Food and Drug Administration
Inspections of
Utah Medical Products, Inc.
1995 - 2004

EXECUTIVE SUMMARY

The U.S. Food and Drug Administration strives to protect, promote and enhance the health of the American people, while minimizing the regulatory burden on the industries it regulates. You have a right to disagree with any agency decision, action, or operation without fear of retaliation. You also have a right to be treated with appropriate courtesy and respect. If you are dissatisfied with any agency decision or action, you may appeal to the supervisor of the employee who made the decision or took the action. If the issue is not resolved at the first supervisor’s level, you may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency’s chain of command.

To resolve a problem with your company’s interaction with FDA, or if you have questions or concerns about FDA rules or procedures, we suggest that you first write or call your district office to explain your concerns. If you are not satisfied with the help provided by the district office, you may take your complaint or concern to the regional office. If that effort is not satisfactory, contact FDA’s Office of the Chief Mediator and Ombudsman for further assistance and guidance.

Source: “Resources for FDA Regulated Businesses” issued by FDA investigators upon inspection of facilities.

Most consumers believe, or want to believe, that the work performed by employees of the Food and Drug Administration (“FDA”) is of superior quality both in the context of science and compliance. This is a reasonable and realistic expectation; but, there are occasions when there is a major, if not complete, collapse of performance contrary to FDA and public expectations.

The multi-year experience of a small specialty device manufacturer, Utah Medical Products, Inc. (“UTMD”) located in the State of Utah is a documented example of failures by

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1 The content of this document relates primarily to activities and performance of personnel within the Office of the Associate Commissioner for Regulatory Affairs (“ACRA”), although the activities and performance of the Center for Devices and Radiological Health (“CDRH”), responsible for technical review and preparation of a formal recommendation for enforcement actions, the Office of Chief Counsel (“OCC”), responsible for review of the legal basis for enforcement actions and recommendation to the Department of Justice (“DOJ”), and the Commissioner’s Office, are also at issue and for which there is documented evidence that is not included in this report.
FDA investigator and supervisory personnel. The functional links in the FDA’s enforcement “chain of command” begin with the FDA inspection by an investigator to evaluate compliance of a facility and supervisory reviews which could end with an evaluation by the Department of Justice (“DOJ”) or U.S. Attorney to accept or reject a recommendation from the FDA Office of Chief Counsel for enforcement action which may include shutting down a Company’s business.

When the DOJ filed a complaint on August 9, 2004 to seek a permanent injunction against UTMD to shut down its business, this action set in motion a discovery process that enabled UTMD to seek the answer to the question, “why?” On the basis of the review of thousands of documents and the sworn testimony of 17 employees of and consultants to the FDA, defects in the functional links of the administrative “chain of command” have been identified and the darkness of FDA’s sinister enforcement cloud has been penetrated by the sunshine of truth.

Since UTMD receipt of a Warning Letter from the FDA in 2001, UTMD has repeatedly explained to the FDA as well as users, shareholders, and the public UTMD’s historical and continuing compliance with laws and regulations administered by the FDA. Through five inspections since 2001 by six (6) FDA investigators from different parts of the U.S.A. and one on-site collection of additional documents by DOJ personnel during discovery consuming more than 90 person days of inspection, neither the safety, nor effectiveness, nor performance of UTMD devices has been questioned.

At no point during this four year period has the FDA either challenged the quality or reliability of UTMD devices or requested/pursued any remedial action against the millions of devices and components annually manufactured and distributed by UTMD. These are facts confirmed under oath by FDA’s designated witness.

How and why is it possible for the FDA and DOJ to invest enormous resources against an entrepreneur with a commendable record of performance for the benefit of patients and healthcare practitioners? What is the root cause for this spectacle and the investment of limited resources by UTMD to defend its precious reputation for high quality?

The answers are revealed by the work product performed by UTMD through discovery and investigation of the performance of the FDA. The problem for UTMD began through the misguided activism of FDA Denver District Compliance Officer Regina A. Barrell supported by an inexperienced FDA Salt Lake City investigator Ricki A. Chase-Off. Contrary to FDA oral and documented expressions to encourage industry dialogue with FDA, UTMD efforts to do so were repeatedly ignored and dismissed. When the 2002 Establishment Inspection Report (“EIR”) prepared by Ms. Chase-Off was disclosed to UTMD in January 2003, UTMD followed the instructions of the FDA to disagree without fear of “retaliation.” Moreover, unknown to UTMD during this process, Ms. Barrell had prepared a prejudicial June 12, 2002 recommendation for injunctive relief that contained false and misleading statements.

Rather than consider the UTMD pleas for due process dialogue in 2002 and 2003, supervisors in the FDA Salt Lake Resident Post, Denver District Office, Dallas Regional Office, Center for Devices and Radiological Health, Office of the Associate Commissioner for
Regulatory Affairs, Office of the Commissioner, and Office of Chief Counsel undertook to simply support the prior and continuing performance of Ms. Barrell and Ms. Chase-Off. A comprehensive March 21, 2003 communication to the FDA Ombudsman about the 2002 FDA inspection was ignored and dismissed in just 2 weeks. Even a request by UTMD’s senior Senator was accorded a patronizing response, including a strangely arranged and coordinated May 15, 2003 “listening” meeting at UTMD requested by FDA personnel.

Nonetheless, these efforts did produce one promise, namely a commitment to investigate the complaint documented in UTMD’s March 21, 2003 letter to the FDA Ombudsman. As confirmed through discovery, even the promise by FDA Regional Director and former Associate Commissioner Dennis Baker that “This agency takes allegations of misconduct of our investigators very seriously.” was a hoax. FDA, the investigative agency responsible for investigating manufacturers, distributors, and users of products representing 25 cents of every dollar spent by consumers of such products, could not investigate itself. The tragedy of this failure by the FDA to initially investigate the root cause for its assault on UTMD and its employees created a completely unnecessary waste of significant government and UTMD resources.

Had the early pleas of UTMD been addressed fairly by responsible and objective personnel, the Warning Letter prepared by Ms. Barrell would not have been issued in 2001 and the reckless 66-page 2002 EIR would have been rejected by competent supervisory personnel. Instead, the documented record established through extensive but, of necessity, limited discovery does support a responsible allegation of indifference by a large number of FDA personnel whose principal interests were to protect their colleagues and disparage the reputation and image of UTMD and its representatives/devices.

UTMD has identified why this litigation was undertaken and who were responsible, but what can be done to correct and prevent future occurrences of this FDA failure? This is an answer that Congress, The Secretary of Health and Human Services, and The Administration can and should provide.

BACKGROUND

Utah Medical Products, Inc. (“UTMD”), www.utahmed.com, was formed in 1978 to manufacture and distribute a specialty line of devices for use by health care personnel. This specialty line continued to develop with a particular interest in providing benefit to women and their babies.

Kevin L. Cornwell became the President and CEO in 1992 and he maintains this position to the present. During 1995, an investigator from the Food and Drug Administration (“FDA”) inspected UTMD and made several observations. UTMD implemented a major initiative to respond to the inspectional observations and conveyed written responses to the FDA Denver
District Office ("DDO") on August 4, 1995. On August 15, 1995, a Warning Letter was issued by the DDO. The majority of the inspectional observations of alleged deficiencies related to the 1978 Good Manufacturing Practice ("GMP") regulation that appeared in 21 C.F.R. Part 820. UTMD responded on August 31, 1995; and, on September 11, 1995, DDO Director, John H. Scharmann, transmitted a letter to Mr. Cornwell advising acceptance of actions taken by UTMD.

During the period September 11-16, 1998, an investigator from the FDA Salt Lake City Resident Post inspected UTMD. The investigator confirmed that UTMD had made all corrections as promised in 1995. In addition, the investigator inspected the facility for compliance with the 1996 revision of the GMP regulation which is known as the Quality System Regulation ("QSR"). The inspection was completed on September 16, 1998. No inspectional observations (i.e., FORM FDA 483) were issued to UTMD signifying that UTMD was in compliance with the QSR appearing in 21 C.F.R. Part 820. A copy of the Establishment Inspection Report ("EIR") was conveyed subsequently to UTMD on July 12, 1999 by DDO Director Gary C. Dean.

During June 2001, UTMD was again inspected by an investigator from the FDA DDO. Several observations were conveyed to UTMD on a FORM FDA 483 dated June 8, 2001. UTMD responded promptly and completely on June 17, 2001 in a letter which requested further dialogue if necessary to resolve inadequacies in lieu of a Warning Letter. UTMD did not receive further communication from the DDO until September 10, 2001 when it received a multiple page September 4, Warning Letter from the DDO Director.

This Warning Letter requested that UTMD obtain the services of a consultant to certify compliance with the QSR. UTMD responded to the FDA DDO and requested the opportunity to meet and obtain the EIR so that it could address issues that may not have been identified in either the FORM FDA 483 or the Warning Letter. UTMD planned during the meeting to explain its

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2 A “Warning Letter” is a communication from an official of the FDA which advises a recipient that the FDA believes there has been or continues to be a violation of laws and/or regulations administered by the FDA.

3 There are approximately 19 FDA District Offices located throughout the United States. Each is staffed with investigatory and compliance personnel ultimately supervised by a District Director who reports to the ACRA Office in Rockville, Maryland. It is the responsibility of the District Office to investigate and evaluate the performance of persons within its geographic territory whose activities are subject to FDA jurisdiction and make recommendations through FDA established “chain of command.”

4 The FORM FDA 483 is the official Federal Government form that is used by FDA investigators to convey to the person inspected “objectional conditions” when observed by the FDA investigator.

5 The EIR is a narrative report prepared by the investigator which describes the nature of the inspection, any FORM FDA 483 observations, and discussions with management during and at the “close out” of the inspection. The EIR is available to the inspected person upon request unless the FDA determines that an “investigation” is ongoing.
position and obtain an explanation for DDO Compliance Officer Regina A. Barrell’s prior verbal statement to Mr. Cornwell that the FDA’s request for the consultant resulted because UTMD was recidivist.

On December 21, 2001, Mr. Cornwell, John Smith, UTMD Manager of Quality Assurance, and Larry R. Pilot, counsel for UTMD, met at the DDO with Howard E. Manresa, DDO Compliance Branch Director and Ms. Barrell. During the two-hour meeting, Mr. Cornwell and Mr. Smith explained their position with regard to the content of the FORM FDA 483 and Warning Letter. This included another explanation of a typographical error in a Device Master Record (“DMR”)\(^6\) which had no impact on safety, effectiveness, or performance because of UTMD’s fail safe procedures, including, but not limited to, those provided through personnel training, and compliance with the Device History Record (“DHR”).\(^7\) The content of this DHR is controlled by a formal engineering approval of any changes to assure continuous entry of required data.

At the conclusion of the meeting, Mr. Cornwell was asked by Ms. Barrell if UTMD planned to retain the services of a consultant. He declined this request on the basis of a lack of justification for it, but did indicate that UTMD was prepared at any time for another inspection.

During four partial or complete days between March 26 and April 3, 2002, UTMD was inspected by Ricki A. Chase-Off, FDA investigator from the Salt Lake City Resident Post. She presented inspecional findings on April 15, 2002 in the presence of her supervisor Elvin R. Smith. The FORM FDA 483 close-out conference with UTMD management was attended by UTMD’s Mr. Cornwell, Mr. John Smith, Mr. Ben Shirley, and, by telephone, UTMD counsel Mr. Pilot. The close-out conference took place over a period of about 4-1/2 hours and was tape recorded. On April 26, 2002, Mr. Cornwell wrote to DDO Director B. Belinda Collins to request a meeting to discuss the recent inspection and close-out conference. There was no FDA response to this letter. On May 9, 2002 UTMD provided a comprehensive written response to the FORM FDA 483 to the DDO. This written response had been preceded by prompt conveyance of copies of the April 15, 2002 tape recordings and a verbatim transcript. UTMD did request comment on the content of the verbatim transcript and detailed written response. The DDO did not respond.

From May 2002 through December 2002, UTMD made repeated requests to FDA District and Headquarters personnel for feedback on its May 9, 2002 response, a copy of the EIRs for 2001 and 2002, and opportunity for dialogue. None of these requests was honored until

\(^6\) The DMR is a required document that described how a device is to be made including specifications for the components and finished devices. Because manufacture of a device may require multiple different manufacturing and assembly practices by trained personnel, the process is controlled by explicit instructions applicable to a particular functional activity. The performance of these instructions, including compliance with specifications, is documented by UTMD personnel for each batch, lot, etc., as part of a required Device History Record (“DHR”).

\(^7\) See Footnote No. 6.
January 13, 2003 when UTMD received copies of the 2001 and 2002 EIRs. Each EIR was accompanied by a January 9, 2003 form letter signed by Ms. Barrell (for Mr. Manresa). These letters conveyed the impression that the FDA was satisfied and the 2001 Warning Letter closed. The UTMD conclusion was based in part on a November 6, 2001 letter, in which Ms. Barrell wrote, “With regards to your request for a copy of the Establishment Inspection Report, we are unable to provide a copy at this time as we consider this to be an open, investigatory case. We will provide a copy upon closure of the Warning Letter.” (Emphasis added.)

UTMD review of the 66-page EIR prepared by Ms. Chase-Off identified significant deviations from fact and procedure as required by FDA’s Investigations Operations Manual (“IOM”). Indeed, 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. On the very day, February 24, 2003, that UTMD was prepared and planned to call Ms. Collins to schedule a meeting about the 2001 and 2002 EIRs, two FDA investigators Karen A. Coleman and Ms. Chase-Off (again) appeared at the facility to conduct another inspection.

Consistent with the attachment to the FORM FDA 482, Mr. Cornwell contacted Ms. Collins to request postponement of the inspection until UTMD had an opportunity for a meeting with DDO regarding the 2002 EIR, or recusal of Ms. Chase-Off. The postponement and recusal requests were both denied, as was an agreed to March 7 meeting because the DDO objected to the requested agenda prepared by UTMD. Appeal efforts with Regional Director Dennis E. Baker were also unsuccessful. Mr. Baker stated that he would ask Ms. Collins for a copy of the current assignment to the FDA investigators for Mr. Cornwell, but he never called Mr. Cornwell as expected.

The FDA inspection, which Ms. Collins described as a “routine follow-up,” was completed on March 12, 2003. On March 21, 2003, Mr. Cornwell sent a letter to FDA Ombudsman Steven H. Unger requesting an investigation of the performance of Ms. Chase-Off and the content of her 2002 EIR. Additional communications were made to Mr. Baker and Associate Commissioner For Regulatory Affairs (“ACRA”) John M. Taylor. On April 1, 2003, UTMD’s request for renewal of Certificates to Foreign Governments (“CFGs”) was denied.

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8 The IOM, published yearly, is the primary source of guidance regarding FDA policy and procedures for field investigators and inspectors, and “adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.”

9 The FORM FDA 482 is the official Federal Government form that is required to be presented by the investigator along with credentials prior to any inspection of a facility. The FORM FDA 482 contains the statutory language that authorizes FDA access to facilities and documents for inspection by authorized FDA personnel.

The attachment describes an administrative appeals process that is to be devoid of retribution.

10 The 1996 Export Reform and Enhancement Act modified the Federal Food, Drug, and Cosmetic Act (“Act” or “FFDCA”) to facilitate export from the U.S.A. of Drugs, Devices, or Biological articles to other countries. Though not required, some foreign governments and purchasers prefer FDA confirmation that the article is in lawful
On May 15, 2003, through a prior FDA request, Mr. Baker, Ms. Collins, and FDA Chief Counsel representative Patricia J. Kaeding met at the UTMD facility from approximately 1 to 5 p.m. The FDA personnel listened to Mr. Cornwell and other UTMD representatives consistent with an agenda prepared by UTMD, but they purposely provided no meaningful dialogue. (Emphasis added.) UTMD subsequently filed a lawsuit regarding the denial of CFGs on June 5, 2003 in an effort to reverse the FDA position.

On September 11, 2003 Mr. Cornwell received a letter dated August 29, 2003 from Mr. Baker stating, “An investigation of CSO Chase-Off’s behavior … found no evidence of misconduct, wrongdoing, or bias ....” Previously on August 15, 2003 Ms. Laurie Lenkel (FDA Ombudsman Office) conveyed a letter to Mr. Pilot stating, “Our review concluded that the materials submitted did not provide adequate evidence … of misconduct, impropriety …” On August 6, 2003, Mr. Taylor left a voice mail for Mr. Pilot stating, “We have conducted an inquiry … I can tell you we found, neither the Ombudsman’s office nor our own internal review has found any evidence of bias on the part of the two [2003] investigators.”

On October 3, 2003 the Department of Justice (“DOJ”) conveyed a “sign or sue letter” to UTMD counsel, but settlement discussions were unproductive. In response to the limited discovery associated with the CFG lawsuit filed by UTMD, a motion was filed with the court to seek disclosure of the contents of 7 documents identified by the Government on a privilege log and alleging, in part, FDA misconduct in support of the motion for disclosure.

On February 2, 2004 three FDA inspectors from different parts of the country arrived at the UTMD facility. The inspection terminated on March 3, 2004 with the issuance of 7 observations on a FORM FDA 483. UTMD provided a comprehensive 1,000 page written response on March 16, 2004, which included the following: “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.” As with numerous previous UTMD requests, there was no response from the FDA. The ensuing discussions with representatives of counsel for the FDA and DOJ continued until August 9, 2004 when the Government filed its lawsuit seeking a permanent injunction.12

11 This type of letter announces to counsel for the recipient the DOJ interest to file a law suit unless the recipient agrees to sign an acceptable consent decree to be filed in Federal Court.

12 A lawsuit seeking an injunction is an effort by the plaintiff (here, the government) to get the Court to order the defendant(s) to do or not to do something requested by the plaintiff. However, the plaintiff has the burden to prove by the preponderance of the evidence that such action by the Court is necessary and just. Here, the Government/FDA seeks to impose its interpretation of the Quality System Regulation (“QSR”) rather than UTMD’s interpretation and application of the QSR.
Extensive discovery began shortly after the filing and through May 2005. Among the many results of this discovery was the FDA confirmation that there were no issues relating to safety, effectiveness or performance of UTMD devices. This discovery effort also produced evidence sufficient to support a counterclaim against the FDA for Abuse of Process and a subsequent July 19, 2005 filing of a claim to the Department of Health and Human Services (“HHS”) for damages under the Federal Tort Claims Act (“FTCA”).

The content of this “BACKGROUND” description is based primarily on what UTMD knew from its interactions and correspondence with representatives of the FDA without the benefit of discovery. Through discovery, UTMD acquired additional facts about the conduct and misconduct of FDA personnel that supports the following narrative. This narrative description is based on review of internal FDA documents and deposition testimony of fact witnesses. These facts relating to the performance and competence of ACRA personnel could not have been identified/proven by UTMD but for this litigation. UTMD believes that there are other relevant documents that have not been disclosed which may provide further support for allegations of FDA misconduct within the Center for Devices and Radiological Health (“CDRH”) and ACRA organizations.

THE 2001 INSPECTION

For reasons that still are not clear, the DDO Investigations Branch forwarded a recommendation to the Compliance Branch based on the June 2001 inspection of UTMD.

Ms. Barrell was the Compliance Officer to whom this recommendation was referred. It was her decision to prepare and recommend a Warning Letter which was signed by her supervisor, Mr. Manresa, acting for DDO Director Thomas A. Allison. This letter was considered a recidivist letter in accordance with the text of an existing FDA Compliance Program. The letter stated that UTMD devices were adulterated because of QSR failures, noted

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13 On August 17, 2005, the Court dismissed without prejudice the counterclaim for Abuse of Process suggesting that the claim should be made first with FDA’s parent HHS in accordance with HHS procedures.

14 Ms. Barrell graduated from college in 1974 with a Bachelors Degree in environmental science and chemistry. She was a graduate teaching assistant during 1974-75, high school teacher during 1975-77, licensed insurance agent during 1977-81, worked for a CPA during 1981-83, director of finance for Centennial Airlines during 1983-85, accounting assistant for IBS during 1986-87 when she was employed by FDA DDO in 1987 as a chemist. In 1992 she became a Compliance Officer, served as a Supervisory Investigator from 1999 for a year and a half even though she never served as an investigator and then returned to her position as a Compliance Officer.

15 Mr. Manresa graduated in 1973 with a Bachelor of Science in medical technology. During 1973-74 he worked at a baby backpacks factory as a cloth and form cutter and also as a research technician for the University of Colorado, as a high school teacher during 1977, worked part time at the Denver Coroner’s office while going to school during 1977-80, and as histologic technical until 1983 when he began employment with the FDA as an investigator. He became a Supervisory Investigator in 1989 until 1995 when he became a Compliance Officer. In 2000, he became Compliance Director in the DDO.
“specific violations”, found that deficiencies were similar to those found in July 1995, and requested that UTMD “submit certification by an outside consultant” of QSR compliance in accordance with a schedule listed in the letter.

In spite of a detailed June 17, 2001 written response to address each observation in the FORM FDA 483 and comprehensive explanation to Ms. Barrell and Mr. Manresa of UTMD’s position about the Warning Letter content during a two-hour meeting on December 21, 2001 at the DDO, at the end of the meeting, Ms. Barrell asked if UTMD was retaining a consultant to submit a certification. Mr. Cornwell stated the he did not believe this was indicated and that UTMD was available for another inspection at any time.

The Warning Letter by Ms. Barrell omitted any mention of the 1998 “no action indicated” (“NAI”) inspection and mischaracterized the significance of a 1997 typographical error among other facts. The only item that could possibly have been considered recidivist was the typographical error. During the deposition of Ms. Barrell and through FDA production of documents, Ms. Barrell reluctantly acknowledged among other statements that

- the 1998 FDA inspection confirmed documentation corrections promised by UTMD in 1995, no QSR deviations were identified, no FORM FDA 483 observations were issued, and the inspection was classified as NAI

- the chronology that she prepared for the file (“FACTS”) and for which she relied to conclude support for her allegation of similar deficiencies was based on the comparison of two different regulations (the 1978 GMP versus the 1996 QS regulation) for which the text was either not identical to or not present in the 1978 GMP regulation.

Ms. Barrell refused to understand or acknowledge that the typographical error about which she considered this a major deviation was irrelevant to the specifications for the finished device and release for commercial distribution. Although Ms. Barrell documented that UTMD was required to hire a consultant, she acknowledged that this was not true. (Emphasis added.)

During 1996, UTMD revised the Device Master Record (DMR) in accordance with a written procedure and the Device History Record (DHR) was also revised to reflect and continuously document compliance with various specifications. Occasional changes were made to the DMR in accordance with written and documented procedures. During 1997, a revision was made to a one-page DMR portion containing approximately 40 sets or combinations of numbers. There was a typo replacing the correct number with an incorrect number for one of the numbers and this was not observed during proof reading. The DHR which was used during every day of production identified a digit for which all devices were checked and released against the correct number 9. During the 2001 inspection, the investigator made note of this typo and the DMR – not the DHR – was promptly corrected. Had the DMR change been intentional, UTMD would have followed and documented its procedure which also would have required a change to the DHR.
She also acknowledged that in her experience in the DDO, this was the only time a device company declined a request to obtain the services of a consultant.\(^\text{17}\)

It is UTMD’s belief that Ms. Barrell was offended by the UTMD belief that hiring a consultant was not the responsible action for it to take, and that she embarked on a project to punish UTMD and its personnel. During the deposition of Mr. Manresa, he acknowledged that he signed the Warning Letter and testified that the letter had been cleared by the CDRH and FDA Office of Chief Counsel (“OCC”). He may have been confused, because there is no evidence to support that either CDRH or the Chief Counsel received any draft of the 2001 Warning Letter that he testified was prepared by Ms. Barrell and him. Moreover, during Ms. Barrell’s deposition she claimed to be the author, acknowledged that the Warning Letter was not subject to OCC review at the time and had no recollection of OCC involvement.

**THE 2002 INSPECTION**

On March 26, 2002, FDA Investigator Chase-Off\(^\text{18}\) arrived at the UTMD facility to conduct an inspection. Some of her introductory comments to Mr. Cornwell and Mr. John Smith were disturbing to them. Nonetheless for part or most of the intermittent four-day inspection beginning on March 26 and concluding on April 3, 2002 (returning on April 15, 2002 solely for presentation of the FORM FDA 483), she inspected the facility and collected documents. At the close-out discussion with management of the presentation of the FORM FDA 483, Ms. Chase-Off was accompanied by her supervisor Mr. Elvin Smith.\(^\text{19}\) This session was tape recorded with the recording later transcribed. Both audio and written copies were provided to the DDO by

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\(^{17}\) The 2002 EIR by Ms. Chase-Off incorrectly states on the first page that UTMD “has not, at any time, elected to hire a consultant.” In fact, UTMD had previously used the services of outside consultants in the refinement of its quality system for many years.

\(^{18}\) Ms. Chase-Off received a Bachelor’s and Masters degree respectively in biology 1994 and 1996. She had a temporary position with a food company in 1997, worked in the environmental area for the City of Dallas for a year during 1997-98, for the Department of Health in Texas for about two years (1998-2000) as an investigator in the drugs and medical devices division when she became an FDA employee as an investigator on June 12, 2000 in the Salt Lake City resident post.

At the time Ms. Chase-Off inspected UTMD, she had less than two years of FDA experience as a generalist relating to food, medicated feeds, good laboratory practice, mad cow (BSE), device and drug inspections.

\(^{19}\) Elvin Smith has been an inspector/investigator for the FDA in the Denver District Office since around the 1980’s. He was a Supervisory Investigator working out of the DDO at the time of Ms. Chase Off’s inspection of UTMD. Mr. Smith was present to evaluate the performance of Ms. Chase-Off.
April 29, 2002 with a request for comment, but no comment was transmitted to UTMD from any representative of the FDA.  

UTMD was genuinely surprised during the FDA 483 close-out discussion about claims by Ms. Chase-Off that the FORM FDA 483 expressed in her opinion violations of law. Mr. Elvin Smith did not clarify or contradict her assertions. UTMD was also surprised that the FDA-483 contained observation #9, a vague “catch-all” (in Ms. Chase-Off’s words), with no factual supporting examples, but subsequently relied on by CDRH to support allegations of repeat violations. Nonetheless, UTMD prepared and transmitted a comprehensive response with supporting exhibits on May 9, 2002. The primary focus of the 2002 FDA 483 was on sterilization validation, a new issue not part of the previous FORM FDA 483 or Warning Letter. Subsequently, UTMD offered repeatedly to provide any additional documentation, clarification, explanation, etc., that would be helpful to the DDO. Mr. Cornwell spoke to and exchanged e-mails with Ms. Barrell in the good faith belief that the DDO was reviewing his responses as assured by Ms. Barrell. Upon discovery, Mr. Cornwell learned that Ms. Barrell had not been truthful with him.

The 2002 EIR by Ms. Chase-Off was 66 pages in length and contained material misrepresentations unknown to UTMD. Yet Ms. Barrell relied on the content of this document to support her preparation of a RECOMMENDATION FOR PERMANENT INJUNCTION signed by Ms. Collins and Mr. Manresa on June 12, 2002. Ms. Collins who had been the DDO Director only since May 2002 testified that this was her first experience with a device injunctive relief recommendation, and that she signed the “RECOMMENDATION” after only reviewing the final document on that day. She did not review any supporting documents, and did not think that reviewing UTMD’s written responses to the FDA 483s was important. She also admitted that she did not know UTMD’s position with respect to the Warning Letter when she approved the June 12 injunction “RECOMMENDATION.” Rather, she relied entirely without question on the assessment of Ms. Barrell and Mr. Manresa. Mr. Manresa testified that he only reviewed portions of the EIR, may have made some wordsmithing/grammatical changes to the “RECOMMENDATION” prepared by Ms. Barrell but “nothing substantive.” When he signed

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20 During review of internal FDA documents, many DDO personnel make uncomplimentary or disparaging references to the tapes and/or transcripts, yet, during testimony under oath, most admitted that they either had not reviewed tapes/transcripts or only skimmed them.

21 The preparation of this report was based primarily on 11 pages of notes and Ms. Chase-Off’s memory. The significance of this EIR will be described later as this relates to UTMD communication with the FDA Office of Ombudsman.

22 Ms. Collins received a BS in Biology in 1976 and began her career with FDA in 1977 where until 1989 she was a consumer safety officer conducting inspections but had no experience inspecting any device manufacturers. In 1989 she became a regional radiological health representative until about 1992 when she became regional radiological health representative for FDA’s southwest region as a Branch Director until May 2002 when she became Denver District Director.
the final “RECOMMENDATION,” he “did not look at every one of” the attachments on the concurrence page. His testimony supports that during his FDA career and the two years he had been Director of the Compliance Branch, this was his only experience with a recommendation for injunction involving a finished device manufacturer.23

The documents and deposition testimony support that the RECOMMENDATION FOR PERMANENT INJUNCTION was the sole work product of Ms. Barrell, and was signed by both Ms. Collins and Mr. Manresa without any knowledge of the truthfulness of the contents or validity of supportive evidence. This included the all important description of the ALLEGED VIOLATION as prepared by Ms. Barrell.

The complete text of the ALLEGED VIOLATION in the June 12 “RECOMMENDATION” appears as follows:

Over the past seven years, inspections of UMP conducted by Denver District, have found continuing, significant deviations from the QSRs. Although formally notified of these deviations through two Warning Letters and face-to-face meeting, the firm has refused to make corrections. Mr. Cornwell submitted responses that indicate an unwillingness to cooperate with the Agency. For example, the September 2001 Warning Letter (attached as Attachment 13) 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 cause the articles to become adulterated.

This recitation of the ALLEGED VIOLATION was the subject of critical testimony by Ms. Barrell during which her comments were defensive and evasive but hardly genuine. Each of the following sentences is taken from the ALLEGED VIOLATION paragraphs and accompanied by comments about factual information that was omitted, distorted, or fabricated by Ms. Barrell:

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23 Mr. Manresa guessed that they may have had another injunctive relief experience in 2002 with a device refurbisher, remanufacturer.
ALLEGED VIOLATION

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

COMMENT

This statement is neither true nor accurate. The seven year period began in 1995 at which time UTMD made “corrections” deemed acceptable to the DDO as expressed by DDO Director Scharmann. These “corrections” related to the GMP regulation in effect at the time which dated back to 1978. There was no quality system regulation (QSR) at the time.

The 1998 FDA inspection, as stated in the EIR, “Verified the firm had corrected all the deficiencies as promised.” This inspection was initiated as a GMP inspection per CP 7382.30 applicable to the QSR which had been finalized in 1996 and appeared in 21 C.F.R. Part 820. Although the inspection focused on one particular device for which no “new GMP deviations were discovered,” “No FDA-483 Inspectional Observation was issued.”

The alleged deviations during the 2001 inspection were the first identified to UTMD under the QSR and their significance were contested by UTMD. At the time that Ms. Barrell prepared this statement, UTMD was not aware of the content of the 2002 EIR. UTMD believed, and was led to believe by Ms. Barrell, that it was in good faith discussions with the DDO about this inspection and UTMD efforts to address any deviations.

ALLEGED VIOLATION

Although formally notified of these deviations through two Warning Letters and face-to-face meeting, the firm has refused to make corrections.

COMMENT

This statement is false. UTMD never refused to make corrections. In 1995, UTMD made corrections acceptable to the DDO as confirmed during the 1998 FDA inspection. Moreover, specific corrections relating to the 2001 inspection were made by UTMD and confirmed during the 2002 inspection as explicitly stated on page 63 of the 2002 EIR. One of particular importance to Ms. Barrell related to the Device Master Record (“DMR”). This had been fully
explained by UTMD in its 2001 written response to the FDA-483 and demonstrated again in the December 2001 face-to-face meeting in Denver.\textsuperscript{24}

Yet, Ms. Barrell under oath denied knowledge that UTMD had corrected a typographical error in the DMR. This, even though Ms. Chase-Off stated in the 2002 EIR that “The Device Master Record has been corrected to reflect the correct specifications for unbalance.”

Furthermore, it is a misrepresentation to imply that there was any system linkage of “these deviations” from the 1995 inspection and the 2001 inspection, because the 1978 GMP regulation differed from the 1996 QSR.

ALLEGED VIOLATION

Mr. Cornwell submitted responses that indicate an unwillingness to cooperate with the Agency.

COMMENT

This statement is \textbf{not true}!

Mr. Cornwell responded to each and every inspectional observation for each FDA inspection during 1995, 2001, and 2002. None of these documented responses support an unwillingness to cooperate. Mr. Cornwell’s travel to Denver to meet on December 21, 2001 with Ms. Barrell and Mr. Manresa was his initiative to engage in dialogue that would constructively address FDA concerns, and to cooperate. Additionally after completion of the 2002 inspection on April 15, Mr. Cornwell sent a letter to Ms. Collins dated April 26, 2002 expressing intent to provide a written response to inspectional observations and requesting the possible opportunity to meet because of concerns about the conduct of the inspection. No one from the FDA DDO acknowledged receipt of the letter or provided any type of response.

In Ms. Collins deposition,

\begin{itemize}
  \item[Q.] (UTMD counsel). Why was it an unwillingness to cooperate with respect to Utah Medical Products?
  \item[A.] (Collins) Because he [Cornwell] didn’t do what he was asked to do.
  \item[Q.] All right. Specifically, what did he fail to do?
\end{itemize}

\textsuperscript{24} The content of the 2003 EIR confirmed that the original 2001 unbalance specification observation in the DMR was just a typographical error.
A. I believe that one of the suggestions here – it is not a suggestion. It is a requirement. “The firm employ an outside consultant to provide verification that corrections had been completed.” He did not do that.

Q. You mentioned that there was a requirement, in the FDA’s view, for the firm to employ an outside consultant. Is that right?
A. That was what it says right here from the September 1st Warning Letter, September 2002 [sic 2001] Warning Letter.

Q. What was the basis for the FDA to require Utah Medical Products, Inc. to employ an outside consultant?
A. What was the basis for it?
Q. Yes, ma’am.
A. They had violations that needed to be corrected.
Q. Is it your understanding as district director that the FDA can require a company to employ an outside consultant under those circumstances?
A. Yes.

It is a matter of considerable record that UTMD was willing to cooperate but that the FDA simply would have no part in such a process. Moreover, there is no provision in laws or regulation administered by the FDA which authorizes FDA to require a company to employ an outside consultant.

ALLEGED VIOLATION

For example, the September 2001 Warning Letter (attached as Attachment 13) 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.

COMMENT

This statement is false and misleading because it mischaracterizes the content of the letter and UTMD conduct. The FDA has no authority to require the firm to employ an outside consultant and the Warning Letter made no statement that “required the firm to employ an outside consultant.” Mr. Cornwell had every right on behalf of UTMD to decline the DDO request, as well as disagree with the observations.

Apart from the fact that UTMD can hire whomever it desires for any lawful purpose, Ms. Barrell’s description is fictitious and a fabrication for which it is fair to express that the motivation was related to retribution, and/or part of an
effort by Ms. Barrell to mislead readers who are expected to rely on the veracity of her descriptions.

ALLEGED VIOLATION

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 cause the articles to become adulterated.

COMMENT

This paragraph correctly references relevant provisions of “the Act” but “the conditions described above” as challenged/qualified as part of this narrative lack both specificity and expected respect for truth, accuracy, and balance.

More important is the fact that the quality, safety, effectiveness, or intended performance of UTMD devices was never an issue.

In spite of extensive, time-consuming and very costly discovery to UTMD and the Federal Government, there is not a scintilla of evidence to support this as well as other statements made by Ms. Barrell, and then both cavalierly and carelessly authorized by Mr. Manresa and Ms. Collins, relating to “ALLEGED VIOLATION.”

The single importance of the content of this “RECOMMENDATION FOR PERMANENT INJUNCTION” relating to “ALLEGED VIOLATION” cannot be overemphasized. Its lawful intent is to objectively inform readers of the specifics of any alleged violation. Its function as intended by Ms. Barrell was to mislead and inappropriately influence readers who were part of the FDA decision making process. Yet, Ms. Barrell and the co-signers Mr. Manresa and Ms. Collins together utilized rhetoric and innuendo to engage the support of readers to participate in an odyssey propelled by vengeance to punish UTMD for exercising its lawful rights. There simply was no significant evidence of a deficient quality system that could reasonably be expected to result in medical devices not meeting specified requirements or UTMD inability/unwillingness to carry out any necessary corrective action.

On the following day and prior to CDRH receipt of the RECOMMENDATION FOR PERMANENT INJUNCTION, Ms. Barrell and Mr. Manresa participated in a telephone conference call with CDRH representatives. Notes of this June 13, 2005 telephone conference, disclose that Ms. Barrell conveyed inflammatory, untruthful and misleading information to the listeners. This included, but was not limited to, false allegations about injury to a mother and her infant the intent of which certainly would stimulate an emotional response by the listener that would be harmful to the interests of UTMD.
As stated in the above referenced notes, it appears that Ms. Barrell conveyed information characterizing UTMD device performance as “Some cracked in utero,” “baby born w/scratch - catheter broke inside mom.” During Ms. Barrell’s testimony under oath she eventually reluctantly acknowledged that the source of these comments appeared to derive from the 2002 EIR prepared by Ms. Chase-Off. The EIR falsely characterized the content of a MedWatch report to convey to the reader that injury occurred. This was contrary to the content of the MedWatch which clearly stated “no injury.” Ms. Barrell agreed under oath “that the MedWatch Form does not “make the statement that Ms. Chase-Off makes in the EIR…” Other inappropriate and slanderous remarks were made about UTMD representatives for which the most likely sources were the DDO representatives. Mr. Manresa denied making such statements. Slanderous remarks made by Ms. Barrell regarding company representatives’ arrogance, belligerence, and “the worst attitude that Regina has ever seen” could not be supported by any example during Ms. Barrell’s deposition.

UTMD COMMUNICATION/COOPERATION EFFORT

On April 16, UTMD hand delivered to the FDA copies of the tape recording of the April 15, 2002 FORM FDA 483 close out conference with UTMD management. On April 29, a written transcript was conveyed by UTMD to Ms. Chase-Off and Mr. Elvin Smith with a request for identification of errors or omissions prior to UTMD’s including a copy with its May 9 written response to the FORM FDA 483 for the DDO. Between that date and January 13, 2003 when UTMD received by mail copies of each EIR for the 2001 and 2002 FDA inspections of UTMD, representatives of UTMD initiated no less than 40 efforts to communicate (mail, e-mail, facsimile, and telephone) with FDA representatives about the 2002 inspection. This included the comprehensive response on May 9, 2002 to the April 15, 2002 FORM FDA 483 observations and a copy of the transcript of the FDA 483 close-out discussion which directly contradicts much of the content of Ms. Chase-Off’s EIR.

The objective of these efforts was to secure acceptance of the UTMD response to the 2002 FDA inspection, and obtain a copy of the 2001 and 2002 EIRs in order to resolve the 2001 Warning Letter.

UTMD was anxious to assure that it had provided an acceptable explanation to the FDA for issues identified during the recent inspection. Subsequent to transmission of the May 9, 2002 FORM FDA 483 response and six (6) days after Ms. Barrell’s June 12, 2002 RECOMMENDATION FOR PERMANENT INJUNCTION, Ms. Barrell wrote in a letter on

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25 Device manufacturers and user facilities are required to report to the FDA certain deaths and injuries associated with the use of a device. The one page “MedWatch” form is used for this purpose and also by others who voluntarily desire to submit such reports.

26 During Ms. Chase-Off’s deposition, she refused to make a similar admission, and maintained that her reference to the MedWatch form in her EIR was correct.
June 18, 2002 to Mr. Cornwell, stating that the May 9 UTMD response was “currently under review” and inviting, “If you have any questions, please do not hesitate to contact me,” even though Ms. Barrell expressed that “Upon completion, we will contact you regarding the adequacy of your response.” Mr. Cornwell accepted this invitation as a good faith effort to establish dialogue, and responded with e-mails and telephone calls in attempts to enter into a dialogue that would constructively resolve any concern regarding UTMD’s QSR compliance. In fact, the June 18 Barrell letter and subsequent contacts with Ms. Barrell and other FDA personnel demonstrated a practice of deception by the FDA that continued for two (2) subsequent years. Further, the FDA never responded to UTMD to comment on the adequacy of the UTMD explanations, or request any clarification or additional supporting documentation, relating to the 2002, 2003, or 2004 inspections.

On June 18, 2002 when Ms. Barrell wrote to Mr. Cornwell, the DDO had already completed its review and forwarded its injunction enforcement recommendations to the CDRH on June 12, followed by the June 13 DDO/CDRH telephone conference at which time Ms. Barrell and Mr. Manresa clearly sought to improperly influence the upcoming review of their recommendation by the CDRH.

Mr. Cornwell upon receipt of Ms. Barrell’s June 18 letter made several attempts during June 21-July 1, 2002 to speak directly with Ms. Barrell. On July 1 Mr. Cornwell left a voice mail message for Ms. Barrell but she did not respond. On July 8, 2002, Mr. Cornwell again called and spoke to Ms. Barrell in general as to whether “we’ve addressed everything in the proper context … to your satisfaction,” and she stated that she and Ms. Chase-Off were “still kind of working on it.” Additionally, she stated “when we are finally done with everything, then give you a call and, you know, again I think there is at least one exhibit or attachment that you had in your response that was … there was one page that was missing from it.” Ms. Barrell did not call back about this or identify any missing page, but on July 19, 2002 she did call Mr. Cornwell for copies of some biocompatibility test reports for which Mr. Cornwell faxed 13 pages of documents to her the same day. Ms. Barrell did confirm receipt through e-mail and continued the deceptive ruse by stating “will be reviewing them shortly.” The next day, July 20, Mr. Cornwell responded by e-mail, requesting again to “Please let me know what else may be missing to complete your review” and expressing concern about an issue that was not part of the 2002 FDA 483. Two days later July 22, Ms. Barrell conveyed an e-mail to Mr. Cornwell stating “I am still reviewing these documents and will contact you if any other questions arise.”

Because he had not heard from Ms. Barrell, on August 20, 2002, Mr. Cornwell sent an e-mail to Ms. Barrell, requesting copies of the EIRs to:

“assure mutual understanding in particular as this may be helpful to UTMD’s refinement of its systems and procedures. We would

27 The complete transcription of this telephone call is more extensive and available for review if requested.
also like to be able to respond formally to the FDA regarding any comments in the EIRs which may benefit from clarification.”

Mr. Cornwell also introduced his message by stating “Since I understood you were actively in the process of reviewing UTMD’s file when we last talked in July … I want to inquire as to the status of your review.28 (Emphasis added.)

Rather than honestly responding to Mr. Cornwell’s e-mail of August 20, Ms. Barrell on August 26 forwarded the e-mail to two individuals in the CDRH as follows:

“Hi Paul and Andrea:

I know that Pat is still working on this inspectional report, but I was wondering what I should say (or not say) to Mr. Cornwell about this. I have not heard back from Cornwell since he sent this but every time the phone rings, I figure that it could be him. I’m sending this to you to ask how I should handle this. Please let me know what you think…

Regina”

Mr. Paul F. Tilton (PT), Consumer Safety Officer/CDRH responded within the hour as follows:

“Regina,

Andrea and I talked about this. If Mr. Cornwell calls, we would advise that you tell him that the EIRs and associated documents are presently under review by CDRH. It’s safe to tell him that you don’t really know the timeframe involved with CDRH’s review. And if he pushes, simply tell him that you’re waiting to hear-back from CDRH.

Thanks for your patience.

PT”

On behalf of Mr. Cornwell, counsel for UTMD called Ms. Barrell on August 28, 2002 and left a voice mail message. On the same day Ms. Barrell responded by voice mail indicating that the status is “all cylinder review.” During a subsequent telephone conversation that day between counsel and Ms. Barrell, she explained that review would be done by the end of next week, “I have been tied up, out 1-2 weeks, Acting-”, and apologized about annual leave. To counsel’s

28 Copies of the complete July 20 and August 20, 2002 e-mails are available on request.
explanation of Mr. Cornwell’s concern about status and inquiry “Is he going to be surprised?” Ms. Barrell responded, “I hope not”; but, consistent with the continuing deception about ‘her review’, she did not inform either Mr. Cornwell or counsel that the “review” was actually taking place at the CDRH.

In spite of numerous contacts with FDA personnel by UTMD counsel beginning on September 2, 2002, it was on September 19, 2002 through a voice mail message from Mr. Manresa to UTMD counsel that UTMD learned that the CDRH was involved and to contact Mr. James L. Woods (Consumer Safety Officer, CDRH). Between September 19, 2002 and January 7, 2003 approximately twenty (20) communications to FDA personnel were initiated by UTMD counsel in efforts to obtain the EIRs, understand status, and accomplish dialogue.

On January 13, 2003 to the surprise and temporary relief of UTMD, it received the EIRs for 2001 and 2002 each of which was transmitted by a form cover letter, consistent with general FDA policy when the investigatory file is closed (also consistent with the November 16, 2001 Barrell representation). The letters were signed by Ms. Barrell on behalf of Mr. Manresa, Director, DDO Compliance Branch. UTMD had good reason to believe that its ordeal was over because of the content of the January 9, 2003 transmittal letters signed by Ms. Barrell, following her November 2001 letter representing that the EIRs would only be released upon closure of the Warning Letter. Additionally, a May 13, 2002 letter from Acting Director, DDO Compliance Branch, Shelly L. Maifarth to Mr. Cornwell stated “Copies of the narrative reports [EIRs] will be released to you when we have concluded our review,” and a January 8, 2003 voice mail message to UTMD counsel from ACRA’s Steven M. Niedelman, expressed “I want to let you know that you will be getting a response to your December 4th letter and there has been a reversal. We will be providing the EIRs to the recent inspections at your client’s facility, Utah Medical.”

The expected relief vanished quickly during an initial review of the EIR prepared by Ms. Chase-Off. The 66-page 2002 EIR contained statements that were troublesome, because they were either false/misleading or were never discussed during the inspection. In the sincere belief by UTMD that it would be able to discuss their reaction to the EIR content with the DDO, it began to prepare a written analysis. Unknown to UTMD until discovery, during the end of 2002, the FDA had decided to conduct another inspection to “strengthen” the June 12, 2002 injunction “RECOMMENDATION.” (Emphasis added.) In fact, on January 15, 2003, two days after UTMD receipt of the EIRs creating the impression of closure, the CDRH sent a 4-page Inspectional Guidance to Ms. Barrell and Ms. Coleman, who had been chosen to conduct another inspection of UTMD the next month. The introduction to the 18 item Inspectional

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29 Ms. Coleman received an associate degree after attending junior college from 1967-69, received a Bachelor of Science Degree with a major in Home Economics, minor in Biology from the University of Montibello in 1971 and a Masters Degree in textiles and clothing from Auburn University in 1974. During 1974-75 she worked part time in the county tax assessor’s office and as a substitute high school teacher in Gadsden, Alabama and then for two and a half years as a social worker in Alabama before becoming employed by the FDA as an investigator in the fall of 1977 where she continues as an investigator.
Guidance made clear that the objective was to support identification of deficiencies in support of an enforcement action. Specifically the CDRH directed that the FDA investigators “determine if the manufacturing operations for the intrauterine catheters have not been corrected.” and “ensure that the firm’s noncompliance with the Quality System requirements consists of systems-wide violations…” (Emphasis added.) UTMD had no inkling at the time that the CDRH and DDO were literally “out to get” the company.

THE 2003 INSPECTION

On February 24, 2003, UTMD was prepared and planned to call Ms. Collins and request a meeting to discuss the 2001 and 2002 EIRs, as suggested by ACRA’s Mr. Niedelman. To UTMD’s great surprise, Ms. Chase-Off and Ms. Coleman arrived to conduct another inspection. Mr. Cornwell contacted Ms. Collins to seek postponement of the inspection until after a meeting with the DDO that would address the contents of the 2001 and 2002 EIRs. When Ms. Collins stated that the inspection would continue, Mr. Cornwell requested the recusal of Ms. Chase-Off. Ms. Collins declined to recuse Ms. Chase-Off but assured Mr. Cornwell that the inspection was a routine follow-up, and that Ms. Coleman was the lead inspector (mitigating Mr. Cornwell’s concern about possible bias). Mr. Manresa and Susan J. Miller, Consumer Safety Officer, called Mr. Cornwell back the next day, February 25 to advise that Ms. Collins misspoke and that Ms. Chase-Off was the lead. Other topics were also discussed.

In accordance with the attachment to the FORM FDA 482, Mr. Cornwell proceeded to appeal to Mr. Baker to obtain the “Center assignment” and request recusal of Ms. Chase-Off. Mr. Baker stated that “people can’t pick and choose inspectors” and that Ms. Coleman as a “technical expert is more important than anything.” After stating that Ms. Chase-Off “can be outspoken” and that he did “not know what she’s working from,” Mr. Baker stated he would talk to Ms. Collins, attempt to get a copy of the FDA inspection assignment for Mr. Cornwell, and call him back. Mr. Baker did not call back.

Even though the inspection continued, Mr. Cornwell requested and Ms. Collins agreed to a March 7 meeting to discuss the 2001 and 2002 EIRs it recently had received. After Mr. Cornwell provided a requested agenda, however, Ms. Collins rejected it shortly before UTMD personnel were scheduled to travel to Denver, Colorado, saying “My staff and I are willing to listen to what corrections your firm has made since the previous inspections. We are interested specifically in what actions you have taken or will be taking to bring your company into compliance. We will not entertain subject matter beyond this scope.” Given this rejection, Mr. Cornwell had no alternative but to continue his appeal through the FDA Ombudsman as well as the CDRH Ombudsman.

30 Under oath, Ms. Coleman denied receiving this “Inspectional Guidance” until just prior to the inspection even though it was faxed to her Atlanta office on January 15, 2003.
The inspection continued through March 6, 2003, at which time the investigators stated that they would take the next few days to prepare for a promised close-out FORM FDA 483 presentation on Monday, March 10. On Sunday night, March 9, at 10:25 p.m., Mr. Cornwell received an e-mail message from Ms. Chase-Off requesting 21 items comprising over 30 specific documents. These were hand delivered by UTMD personnel the next day. Unknown to UTMD until discovery, CDRH and other FDA personnel were actively involved with the function of the investigators who supposedly were simply conducting a “follow-up” inspection.  

During the course of the inspection it had become apparent that the investigators were routinely communicating with FDA personnel in both the DDO and CDRH. Upon discovery, UTMD learned that much of the performance of the investigators was being directed by CDRH personnel contrary to understood FDA policies and practices. Ms. Chase-Off sent routine e-mails to CDRH’s Kimberly A. Trautman, Consumer Safety Officer, and others. During the inspection, Ms. Trautman communicated directly with the investigators and further directed that she review the inspectional observations before these were to be presented to UTMD. The eleventh hour e-mail from Ms. Chase-Off is one of many documents confirming the DDO/CDRH collaboration.

31 In an e-mail dated March 10 (two days prior to the FDA-483 presentation to the firm) from Patricia A. Lefler, Deputy Director, Division of Field Investigations to numerous ACRA personnel, she advised that she had spoken to Ms. Coleman about the delayed FDA 483 issuance until Wednesday, 3-12-03 and that “They [Coleman and Chase-Off] 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.”

32 The performance expectations of FDA investigators is described in Section 169.01 — Professional Stature of the Investigations Operation Manual. (“IOM”) This includes the opening statements “You are the eyes and ears of FDA, and to most of the public you are their only contact with FDA. Your actions may be the basis upon which they judge the entire FDA.” This section continues with the following instructions under the title “Integrity” — “This is steadfast adherence to a strict moral or ethical code. It characterizes a person of deep-seated honesty and dependability with a devotion to accuracy, objectivity and fairness.” This continues with the following direction: “Your job is to gather and present the facts. Accuracy and objective observation are absolutely essential.”

33 The performance of both DDO and CDRH personnel is presently the subject of a claim for damages due to abuse of process under provisions of the Federal Tort Claims Act (“FTCA”). In part, this relates to CDRH involvement in the independent “eyes and ears” function of the investigators as described in the IOM when CDRH official, Kimberly Trautman, on March 7, 2003 instructed the two investigators:

“This 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 [injunction] like some cases because Pilot [UTMD Counsel] will kill us in court.”
During each inspection day, tape recorded discussions between UTMD and FDA representatives occurred to review what observations, if any, were identified by the investigators. The performance and demeanor of the investigators is clearly revealed in these recorded conversations.

The 2003 FORM FDA 483 Management Conference finally occurred on Wednesday, March 12, perhaps because of the delay in “massaging” the observations by others in the FDA. This meeting was also recorded and transcripts prepared by UTMD. Although a written response to the 2003 FORM FDA 483 was provided by UTMD on April 11, 2003, an additional six hundred page detailed response was provided to the 2004 investigators when their inspection turned to review of the 2003 observations. This additional written response addressed every 2003 observation except for those related to sterilization validation, the primary basis for the injunction recommendation in 2003, which later had been “resolved” by Investigator Monica J. Wilkins in 2004 by reviewing essentially the same documentation reviewed by Ms. Coleman in 2003.

During the deposition of Ms. Coleman, she was asked if at any time prior to her appearance at the facility that morning of February 24, 2003 she was instructed by anyone to determine whether or not UTMD had addressed issues from the prior inspection. She was “not sure”/ “don’t remember.” Likewise when Ms. Chase-Off was asked if she was given any explicit direction/instruction prior to this inspection to determine whether or not UTMD had addressed (i.e., made corrections, changes, improvements) FORM FDA 483 observations from her 2002 inspection, she eventually responded in the negative.

THE APPEAL AND INVESTIGATION

UTMD was prompted by its analysis of the 2002 EIR and rejection at the DDO level to apply the appeal procedure description which accompanied the 2003 FORM FDA 482. It followed this procedure notwithstanding prior unsuccessful efforts to dialogue with the FDA, but encouraged by the FDA commitment that “You have a right to disagree with any agency decision, action, or operation without fear of retaliation.”

UTMD sincerely believed that the conduct of the DDO personnel, in particular the content of the 2002 and 2003 EIRs were prejudicial to the interests of UTMD and lacked adequate foundation. In part, because of the FORM FDA 482 Attachment invitation, UTMD prepared a partial analysis of the content of the 2002 EIR and performance of the author, Ms. Chase-Off.

On March 21, 2003 Mr. Cornwell conveyed a letter to the FDA Ombudsman, Mr. Unger, with relevant attachments regarding its initial comparison of the 2002 EIR with the content of the

34 Unlike the 2003 inspection, the investigators during 2004 did review with UTMD the observations made during the previous 2003 inspection and UTMD’s response and related documents.
transcript of the 2002 FORM FDA 483 close-out meeting. This self-explanatory letter and related correspondence appears as Exhibit A.\textsuperscript{35} The content of this correspondence was based on information that was available at the time when UTMD had unsuccessfully sought to discuss this EIR with the DDO earlier in March, although subsequent discovery as part of litigation provided additional surprising evidence.

At about the same time, UTMD sought the assistance of its Senator, Orrin Hatch, for the purpose of seeking an administrative process that would produce progress toward a constructive resolution of the 2001 Warning Letter. (The issues identified in the 2003 FORM FDA 483 had substantially changed from those in 2001.) This was helpful to a limited extent. DDO Director Collins called Mr. Cornwell to arrange a meeting at UTMD facilities, purportedly because she and Mr. Baker were to be in the vicinity around May 15, 2003. UTMD did not know at the time that the FDA initiative was inspired by Senator Hatch’s expression of concern. This was learned through discovery of documents.

Mr. Cornwell, pleased with this first opportunity to meet with FDA since December 21, 2001, welcomed the FDA invitation. An agenda and list of issues for discussion, similar to the one denied for the aborted March 7 meeting, along with the same package of information sent to Mr. Unger, was promptly prepared and transmitted to Ms. Collins and Mr. Baker. Mr. Cornwell requested and Ms. Collins agreed that Ms. Collins and Mr. Baker would read and compare the 2002 EIR with the transcript of the 2002 FDA 483 close-out meeting prior to the meeting, because they were “night and day.” Ms. Collins expressed to Mr. Cornwell when she asked for the meeting that she wished to understand UTMD’s side.

To date there has been no evidence to confirm whether Ms. Collins or Mr. Baker performed the requested comparison, but Ms. Collins during her April 15, 2005 deposition did acknowledge that she did not review the 2002 EIR prior to June 12, 2002.

Q. (UTMD counsel): Did the 2002 EIR contain more explanation about the alleged violations than found in the 483 for the 2002 inspection?

A. (Collins): I didn’t read the 2002 report [EIR].

On May 15, 2003, Ms. Collins and Mr. Baker arrived at approximately 1:00 p.m. to meet with UTMD representatives; and they were accompanied by a FDA attorney whose presence was not previously announced to UTMD. Irrespective, the FDA guests were provided a tour of the facilities and the meeting continued until approximately 5:00 p.m. Although the agenda had

\textsuperscript{35} UTMD expected that this March 21, 2003 letter would prompt an investigation by Mr. Unger. In fact, as learned through discovery, on April 7, 2003 Mr. Unger sent a memo to ACRA’s Niedelman stating “We are planning to draft a brief response to the company indicating that, in our view, it has not substantiated its allegation on bias, and that ORA has appropriately responded to the company’s concerns through use of multiple reviews, subject matter experts, outside consultants, etc.”
been provided in advance and there was no FDA objection to the content or format, the FDA personnel declined to engage in any substantive dialogue regarding the list of issues. They did ask questions and occasionally made broad reference to FDA policy, but there was no dialogue that addressed the issues that had been identified by UTMD.36

Subsequent to the meeting and further correspondence with Mr. Baker, Mr. Cornwell and counsel received communications from FDA personnel relating to results of an investigation of bias prompted by the March 21, 2003 letter to Mr. Unger. The portion of these communications relating to the investigation are as follows:

August 6, 2003:

Mr. Taylor voice mail message to UTMD Counsel

“We have conducted an inquiry, Larry. I can tell you we found, neither the Ombudsman’s office nor our own internal review has found any evidence of bias on the part of two [2003] investigators. We obviously take any allegations like that seriously, but like I said we found nothing to suggest that there was any bias in terms of dealing with your client.”

August 15, 2003:

Ms. Lenkel, Ombudsman, letter to UTMD Counsel

“Our review concluded that the materials submitted did not provide adequate evidence to substantiate allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statues by agency personnel as stated in 21 CFR 19.21. Thus the matter has not been referred to the Office of Internal Affairs.”

August 29, 2003:

Mr. Baker letter to Mr. Cornwell in part

“… we have conducted an investigation of CSO Chase-Off’s behavior and have found no evidence of misconduct, wrongdoing, or bias in connection with the Denver District’s evaluation of the facts documented during the Food and Drug

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36 During Ms. Collins deposition on April 15, 2002 she testified that she and Mr. Baker discussed strategy before the meeting and agreed “that it was our plan to sit and listen …” and that as they listened to those concerns they did not give any substantive response from the FDA’s perspective.
Administration’s March through April 2002 inspection of your facility.”

These representations by FDA personnel surprised and disappointed UTMD, because UTMD genuinely believed that the FDA would fairly and objectively investigate its concerns. Mr. Baker had stated to Mr. Cornwell on his first telephone conversation on February 27, 2003, “We won’t ignore your concerns about Chase. You have done the right thing and started the appeal process. We do take UTMD’s concerns seriously.” UTMD subsequently questioned the method used for the “investigation” and how it could proceed to completion absent any contact with UTMD personnel. In particular, it was expressed by FDA representatives at the May 15, 2003 meeting that they would not discuss any matter relating to Ms. Chase-Off or the recent inspection. No further explanation of the “investigation” was provided by the FDA until after the filing of the August 9, 2004 injunction lawsuit.

Documents and deposition testimony revealed that the content of Ms. Chase-Off’s 2002 EIR did contain false information, and that in fact there was no investigation of her conduct! Ms. Chase-Off’s Supervisor, Teresa C. Thompson, and the DDO Director of Investigations Branch, Ms. Miller, were the FDA personnel responsible for the investigation of Ms. Chase-Off.

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37 As a disappointing matter of fact learned through document production, Mr. Taylor, Ms. Lenkel, Mr. Baker, and Ms. Collins engaged in a joint effort to dismiss UTMD’s request which further misled UTMD. On July 29, 2003, Ms. Lenkel shared a draft letter addressed to UTMD counsel with Mr. John Taylor for his direction and editorial improvements but did not share the draft with Mr. Unger. On August 4, Ms. Collins sent a draft letter prepared by Ms. Miller and Ms. Thompson (described later) to Mr. Baker who responded on August 5 that he needed to hear from John Taylor before sending the letter. Ms. Collins responded that she hoped he wouldn’t send it because it will “make Cornwell even madder.” Mr. Baker responded incorrectly that UTMD’s “already gotten a letter from the Ombudsman” and that Mr. Taylor had told UTMD counsel that “we found no wrongdoing” and that he would be receiving something in writing. The draft Baker letter of August 28, 2003 was edited by Mr. Taylor according to a September 2 e-mail to Ms. Collins and Mr. Baker also wondered if it should not be further reworked. Mr. Cornwell, on September 11, 2003, received the August 29 letter, which was still in draft form on September 2.

38 During discovery there were no documents identified to support that there was any investigation other than to request comments from the two investigators who conducted the 2003 inspection of UTMD.

39 Ms. Thompson graduated from college in 1989 with a degree in home economics with a dietetics concentration. She worked as a trainer for Sears telecatalog center during 1989-90 and became an employee of the FDA in June 1990 as an investigator and became a supervisory investigator in 1993 in North Carolina. In 2003 she became a supervisory investigator in the Salt Lake City Resident Post.

40 Ms. Miller has been an employee of the FDA since approximately 1977. She was an inspector/investigator and was a Food Specialist located in the DDO prior to becoming Director at the Investigations Branch in the DDO in 2001.
On August 4, 2003, Ms. Miller e-mailed a draft letter to Ms. Collins with a copy to Ms. Thompson expressing the conclusion of the investigation of Ms. Chase-Off conducted by her and Ms. Thompson. The draft letter for the signature of Mr. Baker expressed “We conducted a thorough investigation of CSO Chase-Off’s behavior and found no evidence of misconduct or wrongdoing.” (Emphasis added.) Ms. Miller expressed “TCT [Teresa C. Thompson] and I worked on it together. We think it says just enough, but not too much! Susan”

During Ms. Thompson’s deposition, she testified under oath as follows:

1. “I have no recollection of working on the letter.”

2. had “no recollection of ever reviewing … the EIR that she [Ms. Chase-Off] prepared in 2002.”

3. had “… no recollection of being involved in an investigation of CSO Chase-Off’s behavior.”

4. had “… no recollection of any discussion with Susan Miller about an investigation of Ricki Chase-Off.” Previously, Ms. Thompson testified that she had no recollection of seeing the March 21, 2003 letter to Mr. Unger from Mr. Cornwell. See Exhibit A.

When Ms. Miller testified under oath during her deposition, she recalled that her investigation consisted of talking by phone to Ms. Thompson, Ms. Chase-Off and Ms. Coleman and that these telephone conversations were the extent of her investigation. Ms. Miller could not recall whether she reviewed the March 21, 2003 letter to Mr. Unger from Mr. Cornwell in conjunction with her investigation. See Exhibit A. Ms. Miller testified that she did “… not recall the specifics of that conversation [telephone conversation with Ms. Thompson as first line supervisor about Ricki and Karen], any conversations with Ms. Thompson regarding this issue.” Finally, Ms. Miller testified that the thorough investigation, i.e., separate telephone conversations between Ms. Chase-Off, Ms. Coleman, and Ms. Thompson was conducted by “Teresa Thompson and myself.”

In reliance on the “investigation”, Mr. Baker signed the revised draft letter, including deletion of the word “thorough”, and the letter dated August 29, 2003, but sent early in September, expressed to Mr. Cornwell the following:

“At your facility on May 15, I assured you that the Agency takes all allegations of investigator misconduct seriously. I am advising you that our investigation of your allegations is now complete. We have conducted an investigation of CSO Chase-Off’s behavior and

41 There are no notes of these conversations!
have found no evidence of misconduct, wrongdoing, or bias in connection with the Denver District’s evaluation of the facts documented during the FDA March through April 2002 inspection of your facility.”

On the basis of documents produced and deposition testimony under oath about the investigation of Ms. Chase-Off, contrary to Mr. Baker’s statement, there truly was no investigation of the concerns expressed by Mr. Cornwell on March 21, 2003. 42

THE CFG LAWSUIT

The continuation of FDA allegations relating to UTMD compliance with the QSR resulted in denial of access to much needed “Certificates to Foreign Governments” (“CFGs”). 43 As a consequence, UTMD had no reasonable option for relief other than to file a complaint in Federal Court.

On June 4, 2003, UTMD filed its lawsuit to seek acquisition of CFG’s required by some foreign distributors. In discovery for this CFG lawsuit, the Government produced a limited number of documents as part of the Administrative File but denied access to others. 44 A privilege log was supplied by the Government identifying seven documents protected from disclosure. The limited documents which had been produced by the Government appeared to support the request for disclosure of the privileged documents.

UTMD asked an independent consultant who was a former FDA employee and expert in the development and application of the GMP regulation to review the disclosed documents. He

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42 Notwithstanding the complaint about Ms. Chase-Off and the professed investigation by Ms. Thompson and Ms. Miller, Ms. Chase-Off was promoted to the position of Medical Device Specialist in December 2003 after interviews with Ms. Thompson and Ms. Miller. During Ms. Thompson’s deposition she could not recall how much time was applied to the 2003 annual review conversation with Ms. Chase-Off although a midterm interview could take approximately 15 minutes.

43 The “FDA Export Reform and Enhancement Act of 1996” authorized issuance of CFGs to facilitate export of devices, drugs, and biologics in lawful commercial distribution in the United States. At no time since issuance of the 2001 Warning Letter has there been any restriction on domestic distribution or export of any UTMD device. The FDA denial of CFGs has become a self-imposed (i.e., FDA) trade barrier harmful to UTMD and other device firms caused by arbitrary FDA denials.

44 The Government provided 15 volumes of documents which consisted primarily of EIRs and related UTMD documents as well as UTMD/FDA correspondence already known to UTMD. Eight (8) volumes consisted entirely of UTMD and public documents. Of the remaining seven (7) volumes, the range of documents per volume unknown to UTMD was one to 110 (2003 EIR) pages. Of the approximately 6,000 pages in these “15 volumes” approximately 191 pages consisted of documents previously unknown to UTMD including the 110 page EIR for 2003. Other documents (approximately 31) which were produced were prepared by the FDA after the filing of the lawsuit by UTMD.
prepared a declaration based on review of FDA inspection related documents which addressed activities of possible FDA misconduct. This declaration was used in support of a motion to secure release of documents identified by the Government as privileged because they related to deliberative process. On December 18, 2003 the Court denied the motion to compel the production of documents and filed a written opinion on March 31, 2004. The opinion did not make any determination relating to FDA misconduct but did express that “Both parties may well have miscommunicated and misinterpreted each other’s actions. These miscues, however, do not warrant the release of the seven documents in question.” 45

FOLLOW-UP TO THE 2003, 2004 FDA INSPECTIONS AND AUGUST 9, 2004 COMPLAINT FOR PERMANENT INJUNCTION

This 16 day time span of inspection of UTMD during 2003 by two inspectors was represented as a “follow-up” inspection. Unknown to UTMD, the explicit purpose of this inspection was to support a prior request for injunctive relief. Many, if not all, of the observations which were listed either were wrong or unsupported as to the QSR.

The conduct of CDRH and DDO personnel was unusual and extraordinary given that the function of the FDA investigators was to perform as “… the eyes and ears of the agency. They are the fact finders.” Discovery documents and deposition testimony confirmed that CDRH personnel, in particular, with DDO concurrence interfered in a very significant way with the investigational function as the fact finder, eyes, and ears of the FDA.

Although UTMD responded promptly given limited resources, there was no dialogue with UTMD about the 2003 inspection.

On October 3, 2003 the DOJ sent a “sign or sue” letter to UTMD counsel. Efforts to dialogue with FDA and its counsel were repeatedly rebuffed. Another FDA inspection occurred during February/March, 2004. UTMD objected to the length and number of investigators for this inspection, but it was under the impression that the inspection by three (3) new investigators from across the United States was to evaluate and hopefully verify “current compliance” with the QSR. 46 As with the 2003 FDA inspection, UTMD learned upon discovery that this inspection

45 Each of the seven deliberative process documents reviewed in the CFG lawsuit were produced to UTMD after the filing of the August 9, 2004 Complaint for Injunctive Relief, because the deliberative process privilege no longer applied. UTMD also learned as part of the subsequent discovery that documents that should have been produced during the CFG lawsuit either were not produced or were not identified as privileged by the Government.

46 Most of the observations made during the 2003 inspection, including some carried over from 2002 (e.g., sterility), were determined by these investigators to have been unsupportable on the basis of UTMD documents that were available to the investigators at the time of the 2002 and 2003 inspections.
was undertaken by the FDA to support an existing recommendation to pursue a complaint for permanent injunctive relief against UTMD.

Irrespective, UTMD prepared and conveyed to the FDA a detailed written response with exhibits addressing the seven observations. Its efforts toward dialogue with the FDA, even included an offer to participate in a mediation.

The FDA’s refusal of UTMD’s request for non-binding mediation seems to contradict the Regulatory Procedures Manual ("RPM"), Section 6-2-5, which states in part, “FDA strengthens its injunction actions by demonstrating in the complaint that FDA made and has documented a conscious effort to get the objectionable products or practices corrected without court involvement.” Prior to the lawsuit, the FDA refused to provide notice to or dialogue with UTMD as to specific objectionable practices. According to Section 6-2-5, “Rarely in injunction cases will the issuance of the FDA 483 constitute adequate notice, in the absence of further notice from agency compliance officials or senior managers.” No other dialogue about objectionable practices occurred after the December 2001 meeting in Denver. Indeed, the observations from the ensuing 2002, 2003 and 2004 inspections kept changing.

In DDO Director Collins’ deposition:

Q. (UTMD counsel) I'm just trying to understand why you believed that the mediation would not be productive, which is what I understand that you are saying. You did not believe it would be productive. Is that fair?

A. (Collins) That's fair. It's also generally not the way that we go about settling a violative case like this. The firm has to show us clear evidence that they corrected violations. It is not adequate to say we've corrected it or we did not have a violation. The proof is on their shoulders. And he had not done that in the past.

Q. So, because Mr. Cornwell had failed to satisfy you that Utah Medical was in compliance in the past, you saw no reason to engage in a mediation. Is that fair?

A. That's fair.

UTMD continued good faith efforts to seek to communicate with FDA and DOJ counsel to settle differences through dialogue and agreement. Nonetheless these efforts by UTMD were rejected and to the disappointment of UTMD, the Injunctive Relief Lawsuit by the Government was filed on August 9, 2004.

SUMMARY

It is the position of UTMD based upon the extensive discovery that the root cause for the conflict with the FDA was the performance of DDO personnel, most notably Ms. Barrell under no responsible supervision, as exacerbated by the performance of the FDA investigators, Ms. Chase-Off in 2002, and together with Ms. Coleman in 2003.
The refusal of responsible FDA personnel to interact with openness and integrity created a no-win experience for UTMD. The published FDA offer that UTMD has “… a right to disagree with any agency decision, action, or operation without fear of retaliation” was a disgraceful sham. Evidence gathered during discovery supports that no one in ACRA listened to the facts (with the possible exception of Mr. Niedelman in 2002). Its Regional Director, Mr. Baker, as supported by DDO personnel, did not “tell the truth” about UTMD’s request to investigate the performance of Ms. Chase-Off, or Ms. Coleman. The District Director, Ms. Collins, either had no understanding of her job responsibilities or was completely irresponsible in fulfilling them.

UTMD requests that the Office of the Associate Commissioner For Regulatory Affairs act to perform an investigation of the conduct of ACRA personnel at the investigator and supervisory level to determine whether performance of these personnel was consistent with the objectives of the FDA Commissioner’s Office and expectations of the Associate Commissioner for Regulatory Affairs.

UTMD offers the full detailed documented benefit of its experience and the costly expense of this most unusual litigation in support of this request in the sincere belief that this unfortunate experience will produce a beneficial result for the FDA and the device Industry.

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Enclosure: Appendix A