



## A PRIORITY FOR THE FDA: FIX THE “WARNING LETTER” PROCESS

by

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Early in 1991, the Food and Drug Administration (“FDA”) created the “Warning Letter” communication. The Warning Letter replaced the previously well-established “Notice of Advance Findings/Regulatory Letter” with an approach that “empowered” approximately twenty different District Directors to warn recipients of violations of laws and FDA regulations.

Predictably this shift away from a requirement for headquarters approval for most “Regulatory” letters resulted in a plethora of Warning Letters from the various FDA District Offices. In spite of clear FDA procedures relating to applicable criteria and required time frames, the lack of central coordination did result in an increase in the number of Warning Letters that did not meet criteria and/or were issued beyond required time frames.<sup>1</sup> Increased criticism of FDA performance did produce a response from FDA’s parent, the Department of Health and Human Services (“HHS”) which on November 29, 2001 directed the FDA to severely restrict issuance of Warning Letters through review by the FDA Office of Chief Counsel (“OCC”) to assure existence of *evidence* of possible violation of regulatory significance.<sup>2</sup>

The objective in 1991 and again in 2001 was to convey a “warning” to those who the FDA believed were in violation of law and/or regulation in order to accomplish a voluntary correction of the violation or violations. The policies and procedures, including instructions applicable to the use of OCC attorneys, are located in FDA’s “Regulatory Procedures Manual” (“RPM”). The RPM is explicit that the Warning Letter is “correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations.”<sup>3</sup>

Nearly five years after the requirement for OCC review of the “evidence” in support of each request by FDA field or headquarters personnel, it is fair to ask whether this change has made a difference. If yes, what is the nature of the difference? If no, is there any value to continuation of the present Warning Letter system?

To my knowledge, there never has been a comprehensive and objective analysis of the value of Warning Letters since the creation of this system.<sup>4</sup> However, on June 26, 2006, Rep. Henry A. Waxman, Ranking

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<sup>1</sup>FDA fondness for compliance with “required” procedures often forms the basis for issuance of Warning Letters for failures to comply with such procedures. However, cursory review of Warning Letters supports that the FDA often does not follow its own procedures.

<sup>2</sup>See Larry R. Pilot, *New Policy on Warning Letters, A Sensible Move Toward Due Process*, WLF LEGAL OPINION LETTER, Jan., 25, 2002.

<sup>3</sup>The Regulatory Procedures Manual is a reference manual for FDA personnel available on the Internet at [www.fda.gov/ora/compliance\\_ref/rpm/default.htm](http://www.fda.gov/ora/compliance_ref/rpm/default.htm).

<sup>4</sup>The RPM dictates that the FDA Office of Regulatory Affairs (“ORA”) Office of Enforcement review its Warning Letter

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Minority Member of the House of Representatives Committee on Government Reform, issued a Report citing a decline in FDA enforcement activity during the current administration based on a review of Warning Letters (“Waxman Report”).<sup>5</sup> *The Washington Post* reported “Study Cites Marked Drop In FDA’s Warning Letters.”<sup>6</sup> *The Los Angeles Times* reported “FDA Enforcement Actions Fall, Yet Violation Reports Haven’t,”<sup>7</sup> and *The Wall Street Journal* announced “FDA’s Number of Warnings Falls.”<sup>8</sup> Even the *Journal of the American Medical Association* in its August 23/30, 2006 issue announced “Report Criticizes Lack of FDA Oversight.”<sup>9</sup> FDA in its defense proclaimed:

‘FDA enforcement cannot be properly judged by counting the number of actions taken by the agency.’ ‘FDA has increasingly used an enforcement strategy based on efficient risk management principles that focus on combating the greatest public health risks and maximizing our deterrent effect against potential violators.’<sup>10</sup>

Is this pervasively regulated industry and health care complex<sup>11</sup> “guilty” of violations of law and regulation which the FDA is declining to enforce? I think not. Rather, the Waxman Report illustrates support for the termination of the Warning Letter as it now exists.

The Waxman Report concludes that “FDA’s enforcement efforts have been significantly compromised in the last five years.” This incorrectly suggests that a “Warning Letter” constitutes “enforcement.” The Warning Letter is *not*, however, an enforcement action. Its purpose like the Regulatory Letter is to encourage voluntary compliance in instances where the FDA believed companies were out of compliance. While the number of letters issued in the last five years may have declined by 50%, this has nothing to do with valid, supportable, and necessary “enforcement efforts.” The Warning Letter, as a distorted successor to the Regulatory Letter, consists of “allegations” of violations for which the federal court system ultimately provides the opportunity to determine whether any violation exists. Where appropriate, its issuance should be useful. If the recipient is not responsive to the realistic and lawful expectations of the FDA, the burden to prove that a violation exists is the responsibility of the FDA through such statutory enforcement actions as product seizure, preliminary and/or permanent injunctive relief, and criminal prosecution.

During the nearly twenty-year “Regulatory Letter” period rarely, if ever, did the recipient receive a second letter. This is because it was necessary for the FDA District Offices to gather and present “evidence” to FDA headquarters of sufficient quality to subsequently justify a request to the Department of Justice (“DOJ”) for initiation of an enforcement action through the Federal Courts. Evidence, not just allegations, represented the strength of the Regulatory Letter, as well as the fact that those receiving it would have no second chance. In contrast, some recipients of Warning Letters have received multiple numbers of Warning Letters, which undercuts the clarity and certainty of the agency’s message, two qualities Regulatory Letters offered.

Since 1991, numerous recipients of multiple Warning Letters have been threatened with legal action by the Department of Justice (DOJ). Each of them declined to defend against FDA allegations and elected to enter into Consent Decrees filed in federal courts. Presumably, these decisions were made either because FDA’s accusations were correct, or they did not want to defend possible innocence in expectation that the FDA would undoubtedly prevail.

In contrast, a small device manufacturer in Midvale, Utah did what others declined to do – defend itself. Utah Medical Products, Inc. (“Utah Medical”) received a Warning Letter in September, 2001 from the FDA

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procedures every twelve months to evaluate their scope and effectiveness. As of this writing the results of such reviews are not known.

<sup>5</sup>Prescription for Harm, The Decline in FDA Enforcement Activity. U.S. House of Representatives, Committee on Government Reform, Minority Staff, Special Investigation Division, June 2006.

<sup>6</sup>W. POST, June 27, 2006.

<sup>7</sup>L.A. TIMES, June 27, 2006.

<sup>8</sup>WALL ST. J., June 27, 2006.

<sup>9</sup>JAMA, Aug. 23/30, 2006, Vol. 296, No. 8 at 290.

<sup>10</sup>*Supra* note 5.

<sup>11</sup>Clinical investigators, hospitals/pharmacies and related institutions, as well as Institutional Review Boards (“IRBs”) are among recipients of Warning Letters.

Denver District office based on an inspection in June of that year.<sup>12</sup> The previous inspection in 1998 produced no findings and confirmed compliance in 2001, yet the company was advised in 2001 that it was a “recidivist” and advised to hire a consultant. Efforts through meeting and years of additional correspondence and inspections did not resolve the disagreement. The FDA maintained through time-consuming inspections in 2002, 2003, and 2004 that violations existed, and Utah Medical responded with evidence in support of its position. Settlement discussions with the FDA/DOJ were unsuccessful.<sup>13</sup> On August 9, 2004, a Complaint for Permanent Injunctive Relief was filed in the U.S. District Court for the District of Utah, Central Division.

Commencement of discovery began immediately thereafter and continued through May of 2005. During the discovery process, thousands of FDA documents were produced and seventeen FDA witnesses (fifteen employees and two consultants) were deposed. This discovery process did provide sufficient evidence of government incompetence and malfeasance to justify a claim for Abuse of Process under the Federal Tort Claims Act (“FTCA”).<sup>14</sup> During a seven day trial in September and October, 2005, the FDA/DOJ relied only on the testimony of three “expert” witnesses. Incredibly, the FDA/DOJ did not produce any fact witnesses to support that violations occurred. Utah Medical relied on the testimony of company personnel and two experts.

On October 21, 2005 U.S. Senior District Judge Bruce S. Jenkins denied the government’s petition and dismissed the case. In rejecting the FDA position first advanced in a September, 2001 “recidivist” Warning Letter, the court clearly and convincingly rejected the four year mission of the FDA/DOJ against Utah Medical.

Among the conclusions expressed by Judge Jenkins are the following:

*•This is an unusual case. The safety of the products manufactured by Utah Medical has never been at issue.*

*•The court 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.*

*•The fact that the road chosen by Utah Medical may be different in degree than that thought to be appropriate by a regulator, does not mean that it is wrong, or in violation of the regulations.*

*•It makes no sense for the court to order Utah Medical to do something they are already doing.*

The judge’s opinion sends a positive message to regulated entities that when put to the test of evidence in court, Warning Letters may not withstand scrutiny. This holds especially true for the medical device industry, which appears to be the object of most Warning Letters and the harm they bring.<sup>15</sup> Utah Medical’s successful

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<sup>12</sup>The alleged violation related to alleged deviations from the Good Manufacturing Practice (“GMP”)/Quality System (“QSR”) regulation for medical devices. Most Warning Letters for Drug and Device manufacturers relate to alleged violations of respective GMP regulations.

<sup>13</sup>The initiation of a possible lawsuit for injunctive relief generally begins with issuance of a “sign or sue” letter to the recipient. The “sign” signal is in anticipation that the recipient will enter into a consent decree which may require shut down, certification by a third party expert, suspension of distribution, possible recall and other measures to be filed in Federal Court. The “sue” alternative does provide the opportunity to discover whether the FDA can support its allegations.

<sup>14</sup>The initial effort as a Counterclaim by the Utah Medical defendants was subsequently filed with the HHS Department and a petition for reconsideration is pending.

<sup>15</sup>Through a remarkable display of regulatory gall, the FDA has converted the beneficial intent of the Export Reform And Enhancement Act of 1996 into a self inflicted trade barrier for U.S. manufacturers of devices, drugs, and biologics who seek to export their products. The 1996 Act provides FDA with authority to issue Certificates to Foreign Governments (“CFGs”). These CFGs are not required to export most regulated products, but some foreign purchasers and governments may request that U.S. manufacturers supply these. For device manufacturers, nearly every Warning Letter for alleged GMP/QSR violations expresses that no CFG will be issued until FDA in its discretion decides it is satisfied. In 2003 Utah Medical was denied a CFG and there were no safety or effectiveness issues. Because of the business harm to Utah Medical it sued for declaratory and injunctive relief in 2003, but it was not until the 2005 court decision that FDA agreed to resume complying with CFG requests. This FDA policy decision of denial continues to harm U.S. companies attempting to export devices in lawful commercial distribution.

defense represents a confirmation of the repeated failure of the FDA/DOJ to sustain its allegations of GMP/QSR violations.<sup>16</sup>

There are lessons to be learned from the FDA's Warning Letter performance since 1991, the Waxman Report, and the decisions of federal courts across the U.S., including the recent Utah Medical adjudication. The appearance of a new Commissioner, coupled with congressional oversight, should be directed toward a more effective method of communicating with the regulated industry. It is probable that most recipients are in reasonable compliance with laws and regulations administered by the FDA and that the FDA does not possess the evidence to support the issuance of most Warning Letters.

While the FDA recently proclaimed that its enforcement strategy is "based on efficient risk management principles," the very recent experience of Utah Medical contradicts such FDA claims. At no time was any device manufactured and distributed by Utah Medical during a four year period of resource intensive scrutiny by the FDA the subject for any remedial action. There were no recalls, supportable reports of patient injury, defective devices, or any other issues of possible risk to patients. In spite of repeated requests to the FDA as to why it pursued this unsuccessful assault on a very good, responsible, and appropriately confident company, no one from the FDA has stepped forward to answer.

Until a major revision of the Warning Letter system is completed, the FDA itself should adhere to its own written procedures in effect since 1991. No recommendation for issuance of a Warning Letter by competent supervisory personnel should be considered unless there is sufficient evidence to support a request to the FDA OCC and ultimately to the DOJ. Both FDA and OCC personnel must adhere to the strict time limits in the RPM procedures.<sup>17</sup> In an effort to be fair to Warning Letter recipients, the FDA must decline to publish Warning Letters until the recipient has provided a response within the fifteen working day period expressed in the Warning Letter or a period equivalent to the period of time taken by the FDA to process a Warning Letter. Likewise, the FDA should honor a request to publish the reply along with the Warning Letter if requested by recipient.<sup>18</sup>

In the meantime, the "Warning" to those who receive a Warning Letter, apart from what is considered appropriate business management and response to completion of an inspection or investigation, is to carefully evaluate whether its content is appropriate. Are the facts as gathered by the FDA adequate to confirm that a violation of explicit requirements of law and/or regulation has occurred? If internal resources are not sufficient to complete an analysis, obtain the advice of experienced, knowledgeable, and competent counsel and/or consultants. If necessary, pursue available administrative remedies to seek a resolution. If unsuccessful, and the belief in innocence is supported and maintained, the receipt of a "sign or sue" letter from the DOJ may require initiation of discovery to dislodge the "hidden" FDA facts. Such discovery, while time consuming and expensive, may produce the "truths" that could result in amicable settlement or vindication through trial.

Perhaps, as expressed by Congressman Waxman the agency "is adrift and floundering," but this is a good time for the administration, as managed by a new Commissioner and Congress, to function as partners in fixing a broken communication system.

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<sup>16</sup>Since 1978 a total of four injunctive relief complaints against medical device manufacturers for alleged GMP violations have been pursued by the FDA/DOJ. All defendants, including Utah Medical, have prevailed through each trial.

<sup>17</sup>Upon completion of an inspection any recommendation for Warning Letter issuance is to be submitted in fifteen working days and reviewed by the OCC within another fifteen working days. If the OCC does not respond OCC concurrence is to be presumed. Few Warning Letters are issued within the required time period. For example, on August 31, 2006, a Warning Letter was issued by a District Office for an inspection that occurred on December 6-9, 2005.

<sup>18</sup>A review of Warning Letters issued recently revealed FDA public release of a Warning Letter before the recipient had the opportunity to respond within the fifteen working day response period requested by the FDA. For another, the FDA refused to publish the firm's response.