did not issue an FDA 483, thus signifying that Utah Medical was in full compliance with the QSR. The 2001 inspection was the next inspection following the clean 1998 inspection. In 2001, except for routine upgrading and improvements, Utah Medical's manufacturing processes, products and quality system were substantially the same as in 1998. If anything, the Company's quality system was more robust than in 1998.

In response to the September 4, 2001 Warning Letter from the FDA, Utah Medical requested and obtained a meeting with the FDA to try to better understand the basis for the Barrell recidivist statement and Barrell statements in the Warning Letter that didn't seem to be supported by the FDA-483, and to clear up any misunderstandings about its written explanations or provide additional needed details to reach resolution of any FDA concerns. On December 21, 2001, Mr. Cornwell, John Smith (Utah Medical's Manager of Quality Assurance) and Utah Medical's counsel Larry Pilot met at the DDO with Barrell and Howard Manresa, the DDO Compliance Branch Director and Barrell's supervisor. Utah Medical persuasively demonstrated it was in compliance with the QSR. The FDA officials listened to Utah Medical's presentation, without substantively responding or explaining why in view of the evidence presented by Utah Medical that FDA believed that Utah Medical was not in compliance.

Throughout the four year ordeal, until the Court required the government to present its claims, FDA refused to tell Utah Medical what it was violating. The government took the position that the FDA-483s gave the company the "feedback" it needed to identify its violations. That position is flawed in several respects. 1) As a practical matter, most of the FDA-483 observations did not withstand scrutiny of FDA reviewers and were not part of the FDA claims at trial. For example, the primary pretextual inspection which set up the ultimate acceptance of the injunction recommendation by FDA Chief Counsel, contained 53 discrete items, only five of which were included as part of the lawsuit. 2) The observations changed from year to year. For example the primary observations upon which the 2002 and 2003 injunction recommendations were based, lack of sterilization validation, were not part of the 2001 FDA-483 or the Warning Letter, and were "resolved" in 2004 by a different inspector reviewing essentially the same information available to the prior inspectors. (The government misrepresented in Court, as an explanation why the most serious observation

had disappeared and was not part of the lawsuit, that Utah Medical presented new information in 2004 that the previous inspectors did not have.) 3) The FDA's own internal policies clearly state that FDA-483s, of themselves, do not represent "violations" of the QSR. The inspectors in 2003 committed to the company that FDA reviewers would link QSR violations to their observations. Nothing was ever provided until after the lawsuit was filed.

As a counterproposal to the October 2003 "sign or sue" letter, Utah Medical offered to fix by a date certain whatever changes to its quality system that FDA identified as needed, without contesting relevance to the QSR. The FDA refused to identify any. After the 2004 inspection and its 1,000 page written response to the FDA-483, having received no feedback whatsoever from reviewers (Barrell/ Trautman) since the 2001 meeting and having obtained consent from FDA's CDRH Ombudsman to act as mediator, Utah Medical requested non-binding mediation in an effort to understand what FDA believed it was violating. Mediation was refused.

At the conclusion of the December 2001 meeting, Barrell's only substantive response was to question Mr. Cornwell whether Utah Medical was going to retain the services of a consultant as required by her Warning Letter, despite the fact that the FDA had no legal authority to require a consultant. Mr. Cornwell responded that Utah Medical could not justify retaining the services of a consultant if it is in full compliance with the QSR, but told her that Utah Medical was prepared for another inspection at any time.

**The 2002 Inspection**

On March 26, 2002, the FDA commenced a four-day inspection (five days including the FDA-483 presentation) of Utah Medical conducted by Ricki Chase-Off ("Chase"). Rather than following FDA instructions that the focus was to be "a limited follow-up inspection" to review the company's actions in response to the 2001 EIR and Warning Letter, Chase engaged in a fishing expedition to find and/or fabricate new violations. Her comments to Utah Medical officers at the beginning of inspection, including pointing out with pride in being instrumental in "bringing down" Abbott, demonstrated that she was biased and intent on finding violations rather than conducting an unbiased inspection.

The close out conference at Utah Medical during which Chase disclosed her purported inspectional findings lasted for approximately four and a half hours and was tape recorded. During the conference, in violation of FDA policies, Chase improperly contended that Utah Medical had violated the QSR in a number of respects. Under the IOM, Chase was only permitted to "[ex]plain, in your judgment the conditions . . . [she] observed may be determined by the FDA, after review of all the facts, to be violations." Because of Utah Medical's concern about Ms. Chase and the biased nature of her

inspection and purported findings, Utah Medical requested a meeting with DDO Director Belinda Collins ("Collins") to discuss the inspection and close out conference. Utah Medical's request was ignored. Consequently on May 9, 2002, Utah Medical provided a comprehensive written response to the FDA-483 to the DDO in addition to previously having provided copies of the tape recordings and verbatim transcript of the close out conference to demonstrate Chase's improper conduct and bias. Utah Medical's detailed written response with fourteen exhibits demonstrated that it was in full compliance with the QSR. The items listed by Chase in her FDA-483 had little connection with the prior 2001 FDA-483 even though that prior FDA-483 was to be the focus of the inspection.

Moreover, in this and subsequent inspections, the FDA inspectors violated the IOM by refusing "to relate each listed condition (FDA-483) to the applicable sections of the laws and regulations administered by the FDA." After 2002, when asked, Chase and the other inspectors refused to relate alleged deficiencies to any laws or regulations.

Mr. Cornwell subsequently attempted to determine the status of the FDA's review of Utah Medical's response to the 2002 Form FDA 483 and to obtain copies of the 2001 and 2002 EIRs. On May 13, Shelly Maifarth, Acting Director, Compliance Branch, DDO wrote a letter to Utah Medical acknowledging receipt of the Company's May 9 written response to the FDA-483 and responding to Mr. Cornwell's request for a copy of the 2001 and 2002 EIRs.

> "You have also requested a copy of the last two Establishment Inspection Reports for your review to assure that our office has the benefit of your position relative to the reports' content. Be advised that we do not release reports for such a purpose. **Copies of the narrative reports will be released to you when we have concluded our review** (emphasis added)."

Barrell misrepresented that she was still reviewing the file when in fact she had already completed and sent in a month earlier her recommendation that the FDA commence an injunction action against Utah Medical, which recommendation had been preceded by a "heads up" telephone call she made to CDRH during which she made false, defamatory statements against Utah Medical and its employees. Barrell's injunction recommendation was approved by her supervisor Manresa and DDO Director Collins even though they had not even read the FDA-483, EIR and Utah Medical's detailed response, and had no legitimate basis for approving the recommendation. They simply rubber-stamped Barrell's recommendation.

The alleged violations claimed by Barrell in June 12, 2002 injunction recommendation were egregiously false:

> "Over the past seven years, inspections of UMP conducted by Denver District, have found continuing, significant deviations from

> the QSR. Although formally notified of these deviations through two Warning Letters and face-to-face meetings, the firm has refused to make corrections. Mr. Cornwell submitted responses that indicated an unwillingness to cooperate with the Agency. For example, the September 2001 Warning Letter . . . required the firm to employ an outside consultant to evaluate and suggest corrections, instead hiring Mr. Larry Pilot as their attorney to refute the observations made not only in the 2001 inspection, but in the 2002 inspection, as well.
>
> Because of the conditions described above, the firm's medical devices are adulterated within the meaning of Sections 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The firm and its responsible individuals violated Section 301(k) of the Act by manufacturing, packing, storing, and holding for sale articles of device, after shipment of one or more of their components in interstate commerce, under conditions that caused the articles to become adulterated."

Utah Medical had not been found over the past seven years to have continuing significant deviations from the QSR. The QSR was not in effect in the 1995 inspection. In 1995, Utah Medical immediately had made necessary minor corrections with respect to the prior GMP regulation in response to that inspection that were accepted by the DDO Director and confirmed in the 1998 FDA inspection during which no deviations were discovered and no FDA-483 was issued. The alleged deviations during the 2001 inspection were the first identified under the QSR, and their significance or correctness was contested by Utah Medical. Utah Medical's attempt to engage in good faith discussions with DDO about the inspection was ignored. After the 2002 inspection, Barrell failed to disclose Utah Medical's repeated attempts to discuss alleged deviations. Utah Medical never refused to make necessary corrections. Utah Medical did make specific corrections relating to the 2001 inspection which the FDA acknowledged in its 2002 EIR, as well as in ensuing inspections. Utah Medical further demonstrated that no other corrections were necessary with respect to the 2001 or 2002 or 2003 or 2004 inspections, and the United States District Court ultimately confirmed that position. Moreover, it was blatantly false for Barrell to state that there was any linkage between deviations in the 1995 inspection and the 2001 inspection relating to a typographical error in a device master record, or later the 1995 and the 2003 inspection as it related to injection molding and extrusion.

The Company had also not demonstrated any unwillingness to cooperate with the agency. Mr. Cornwell promptly responded to each inspectional observation for each inspection, demonstrating a complete willingness to cooperate. The Company's

responses later proved to have been dispositive, if a reader had been open-minded and objective rather than intending to shut the Company down. Mr. Cornwell repeatedly sought substantive discussions with FDA compliance officials in an effort to cooperate and address the FDA's concerns, to no avail. The FDA officials refused these efforts because Mr. Cornwell and Utah Medical were not willing to "knuckle under" and comply with Barrell's unlawful and unjustified demand that Utah Medical spend hundreds of thousands of dollars to hire a consultant.

Barrell's criticism of Utah Medical for hiring an attorney to protect its interests speaks eloquently of her view that Utah Medical should just do what she had commanded, and should not have the temerity to challenge her unfounded opinions, or ensure that its constitutional and legal rights were protected.

Finally, contrary to Barrell's reckless charge, Utah Medical's medical devices were not adulterated. As stated above, the FDA ultimately admitted in the FDA action that there was no evidence that Utah Medical's devices were unsafe, or defective, or ineffective.

From May through December, 2002, Utah Medical (not knowing of the secret injunction recommendation) made repeated requests to FDA's DDO and FDA headquarters personnel for feedback on Utah Medical's May 9, 2002 response, a copy of the EIRs for 2001 and 2002, and an opportunity to discuss the issues to seek resolution. The FDA ignored these requests until January 13, 2003 when Utah Medical finally received copies of the 2001 and 2002 EIRs, which implied to Utah Medical that the FDA was satisfied and the 2001 Warning Letter closed, based on the May 13 letter from Maifarth and Barrell's prior statements to Mr. Cornwell that the FDA was unable to provide a copy of the EIRs until the Warning Letter was closed. The EIRs were actually provided at the same time that FDA was planning another inspection for which a list of violations to be found was prepared in advance by CDRH and given to the inspectors, and for which the "district is willing to go further and document deficiencies for all devices." (Trautman quote) In fact, no deficiency for any finished device was ever alleged by FDA.

When Utah Medical finally received a copy of the 2002 EIR, it learned that Chase-Off had prepared a 66-page EIR in connection with the 2002 inspection. The EIR was replete with material misrepresentations and inaccuracies. The majority of the EIR was simply a biased revision of the April 15, 2002 close out discussion for which there was a verbatim transcript of the audiotape.

**The 2003 Inspection**

On February 24, 2003, two FDA investigators, Karen Coleman ("Coleman") and Chase, appeared at Utah Medical's facility for yet another inspection. Cornwell contacted DDO Director Collins to request postponement of the inspection until Utah Medical had an opportunity to meet with the DDO regarding the 2001 and 2002 EIRs. Cornwell also requested that Chase be recused from the inspection because of her obvious bias and prejudice. These requests were summarily denied and the FDA refused to meet with Utah Medical on March 7, 2003 as previously agreed because the FDA would not accept the agenda prepared by Utah Medical. In other words, the FDA was only willing to discuss Utah Medical acceptance of its unlawful demand that Utah Medical hire a consultant to certify its quality system. The DDO Director, and later on appeal, the Regional Director, Dennis Baker, refused to recuse Chase from the 2003 inspection. Baker indicated to Mr. Cornwell on the telephone on February 27, 2003, "We do take Utah Medical's concerns seriously, but recusing Chase is not an option. We won't ignore your concerns about Chase." Later in September 2003, Utah Medical received this in a letter from Baker:

> "During our meeting with you at your facility on May 15, 2003, Denver District Director B. Belinda Collins and I assured you that the Agency takes all allegations of investigator misconduct very seriously. As a courtesy, I am advising you that our investigation of your allegations is now complete. Based on the information that you provided me and Ms. Collins, we have conducted an investigation of CSO Chase-Off's behavior and have found no evidence of misconduct, wrong-doing, or bias in connection with the Denver District's evaluation of the facts documented during the Food and Drug Administration's (FDA) March through April 2002 inspection of your facility."

Deposition testimony of the FDA people who were supposedly charged with the "investigation" revealed that no investigation had been done, or if done, not documented anywhere. In the FDA's terms, if it isn't documented, it didn't happen. Furthermore, isn't it reasonable to expect that the entity making a complaint would be contacted for information during a proper investigation? Utah Medical was never contacted. Baker's conclusion was parroted by other senior FDA officials as if it were fact, including John Taylor and Ombudsperson Laurie Lenkel.

Mr. Cornwell allowed the 2003 FDA inspection to proceed because Collins misrepresented to him that the inspection was a "routine follow-up" to the 2002 inspection. In fact, as Utah Medical learned during discovery in the FDA Action, the inspection was not a "routine follow-up" but was instead a pre-scripted calculated attempt by the FDA to obtain pre-filing discovery from Utah Medical in support of an injunction action that the FDA had already decided to institute. During her deposition in the FDA Action, Chase stated that she had not been given any direction or instruction prior to the inspection that she should determine whether or not Utah Medical had addressed the FDA-483 observations from her 2002 inspection. Coleman likewise was unable to

remember any such directions or instructions. At the beginning of the 2003 inspection, Mr. Cornwell requested that they review together the Company's written response to the 2002 FDA-483, since the Company had received no feedback to it. Chase refused to discuss it.

During the course of the 2003 inspection, the investigators routinely communicated with FDA personnel in both the DDO and CDRH to attempt to build a case against Utah Medical for the planned injunction action. Chase-Off sent routine e-mails to CDRH's Trautman and others. During the inspection, Trautman communicated directly with the investigators and further directed that she review the inspectional observations before these were presented to Utah Medical so that she could "massage" the observations to bolster the case against Utah Medical. On February 28, 2003 during the inspection, Trautman sent the following e-mail which included specific instructions to the inspectors, and copied Weixel (who had prepared the list of violations for the inspectors to find) and Barrell,

> "These are the three big areas I want to focus this inspection on and *any future action* (emphasis added). So I need specific issues or items to be tied back to these big system failures.
>
> PLUS please do not forget that we must be able to prove that these problems are not just with the one product that FDA historically has focused on. We need some examples with other products if possible. We need to prove these are global system problems not just with one product line.
>
> Please do not hesitate to email or call me. I will be in the office early Monday 6:30am my time so do not hesitate to call – ***I am here to help you guys so that we can jointly make the best case possible.*** (emphasis added) Thanks for the update and keep your chins up – ***you are doing an impossible job***."

So much for independent objective review by the FDA's senior quality systems expert who would be the only FDA representative to testify at trial, as an expert witness. Trautman was honest about one thing: The inspectors <u>were</u> doing an impossible job – trying to find a basis for the Company to be in violation of the QSR when it had an excellent quality system in full compliance with the QSR, and no evidence of defective products! These communications violated FDA policies and procedures, and the Administration's code of ethics. In short, the investigators acted not as unbiased investigators objectively assessing evidence of compliance, but as prosecutors under the thumb of their superiors attempting to build a predetermined injunction case against Utah Medical.

The 2003 FDA-483 discussion occurred on Wednesday, March 12, 2003. This meeting was recorded and transcripts prepared by Utah Medical. Utah Medical prepared

a written response with five exhibits to the FDA-483 sent by federal Express on April 11, 2003 demonstrating compliance, particularly in regard to the highest level alleged objectionable condition, lack of sterilization validation. But Barrell didn't wait for it. She had already rushed a new injunction recommendation to CDRH. Once more, Utah Medical's response and its requests for discussion fell on deaf ears.

The primary basis for the 2003 injunction recommendation and the primary focus of the Form 483 was Utah Medical's alleged failure to validate sterilization of its devices. This claim was absolutely false as the FDA itself was forced to admit when it later conducted a 2004 inspection and a new sterilization expert, Monica Wilkins, reviewing essentially the same documentation as reviewed by Coleman in 2003, concluded that Utah Medical's sterilization validation procedures did not violate the QSR. In the 2004 EIR obtained during discovery, Wilkins wrote more than one hundred pages of detail explaining what she reviewed and why she concluded that there was no evidence that Utah Medical's sterilization and packaging were "objectionable," in stark contrast to the fabrications of Chase and Coleman (or Barrell and Trautman) in 2002 and 2003.

**The FDA Retaliates by Denying Certificates to Foreign Governments.**

Continuing its retaliation against Utah Medical, on April 1, 2003, the FDA denied Utah Medical's request for renewal of Certificates to Foreign Governments ("CFGs") necessary for Utah Medical to distribute its medical devices in some foreign countries. The FDA denied Utah Medical's request for all of its product lines when the FDA had not even assessed whether such product lines were being manufactured and distributed in accordance with applicable regulations, and despite the fact that four days earlier on March 27, 2003, the FDA's Weixel had told Barrell that the FDA's own outside consultant could not support an injunction except as to one product line on which the FDA had focused. The FDA took this irresponsible action that restricts American commerce in direct contravention of the intention of Congress in order to punish Utah Medical for refusing the FDA's unlawful demand that Utah Medical hire a consultant. Utah Medical was forced to file a legal action against the FDA to try to expose the basis for the decision to deny CFGs. After the judge denied Utah Medical's motion to compel release of internal FDA documents (that were ultimately obtained as part of discovery in the FDA's injunction lawsuit), realizing the basic issue of QSR compliance was common to both actions and not wishing to fund two lawsuits for the same underlying dispute, Utah Medical withdrew its CFG complaint.

**October 2003 Sign or Sue Letter**

Utah Medical first learned of the government's intention to pursue an injunction in October 2003. The consent decree that had been offered Utah Medical in October 2003 required that Utah Medical shut down operations, destroy all of its inventory and hire a consultant to certify its quality system, after which it could reopen its business after

acceptance solely by FDA (no doubt, in the person of Trautman) of the consultant's certification. As this draconian offer was tantamount to destruction of Utah Medical's business, it was not a feasible option. To Utah Medical, it certainly didn't make sense to destroy millions of dollars of inventory when no devices had been identified that did not meet specifications. Still not knowing what it was supposedly violating, Utah Medical provided its counterproposal that if the FDA would identify what specific quality system changes they wished to be implemented, Utah Medical would commit to a date certain that they would be done without arguing whether or not they were requirements under the QSR. The government was only willing to allow it's offer, which was the remedy sought in its lawsuit, without the benefit of due process, so discussions terminated.

**The 2004 Inspection**

On February 2, 2004, three FDA investigators from different parts of the country arrived at the Utah Medical facility. The investigators were given an "injunction list" of information to gather to attempt to support an injunction action, which Medina referred to audibly on two occasions during the inspection. The inspection terminated on March 3, 2004 with the issuance of seven observations on a FDA-483. Utah Medical promptly provided a comprehensive 1000-page written response on March 16, 2004 in which Utah Medical again requested a dialogue with the FDA as to any issues for which the "responses are deemed inadequate, so that an exhaustive discussion can occur."

One more time, the FDA thumbed its nose at Utah Medical and refused to respond. The allegation of lack of validation of injection molding and extrusion molding became the FDA's number one issue at trial. Utah Medical's nationally recognized expert on injection molding and extrusion, Professor Stephen Burke Driscoll, Department of Plastics Engineering at The University of Massachusetts Lowell, performed an on-site audit in contrast to any of the FDA's experts testifying at trial. Professor Driscoll submitted a written expert's report on January 8, 2005 and testified later at trial that Utah Medical's procedures were appropriate and fully complied with the QSR, and the court so ruled. Professor Driscoll had been retained by the FDA in the 1980s and early 1990s to train FDA inspectors and other compliance personnel in the fundamentals of plastics processing. The FDA's outside expert on validation of injection molding and extrusion, Anita Thibeault, was first trained in Professor Driscoll's training course. Professor Driscoll's expert report states in Section II. Summary of Opinions,

> "As further described in this report, the FDA fundamentally misconstrues and misunderstands the nature and principles of plastics parts manufacturing, such as injection molding and extrusion. This is evident, for example, from the deposition of Ms. Trautman and its Exhibit 1 (May 24, 2004 [CDRH] Memorandum [written by Trautman supporting the DDO injunction recommendation]), which are ***distorted, inaccurate, and unreasonable*** (emphasis added) in many respects. My report explains my opinions (and the basis and reasons for my opinions),

including the opinions summarized below and/or otherwise discussed in this report:

1. Plastics parts manufacturing (specifically, extrusion and injection molding) is by its nature an inexact and imperfect science that relies on personal experience and Edisonian adjustment;

2. Utah Medical has properly established process parameters and Utah Medical maintains procedures and protocols to monitor and control process parameters;

3. Utah Medical's procedures and guidelines related to extrusion and injection molding operations and process control are superior;

4. Utah Medical's sampling plans are rational and more than adequate to ensure that products meet specifications;

5. Utah Medical maintains appropriate process controls for its extrusion operations and its injection molding operations;

6. Utah Medical confirms, through inspection and testing (including objective evidence), that its products meet specified requirements and destructive testing is not necessary; and

7. Utah Medical establishes (including by objective evidence and with a high degree of assurance) that its processes consistently produce products that meet predetermined specifications .

Ironically, the inspectors in 2004 knew that Utah Medical had retained an independent plastics processing expert after the 2003 inspection in which injection molding and extrusion process validation first came up, to provide an opinion regarding its injection molding and extrusion process validations. The resulting favorable opinion attached as Exhibit R10 was provided to FDA prior to the filing of the lawsuit, but once again ignored.

**The FDA Action**

On August 9, 2004, the FDA commenced its injunction action against Utah Medical in accordance with the FDA's long-standing plan. Utah Medical was forced to expend millions of dollars in defending that claim and incurred millions of dollars of lost profits as a result of the claim, even though the FDA officials responsible for instigating the lawsuit and pursuing the lawsuit knew, or should have known, that the claims were baseless. Despite the fact that the FDA later admitted it had no evidence that Utah Medical's products were unsafe, the FDA issued a misleading press release aimed at punishing Utah Medical and damaging Utah Medical's relationship with its customers in which FDA Acting Commissioner Lester M. Crawford stated that "FDA will not tolerate

manufacturing practices that can potentially put patients at risk" and that "patients have a right to expect that the medical devices used to treat them are safe and ineffective."

At trial, Utah Medical presented the testimony of its expert witness, Edward J. McDonnell. Mr. McDonnell was employed by the FDA for 28 years ending in 1994. Among other positions, he served as District Director of the FDA's New England District and received from the Commissioner of the FDA the FDA Award of Merit and the FDA Distinguished Career Service Award. Mr. McDonnell testified, among other things, that Utah Medical fully complied with the QSR, that the investigators who conducted the Utah Medical inspections engaged in practices in disregard of explicit instructions and policies stated in the FDA's Investigations Operations Manual and prepared EIRs that contained numerous misrepresentations and material omissions of the facts. After a trial lasting several days, the judge presiding over the trial in the United States District Court for the Central District of Utah ruled in Utah Medical's favor that it was in compliance with the QSR and that the FDA's claims to the contrary were without merit. The court denied in all respects the FDA's request for an injunction.

In this regard, although the FDA had demanded prior to filing suit that in order to settle the matter Utah Medical agree, among other things, to destroy its inventory and stop sales of product (which the court noted was "draconian relief") and the FDA alleged in its complaint that Utah Medical should be required to stop sales of product – which included the sales of components not regulated by the FDA to other medical device companies, the FDA ultimately was forced to face reality and limit the relief it sought to "simply regulatory compliance." Despite the plethora of alleged violations asserted by the FDA as result of its numerous inspections, at trial the FDA jettisoned all of its baseless claims except the claim that Utah Medical had not properly validated its extrusion and injection molding processes, had not properly validated its software programs used as part of production for the quality system and had not properly processed complaints with respect to lookbacks and failure codes. The court held in accordance with the testimony of Utah Medical's expert, Mr. Driscoll, that Utah Medical had properly validated its extrusion and injection molding processes. The court further ruled that Utah Medical had properly validated its software programs and that Utah Medical had properly processed complaints. The court noted that it "has been impressed as well by the 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."

## ABUSE OF PROCESS

In committing the outrageous acts, generally but not exhaustively, described above, the FDA officials committed the tort of abuse of process under Utah law which defines abuse of process as "the misuse of the legal process, whether criminal or civil,

against another primarily to accomplish a purpose for which the process is not designed." *Gilbert v. Ince,* 981 P.2d 841(D.Utah 1999) ("Restatement(2d) of Torts §682 at 474 (1977)"). Under the Federal Tort Claims Act, the United States has waived immunity for claims of abuse of process when the claim arises out of the actions or omissions of "law enforcement officers." 28 U.S.C. §2680(h). For the purposes of this section, the term "law enforcement officer" means "any officer of the United States who is empowered by law to execute searches, to seize evidence, or to make arrests for violations of federal law. . ." The FDA officials constitute "law enforcement officers" because they are empowered to search and seize evidence. *See* 21 U.S.C. §374; FDA Regulatory Procedures Manual, CH.6, 6-50 (March 2004). The following federal agents have been held to "law enforcement officers" within the meaning of §2680(h) of the FTCA: (1) postal inspectors (*Harms v. United States*, 972 F.2d 339 (4th Cir. 1992); (2) agents of the Drug Enforcement Agency (*Van Schaick v. United States*, 586 F.Supp. 1023 (D.S.C. 1983)); (3) FBI agents (*Brown v. United States*, 653 F.2d 196 (5th Cir. 1981)); (4) customs inspectors (*Jackson v. City of Kenner*, 1987 WL 18149 (Ed. La. 1987).

The discretionary function exception to the Federal Torts Claims Act precludes claims against the United States that are "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved was abused." *See* 28 U.S.C. §2680(a). In order to determine whether this exception applies, the courts engage in a two-part analysis. First, the court determines whether the challenged conduct involves "an element of judgment or choice." *United States v. Gaubert*, 499 U.S. 315, 322 (1991). This requirement is not met in the present case because the inspection procedure is closely regulated by the standards set forth in the FDA's IOM which precludes the agents from exercising discretion in tailoring their conduct and observations to the requirements set out in their procedural guide. Second, if the conduct involves some element of judgment or choice, the court determines whether the conduct implements social, economic, or political policy considerations. *See Gaubert,* 499 U.S. at 322-23. In the present case, the falsification of records, improper use of an inspection to conduct pre-complaint discovery and the filing of a lawsuit to punish Utah Medical contravenes regulations and/or FDA guidance materials. Therefore, the discretionary function exception does not apply because FDA officials had no discretion to deviate from the course prescribed by the IOM and Guide to Inspections, and the compliance officials were violating regulatory guidelines, one of the most significant of which is "Inspectional observations relative to those [QS/GMP] systems should be related to noncompliances of significant risk." (FDA Guide to Inspections) The FDA admitted it had never undertaken a risk analysis, in a four year campaign to shut down the Company!

The FDA officials committed an abuse of process under Utah law by the outrageous conduct in which they engaged, including their improper use of the 2003 and

2004 inspections to conduct pre-complaint discovery, and filing the FDA Action primarily for the purpose of retaliating against and punishing Utah Medical for declining to hire a consultant (in 2001) to certify its quality system as improperly demanded by (Barrell) the FDA.

## 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 persecution 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 outrageous conduct of the FDA.

## CONCLUSION

In its investigations of Utah Medical, the FDA officials committed flagrant abuses of process damaging Utah Medical's reputation and business to the tune of millions of dollars. The FDA created a fraudulent (some of it still potentially) public record, unfairly harming Utah Medical's reputation, particularly by defamatory remarks within and outside the agency and the August 10 press release, a reputation for manufacturing innovative, safe and effective medical devices which was built over decades by hundreds of honest, law-abiding and hard-working citizens.

The FDA violated its principles set forth in Chapter 2 of the IOM that it will be "honest, fair, and accountable in all our actions and decisions." FDA reviewers, managers and counsel failed to independently do their jobs, rubber-stamping recommendations and relying on inaccurate and defamatory input from others. The FDA violated its policy that dialogue should be undertaken to ensure companies have fair notice and an opportunity to disagree. The FDA's Regional Director falsely represented that the FDA had conducted an investigation of Utah Medical's claims of biased inspectors. Inspectors Chase and Coleman committed fraud in their FDA-483s and EIRs. The CDRH's Quality Systems Expert Trautman fabricated violations out of whole cloth, and tried to control the FDA-483 and EIR output of inspections. The FDA violated its policy that litigation should be the last resort in getting companies to comply with the QSR. The FDA violated the June 30 DFI Field Alert that investigators that actually conduct an inspection and observe conditions or practices should prepare the FDA-483, and that it is the inspector's responsibility to be able to attest in court that he/she personally observed the FDA-483 observations and the supporting evidence.

The tortious, willful, fraudulent and bad faith conduct which began in 2001 continued through discovery and trial in 2005. Why? The simple and clear answer was to use the enormous power of the United States government to unfairly punish a Company that exercised its right to disagree on its need to hire a consultant to certify its quality system in 2001. Utah Medical should be entitled to the fair remedies listed herein for the outrageous conduct of the FDA officials.

DATED this 10th day of July, 2006.

BURBIDGE & MITCHELL

By

Stephen B. Mitchell
Attorneys for Utah Medical Products, Inc.

P:\JGlines\Clients\UTAH MED PROD\REQUEST FOR RECONSIDERATION.doc