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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	CASE NO. 2:04-CV-00733-BSJ
v.)	
)	PLAINTIFF'S TRIAL BRIEF
UTAH MEDICAL PRODUCTS, INC., a)	
Corporation; and KEVIN L.)	
CORNWELL and BEN D. SHIRLEY, individuals,)	
)	
Defendants.)	
_____)	

INTRODUCTION

The United States seeks permanent injunctive relief under the Federal Food, Drug, and Cosmetic Act ("the Act") to enjoin Utah Medical Products, Inc. ("Utah Medical"), Kevin L. Cornwell, and Ben D. Shirley (hereinafter, collectively, "defendants"), from manufacturing and distributing adulterated medical devices in violation of 21 U.S.C. §§ 331(a) and (k). The

defendants manufacture medical devices that are used in labor and delivery, neonatal intensive care, gynecology, urology, electrosurgery, and blood pressure monitoring.

At trial, the United States will establish that Utah Medical's devices are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, and storage are not in conformity with current good manufacturing practice, as set forth in the Quality System ("QS") regulation, pursuant to 21 U.S.C. § 360j(f)(1) and 21 C.F.R. Part 820. Specifically, the defendants have failed to validate their extrusion and injection molding manufacturing processes, as well as computer software used in production and quality control. In addition, they have failed to establish and maintain an adequate and effective corrective and preventive action ("CAPA") program. The defendants do not believe that they are operating out of compliance with the QS regulation. Thus, absent injunctive relief, the defendants' unlawful conduct will continue.

FACTUAL BACKGROUND

A. The Defendants

Defendant Utah Medical is a Utah corporation that develops, manufactures, and markets a broad range of disposable and reusable specialty medical devices for use in labor and delivery, neonatal intensive care, gynecology, urology, electrosurgery, and blood pressure monitoring. Some of Utah Medical's devices are used in high-risk procedures including, but not limited to, high-risk childbirth. Utah Medical regularly manufactures devices from components that it receives from sources outside the state of Utah and introduces finished devices into interstate commerce.

Defendant Kevin L. Cornwell is the company's Chairman and Chief Executive Officer. Mr. Cornwell is involved in the day-to-day operations of Utah Medical and has authority over all

of its operations. Mr. Cornwell is ultimately responsible for Utah Medical's compliance with all applicable laws and regulations. Defendant Ben D. Shirley is the Vice President of Quality Assurance and Product Development at Utah Medical and is also responsible for the firm's compliance with the QS regulation.

B. FDA Inspections Of Defendants' Facility

The government will establish that from June 2001 through March 2004, the Food and Drug Administration ("FDA") inspected Utah Medical four times, and during each inspection, FDA investigators found significant and recurring deviations from the QS regulation. The QS regulation for devices is set forth at 21 C.F.R. Part 820 and establishes the minimum requirements for determining whether production methods, facilities, and controls are in compliance with the Act. The QS regulation is prophylactic in that it establishes requirements for manufacturing processes rather than for finished products. Responsible device manufacturers strive to exceed the minimum standards in the QS regulation to ensure the safety and effectiveness of their devices.

During the most recent FDA inspection of Utah Medical, conducted between February 3-March 3, 2004, the most significant deviations from the QS regulation found by the FDA investigators included, but were not limited to: failure to validate the extrusion and injection molding processes; failure to validate computer software used in production and quality control; and failure to establish and maintain an adequate CAPA program. FDA investigators found the same or similar QS deviations at the inspections conducted in June 2001, March-April 2002, and February-March 2003.

At the end of each inspection in 2001, 2002, 2003, and 2004, FDA investigators issued a detailed List of Inspectional Observations ("Form FDA-483") to the defendants and discussed

the investigators' observations with them. During each of these discussions, the defendants asserted that they believed that they were in compliance with the QS regulation. In addition, the defendants responded in writing to each of the Forms FDA-483 issued to them and steadfastly maintained in these responses that they were in substantial compliance with the QS regulation. In their discussions of the Forms FDA-483 with the FDA investigators, and in their written responses, the defendants also repeatedly refused to commit to correcting most of the QS violations identified by FDA.

In September 2001, FDA issued a Warning Letter to the defendants following the 2001 inspection. The Warning Letter emphasized the serious nature of defendants' violations and notified them that further regulatory action could result if they did not implement corrections. The defendants responded to the Warning Letter in writing, and stated that they believed Utah Medical was operating in compliance with the QS regulation. The defendants requested a meeting with FDA's Denver District Office to discuss the Warning Letter, and both during this meeting, which took place on December 21, 2001, and in a subsequent letter summarizing the meeting, defendants repeated their belief Utah Medical was in compliance with the QS regulation. Despite defendants' claims that Utah Medical is in compliance with the QS regulation, FDA investigators observed that significant violations of the QS regulation persisted at subsequent inspections in 2002, 2003, and 2004.

C. The Defendants' Recent Validation Attempts

Throughout the FDA inspections from 2001-2004, the defendants continually claimed it was not necessary to validate their extrusion and injection molding processes. During the close-out discussion at the 2004 inspection, and in their written response to the 2004 FDA Form-483, the defendants stated they did not need to validate these processes because they could verify that

the processes were under control through subsequent inspection and testing of the extruded and injection molded parts.

However, during discovery, the defendants produced documents to the government that detailed their recent attempts to retrospectively validate their extrusion and injection molding processes, and now claim the processes have been adequately validated. The defendants did not begin these retrospective validations until after the commencement of this litigation. Both of the government's expert witnesses, Kimberly Trautman and Anita Thibeault, believe the defendants' retrospective validations are inadequate, and reveal violations of the QS regulation that are serious, extensive, and reflect a recurring pattern of objectionable practices.

ARGUMENT

I. The Government Will Prove That Defendants' Devices Are Adulterated Because They Were Not Manufactured In Compliance With The QS Regulation.

A. The Purpose of the QS Regulation Is To Build Safety And Quality Into Devices During The Manufacturing Phase.

The Act, 21 U.S.C. § 351(h), specifically regulates the device manufacturing process, rather than the end product of that process. Therefore, if the manufacturing process does not conform to the law, the devices are deemed to be adulterated as a matter of law. 21 U.S.C. § 351(h).¹ The CGMP provisions of the statute for drugs and devices and their

¹ A drug that is not manufactured in conformity with CGMP is likewise deemed to be adulterated under 21 U.S.C. § 351(a)(2)(B), a parallel provision that is comparable to the device CGMP provision. The CGMP regulations for drugs are set forth at 21 C.F.R. Parts 210 and 211.

There can be no dispute that the case law construing “good manufacturing practice” in the context of pharmaceutical products applies equally to medical devices. The Supreme Court recognized that there is no difference between drugs and devices with respect to a regulated entity’s obligation to comply with the Act:

[I]t is clear that two parallel definitions [drug and device] were provided for semantic reasons only; for the purposes of the Act,

implementing regulations are prophylactic measures designed to prevent the distribution of poorly manufactured devices and drugs "by giving the Food and Drug Administration ... additional authority to require that sound methods, facilities, and controls be used in all phases of [device and] drug manufacturing and distribution." United States v. Bel-Mar Labs., Inc., 284 F. Supp. 875, 881 (E.D.N.Y. 1968); see also United States v. An Article of Drug . . . White Quadrisect, 484 F.2d 748, 751 (7th Cir. 1973). "The essential purpose of CGMP requirements is to maintain the safety and quality of [products] during the manufacturing stage, rather than to address problems only after they have caused harm to consumers." United States v. Various Articles of Drug, Bulk Antibiotics, 1996 U.S. Dist. LEXIS 22868, * 9-10 (D. Md. 1996), attached as Exhibit 1. Simply put, the QS regulation is intended to be preventive, by requiring manufacturers to build quality into their devices, rather than permit the possibility that some harm may occur because a defective device has been distributed and used in treating patients. John D. Copanos and Sons, Inc. v. FDA, 854 F.2d 510, 514 (D.C. Cir. 1988); United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, 799 F. Supp. 1275, 1285 (D.P.R. 1992).

Additionally, it is not necessary for the government to establish that a device is "actually deficient" as a result of a CGMP violation in order to prove noncompliance with the QS regulation. United States v. Various Articles of Device . . . Proplast II, 800 F. Supp. 499, 502 (S.D. Tex. 1992). Courts applying the parallel human drug CGMP provisions have invariably applied this interpretation of a violation of the CGMP provisions. See United States v. Western

the two definitions had the same effect of subjecting both drugs and devices to the adulteration and misbranding provisions.

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 797 (1969).

Serum Co., 498 F. Supp. 863, 867 (D. Ariz. 1980), aff'd, 666 F.2d 335 (9th Cir. 1982); United States v. Lit Drug Co., 333 F. Supp. 990, 998 (D.N.J. 1971) ("a drug may be pharmaceutically perfect in content but still be regarded as adulterated under the law"); Bel-Mar Labs., 284 F. Supp. at 880-81 (criminal prosecution in which adulteration of a drug was found and defendants convicted without evidence that the drug was actually deficient in some respect).

Thus, in enacting the Act's adulteration provision, which relieves FDA of the burden of proving actual contamination or defect in each case, Congress recognized that manufacturers are in a superior position to control risks to the public from the products they manufacture. Bel-Mar Labs., 284 F. Supp. at 880-81; S. Rep. No. 87-1744, reprinted in 1962 U.S.C.C.A.N. 2884, 2890 (1962). Requiring manufacturers to comply with CGMP requirements such as the QS regulation in manufacturing their products before they distribute them in interstate commerce, results in better, safer, more reliable devices and a more effective system of enforcement. See Bel-Mar Labs., 284 F. Supp. at 880.

B. The Most Effective Industry Standards Are Incorporated Into The QS Regulation.

The QS regulation was not intended to always provide specific instructions to device manufacturers on how to meet particular requirements, such as how to validate a manufacturing process. Instead, the QS regulation was drafted to provide guidance to a large variety of device manufacturers with varying degrees of complexity involved in their manufacture (gloves to heart-lung machines to everything in between), and is flexible enough to allow manufacturers to adopt current and appropriate industry standards as they develop. As the preamble to the Final Rule establishing the QS regulation states:

Because this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all

manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

61 Fed. Reg. 52602, 52603 (October 7, 1996).

The preamble to the analogous Final Rule for the parallel human drug CGMP regulations also makes clear that a particular practice cannot be just "widely prevalent" in the industry to meet CGMP requirements, but it must also be "feasible and valuable in assuring drug quality." 43 Fed. Reg. 45013, 45018 (1978). The court in Nat'l Ass'n of Pharm. Mfrs. v. Dep't of Health and Human Services interpreted the CGMP regulations as evolving with the most current and effective industry standards because "to accept [the] contention that CGMP regulations must reflect 'actually prevailing manufacturing practice in the drug industry' would leave the establishment of CGMP requirements in the hands of manufacturers and would tend to freeze the development of better practices over time." 586 F. Supp. 740, 752 (S.D.N.Y. 1984). Simply put, the CGMP regulations, as well as the analogous QS regulation, require manufacturers to adopt manufacturing practices that are "'good' as well as 'current.'" Id.

Device manufacturers, therefore, have a duty to ensure not only that they are meeting the minimum requirements that are stated specifically in the language of the QS regulation, but also to keep up-to-date with and adopt the most current and effective procedures and technologies available to the industry to fully implement the requirements. A manufacturer can stay abreast of recent developments, and help resolve any ambiguities in the QS regulation by referring to the ample guidance in FDA reports and guidance documents, literature from industry seminars and related device firms, textbooks and reference books, or by applying sound scientific judgment in the rare instance where such guidance is lacking. United States v. Barr Labs, Inc., 812 F. Supp. 458, 465 (D.N.J. 1993).

- C. The Government Will Prove That Defendants Have Failed To Properly Validate Their Extrusion And Injection Molding Processes.
- i. Under The Language Of The QS Regulation, And According To The Most Effective Industry Standards, The Defendants' Extrusion And Injection Molding Processes Do Not Produce Results That Can Be Verified By Subsequent Inspection Or Test, And Therefore, They Must Be Validated.

Under 21 C.F.R. § 820.75(a), validation is required for any manufacturing process whose results “cannot be fully verified by subsequent inspection and test.” Process validation is a procedure by which a manufacturer scientifically establishes documented evidence that a particular process or processes will consistently produce a product meeting predetermined specifications or attributes. In other words, process validation must be performed for a manufacturing process to ensure that, if the steps described in the written procedures are followed, the results of that process will be "practically guaranteed" to be consistent from lot to lot. See Global Harmonization Task Force ("GHTF"), Process Validation Guidance, Edition 2, January 22, 2004, attached as Exhibit 2.

Manufacturing processes must be validated if they produce a product with critical quality characteristics that can only be fully tested for the product’s intended use through destructive testing. This ensures that hidden flaws are prevented at the manufacturing stage when they otherwise might only become apparent with active use. This is the case for the defendants' extrusion and injection molding processes. For example, the defendants' extrusion process produces a thin plastic tubing component that is used primarily in catheters. If the interior diameter of the tubing is not wide enough, it could impair the flow of any fluid through the tubing and cause a malfunction during a medical procedure. On the other hand, if the interior diameter of the tubing is too wide, the tubing wall could be too thin, resulting in a weakness in the tubing. Although the defendants claim they can test the diameter of the entire length by

inserting differently sized measuring pins into either end of the tubing and then assuming that the diameter is consistent throughout the length of the tubing if the diameter is the same at both ends of the tubing, this is simply wrong. If there are hidden errors or flaws during manufacturing, the interior diameter can vary in width along the length of the tubing, even if it happens to be the same at both ends. Therefore, the interior diameter of the extruded tubing cannot be measured without cutting the tubing in various places, thus destroying the product.

Similarly, the defendants' injection molding process produces small plastic components that cannot be fully tested without destroying them. Injection molded components may contain air bubbles, or fatigue or stress points, in the plastic. In addition, the plastic may not "set" properly, causing it to be either too soft or too brittle for its intended use. These defects, which cannot be seen by the naked eye, can cause the injection molded components to be more likely to break or bend inappropriately during a medical procedure. Thus, the components must be sliced open and effectively destroyed to determine if such defects exist.

Because the above-described defects in the extruded and the injection molded components could significantly affect the functioning of the finished medical device in which the components are contained, testing only a sampling of each lot of components would not ensure the safety and effectiveness of every device containing these components. Only process validation will ensure that extrusion and injection molding will produce components that are consistent in quality and reliability because they have been found to meet predetermined specifications that have been designed to prevent defects from occurring. In fact, the preamble to the QS regulation and the GHTF Process Validation Guidance, specifically name "injection molding" as a process that requires validation. See 61 Fed. Reg. 52631; GHTF Process Validation Guidance, § 3.2. In addition, The Quality System Compendium: GMP Requirements

& Industry Practice, co-edited by Edward McDonnell, the defendants' expert witness, also states that injection molding and extrusion are processes "that traditionally have been considered by FDA to require validation" under the QS regulation. Association for the Advancement of Medical Instrumentation ("AAMI"), The Quality System Compendium: GMP Requirements & Industry Practice, ("The Quality System Compendium"), (1998), at 114. Thus, there is no question that both FDA and the medical device industry consider extrusion and injection molding to be processes that require validation to produce safe and effective devices.

- ii. It Is The Accepted, And Most Effective, Industry Standard That A Process Validation Must Consist Of An Installation Qualification, An Operational Qualification, And A Performance Qualification.

As explained above, the QS regulation does not provide specific instructions on how to validate each individual process. The defendants have argued that Utah Medical's procedures for extrusion and injection molding meet, in some general sense, the QS regulation's definition of validation, which is "confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled." 21 C.F.R. § 820.3(z). However, it is generally accepted within the medical device industry, and set forth in guidance documents published by FDA and other medical device industry organizations, that process validation has three steps: installation qualification, operational qualification, and performance qualification. See, e.g., GHTF, Process Validation Guidance, § 3, Edition 2, January 22, 2004.

To perform an installation qualification, a manufacturer must establish through objective evidence, gained from the manufacturer's studies and testing based upon a scientific rationale, that all equipment for a particular manufacturing process has been properly installed and operates within predetermined specifications. An operational qualification requires the

manufacturer to establish, through objective evidence, that a manufacturing process's parameters (e.g., time, temperature, speed) will produce products that meet all predetermined specifications. A performance qualification requires the manufacturer to establish, through objective evidence, that a particular manufacturing process, under all anticipated circumstances, including foreseeable adverse events such as power outages and equipment repair and/or maintenance, consistently produces products that meet all predetermined specifications. Simply put, to perform an adequate process validation, medical device manufacturers have to present evidence that they have installed their equipment properly, that they have established and implemented adequate process parameters, and that the process performs reliably and consistently, even under foreseeable adverse circumstances, to produce uniform products. Therefore, at a minimum, device manufacturers must be able to show that they have adequately performed installation, operational, and performance qualifications to meet the QS regulation's requirement for process validation at 21 C.F.R. § 820.75(a).

- iii. The Government Will Establish That The Defendants Have Not Validated Their Extrusion And Injection Molding Processes, And Their Testing And Inspection Procedures For The Extruded And Injection Molded Components Are Inadequate.

At the most recent FDA inspection in February-March 2004, the defendants asserted, as they have since 2001, that they could verify that their extrusion and injection molding processes were under control by subsequently inspecting and testing the parts produced by these processes. Contrary to their earlier position that validation is unnecessary, the defendants now argue that the documents they provided to FDA during the February-March 2004 inspection, which included training procedures, set-up sheets, run sheets, and statistical process control, showed that their extrusion and injection molding processes had been validated. The defendants are

wrong on both arguments. None of the documents provided to FDA investigators during the 2004 inspection, or with the defendants' written response to the Form FDA-483, contained any evidence that the defendants had performed an adequate installation, operational, or performance qualification on their extrusion or injection molding processes.

For instance, the defendants failed to produce any installation manuals or other documents showing that their extrusion or injection molding equipment had been properly installed. The defendants also failed to provide any evidence to show how the extrusion or injection molding process parameters were chosen or developed, as is required in an adequate operational qualification. Similarly, the defendants did not provide any evidence that their extrusion and injection molding processes will continue to produce products meeting predetermined specifications under all foreseeable circumstances, as is required in an adequate performance qualification. Without evidence of these three steps, the defendants' extrusion and injection molding processes are not validated.

Additionally, throughout the FDA inspections and in their written responses to Forms FDA-483, the defendants have consistently argued that the lack of both customer complaints and evidence of product failures "validates" their extrusion and injection molding processes "with a high degree of assurance." However, FDA has identified and the government will establish at trial, from documents produced at inspections and during discovery, numerous examples of complaints of Utah Medical's products failing to meet specifications. Moreover, it is well-settled among medical device quality experts, including the governments' expert witnesses Ms. Trautman and Ms. Thibeault, that a lack of complaints or product failures is not a good indicator of the quality or effectiveness of a manufacturing process. See, e.g., Roger W. Berger, et al.,

The Certified Quality Engineer Handbook 51, 57, 264-65 (ASQ Quality Press 2002); see also Frank M. Gyra, Quality Planning and Analysis, 4th ed. 609-13 (McGraw-Hill Irwin 2001).

The documents that the defendants provided to FDA during the inspections from 2001 to 2004 showed that the defendants have failed to adequately validate their extrusion and injection molding process. Those documents also showed that the defendants are not adequately testing the extruded and injection molded components to verify that they are consistently meeting predetermined specifications. The government will show that the defendants' test procedures for extrusion consist of pulling one extruded in-process component from the process once an hour. For injection molding, the defendants pull four injection molded in-process components from the process every two hours as long as no defects are found. If a defect is found, the defendants increase the sampling to four injection molded components every hour until three consecutive samplings find no defects. Both the sampling plans for extrusion and injection molding yield very small samples; in some cases, only 0.05% of an entire lot is pulled for attribute testing. In addition, the defendants could not produce any statistical analysis to support the number of samples that they took per lot to test critical attributes. This failure to base sampling plans on valid statistical rationale is also a separate violation of 21 C.F.R. § 820.250(b).

The government's witnesses will establish that the attribute testing that the defendants perform on these small samples is also inadequate. The few in-process attribute tests that the defendants perform provide them with very little meaningful information about whether all of the components being produced met predetermined specifications or whether their manufacturing processes were operating in a state of control. This deficiency in the defendants' testing of the attributes of their injection molded and extruded parts is so inadequate that it constitutes an independent violation of the QS regulation, 21 C.F.R. § 820.80(c) and (e), which

requires manufacturers to adequately establish, maintain, and document acceptance procedures, including attribute inspections, to ensure that specified requirements for in-process product are met. For example, the testing procedure form to be filled out for the injection molded parts only requires four attributes to be tested, even though Utah Medical's Quality Assurance Procedure QC-GE-12 identified 38 visual criteria to be tested. In addition, the attributes tested for the extruded parts have no relation to any process parameters. According to the defendants' procedures, if the extrusion process produces a part with attributes that do not conform to a specification, the operator is instructed to merely alter the process until a conforming part is produced, rather than trying to determine if the process parameters had not been met or needed to be changed. This means that there is no predictability or reliability in any additional products manufactured under the original or the altered procedures.

Moreover, many of the defendants' attribute testing procedures contain ambiguous language, such as the statement that appears in an injection molding training document telling the operator to make "minor adjustments" to the process parameters if any components are found to be out of specification. The procedure does not define the term "minor adjustments." Similar language appears in the extrusion procedures, such as instructions to "tighten" or "loosen" certain equipment if the tubing wall width was found to be out of specification, without any limits on how "tight" or "loose" to make the equipment. This ambiguity in the defendants' written procedures reveals not only the lack of adequate process validations, but also the lack of adequate process controls "for developing, conducting, controlling, and monitoring of production processes" as is required by 21 C.F.R. § 820.70(a).

Further, as discussed above, the government will prove that the defendants fail to test the attributes of the extruded or injection molded parts that are most likely to cause the parts to be

unsafe or ineffective. The defendants do not perform any sectional analysis for air bubbles, or any stress or strain analysis on injection molded parts. In addition, as discussed above, the defendants' measuring of the inner diameter of extruded tubing by inserting pins into either end cannot provide any assurance that the inner diameter is consistent for the entire length of the tubing. Clearly, the defendants' subsequent inspection and testing of extruded and injection molded parts can in no way verify that these manufacturing processes are operating in a state of control and producing consistent, safe, and effective devices.

iv. The Government Will Show That The Defendants' Retrospective Validation Is Inadequate And Does Not Cure Any Previously Observed Inadequacies.

During discovery, the defendants provided the government with "retrospective validation" documents, created during August to October 2004 for both the extrusion and injection molding processes. Ordinarily, process validation must be conducted before the manufacturing process begins to ensure that discrepancies and errors are identified and corrected before they can affect finished product. The defendants, however, contend that "after the fact" or "retrospective validation" should suffice. In effect, they want to reach back in time and recreate the manufacturing process. Although occasionally acceptable, retrospective validation can only be implemented where there is adequate and contemporaneous recordkeeping during the manufacturing step, and based on that record, one can assess and evaluate the process and its steps. It will not work, however, in cases such as these where the defendants' recordkeeping has been incomplete and inadequate. Essentially, the defendants merely repackaged old procedures and test results into documents that supposedly show installation, operational, and performance qualifications. Retrospective validations, however, are only as good as the historical information that a manufacturer has collected. Indeed, the GHTF Process Validation Guidance states, "a

complete validation based on historical data is not feasible if all the appropriate data was not collected, or appropriate data was not collected in a manner which allows adequate analysis." GHTF, supra, at § 7. The defendants' documents are not adequate process validations, because they contain the same deficiencies that were observed by FDA at the 2004 and previous inspections.

Most importantly, the defendants have failed to provide any additional information in the retrospective validation documents that shows that they have performed adequate installation, operational, or performance qualifications on either their extrusion or injection molding processes. The installation qualifications included in the retrospective validation do not contain evidence that the defendants currently have the appropriate equipment drawings and installation manuals to show that the equipment used in the extrusion and injection molding processes has been properly installed. There is also no evidence that the equipment functions properly; for example, the defendants have not shown that when they set a machine's dial at a certain speed, the machine actually attains that speed. Nor do the installation qualifications provide any explanation to support the defendants' conclusion that calibrating their extrusion and injection molding equipment once a year is sufficient to ensure the equipment will function properly. Moreover, even though equipment used in both the extrusion and injection molding processes relies on computer software, the installation qualifications did not contain any reference to the validation of that software. As will be discussed below, without adequate validation, there is not a high level of assurance that any computer software used in production is reliable and consistent for its intended use.

The retrospective validation documents also do not provide any evidence of adequate operational qualification for either the extrusion or injection molding processes because the

defendants have still not explained how they determined the process parameters for either extrusion or injection molding. Without these explanations, it cannot be determined if the processes are under control, and if they will consistently produce products that meet predetermined specifications.

The defendants have also failed to explain, as part of an adequate performance validation, why they have made certain changes over time to process parameters in both their extrusion and injection molding processes, and whether these changes affect the ability of the processes to produce products that meet predetermined specifications. In addition, the performance qualifications in the retrospective validations are inadequate because they fail to document and measure the effects of maintenance and/or repairs that have been conducted on the extrusion and injection molding equipment.

Moreover, the retrospective validation documents show the same ambiguity and lack of clarity as the process control procedures produced to FDA during the inspections. For example, many of the retrospective validation documents for both extrusion and injection molding rely on "pass/fail" or "go/no go" criteria. In other words, a product is merely found to either meet specifications or not, and is labeled a "pass" or a "fail," and actual product measurements are not provided. According to the Quality System Compendium, in a retrospective validation, "the accumulated data need to be more than pass/fail results demonstrating lot-to-lot conformance to specifications" because "this type of validation requires measurement data." AAMI, supra, at 126.

In addition, the written procedures in the retrospective validation documents for both extrusion and injection molding are filled with ambiguous terms and are difficult for the reader to follow. The operator instructions for both extrusion and injection molding contain subjective

and descriptive terms, including, but not limited to, "excessive," "approximate," "slowly," "fast," and "three point test." It is also unclear from the injection molding retrospective validation documents whether each of the "Arburg" and "Toyo" model machines used for the injection molding process are interchangeable for the purpose of validating the process. If there are differences in the models of these machines, then these differences must be taken into account in the process validation.

Clearly, the lack of adequate installation, operational, and performance qualifications, and the vagueness of the retrospective validation procedures, reveals that the defendants continue to operate in violation of 21 C.F.R. § 820.75(a). Furthermore, the retrospective validation documents establish that the defendants still do not have a valid statistical rationale, as is required by 21 C.F.R. § 820.250, for any of the sampling plans that they use in their extrusion and injection molding processes or for their decision to use three lots of products to validate both processes. The defendants have also failed to correct the inadequacies in their attribute testing, in violation of 21 C.F.R. § 820.80(c) and (e), as they have still not provided documented evidence that they are testing in-process or finished products for all of the critical attributes that they have identified. Additionally, as discussed above, the defendants' continued use of ambiguous terms throughout their retrospective validation documents shows that they are still have not developed adequate process controls, as is required by 21 C.F.R. § 820.70(a).

D. The Government Will Establish That The Defendants Have Failed To Adequately Validate Computer Software That Is Used In Production Or Quality Control.

Under 21 C.F.R. § 820.70(i), medical device manufacturers must validate all computer software for its intended use according to an established protocol, when computers or automated data processing systems are used as part of the production or quality system. Failure to validate

computer software used as part of production may result in: an inability to consistently produce product meeting established specifications; an inability to effectively monitor the quality of manufactured product; and a lack of credibility for the reliability of manufacturing test systems. In addition, the failure to validate automated systems used as part of the quality system may result in an inability to: track equipment maintenance and calibration requirements; to monitor environmental conditions for manufacturing processes; to accurately evaluate the effectiveness of production systems; to monitor field failures for adverse trends; to verify that complaints are being addressed in a thorough or timely manner; and to verify the effectiveness of corrective and preventive actions. Even computer software that is purchased "off-the-shelf" needs to be validated for its intended use, because all purchased software programs are not necessarily free of defects and may not have been designed for a manufacturers' intended use, and improper or incomplete data may be introduced due to improper configuration or operator errors.

According to FDA guidelines and current industry standards, an adequate computer software validation consists of, at a minimum, three steps: a requirements specification, a test procedure, and a test report. See, e.g., FDA, "General Principles of Software Validation," January 11, 2002; AAMI, Quality System Compendium, *supra*, p. 106-107; International Organization for Standardization ("ISO"), ISO 90003:2004, "Guidelines for the Application of ISO 9001:2000 to Computer Software" (2004); Institute of Electrical and Electronic Engineers ("IEEE"), IEEE 1012a-1998, "Standard for Software Verification and Validation - Supplement to 1012-1998" (1998); International Electrotechnical Committee ("IEC") IEC 60601-1-4:2000, "Medical Electrical Equipment Part 1: General Requirements for Safety" (2000). A "requirements specification" is the manufacturer's detailed definition of the software's intended

use. A test procedure sets forth how a manufacturer will show that the software meets all necessary parameters to perform its intended use, and the test report documents that procedure.

Every FDA inspection since 2001 has revealed that the defendants have failed to have adequate computer software validations for all of the computer software that they have identified as being used in production or quality control. At each inspection, including the most recent inspection in February-March 2004, and in each written response to the Form FDA-483s, the defendants have admitted their computer software validations were incomplete, but repeatedly stated that they were close to completing them.

During discovery, the defendants provided FDA with an updated software validation plan, dated February 15, 2005. The government's expert witness on computer software, Daniel Olivier, reviewed this plan and determined the defendants had failed to include a requirements specification for any of the software validations, even though Utah Medical's own procedure calls for the inclusion of this step. In addition, many of the validation test reports pre-date the test procedures, revealing that the defendants drafted their procedures to support known test results.

Several of the test reports submitted with the software validation plan contained execution dates between the years 1902 and 1910, revealing that the defendants have not corrected the "Y2K problem," and perhaps other problems, in their computer software. This failure to correct such a common software problem is further evidence that the defendants have not adequately validated their computer software. All of these deficiencies reveal that, after four inspections and the beginning of enforcement litigation, and numerous promises to correct this violation, the defendants still have not adequately validated their computer software used in production or quality control as is required by 21 C.F.R. § 820.70(i).

E. The Government Will Establish That The Defendants Do Not Have An Adequate CAPA System.

The defendants have failed to establish and maintain adequate CAPA procedures, as is required by 21 C.F.R. § 820.100. The purpose of a CAPA system is to collect and analyze quality information, identify and investigate product and quality problems or potential problems, and take appropriate corrective and preventive action(s) to prevent recurrences. 21 C.F.R. § 820.100(a). The defendants' CAPA system does not adequately perform any of these functions.

For example, in an effective CAPA system, "failure codes" are often used in quality records to identify device or component non-conformities, which, under 21 C.F.R. § 820.90, must be evaluated to determine the need for an investigation into the underlying manufacturing processes. When failure codes are adequately descriptive and used consistently, firms can search their quality records to identify and correct recurring problems. At the most recent inspection of Utah Medical, FDA investigators observed the defendants' CAPA procedures do not define failure codes and lack instructions on how to use the failure codes properly. Thus, identical quality problems have been assigned different failure codes in the defendants' quality records. These inconsistencies mean that the defendants cannot reliably analyze the quality data and may cause them to overlook or misidentify recurring problems with non-conforming devices or components, in violation of both 21 C.F.R. §§ 820.90 and 820.100.

The defendants claim the failure codes are not used for "quality" purposes, but rather, for reasons that are related only to Utah Medical's financial status. However, the failure code quality data for each product family is reviewed during Utah Medical's Material Review Board ("MRB") meetings. Utah Medical's MRB is responsible for reviewing quality data to identify

existing and potential product and quality problems. Thus, it is only logical that the MRB is using the failure code data to make decisions regarding quality problems. The defendants' failure to define the failure codes can result in poor or meaningless quality data being presented to the MRB. Consequently, as a result of the inconsistent use of these failure codes, necessary corrective and preventive actions may not have been taken by the MRB and the MRB may have used this failure code data ineffectively in the firm's quarterly quality analysis.

The defendants also fail to ensure that product complaints "are processed in a uniform and timely manner," as is required by 21 C.F.R. § 820.198(a)(1). For example, the defendants' complaint handling procedures contain vague and ambiguous instructions such as, "enter the event information and problem description in the space provided in Easy Trak as soon as possible after the complaint is received." The phrase "as soon as possible" for one person may be a matter of minutes or hours, whereas for another it may be a matter of days. The medical device industry typically requires specific time frames in complaint handling procedures for entering complaint files into the record system, carrying out complaint investigations, and closing out complaint files. Another Utah Medical complaint procedure states that "complaints should be evaluated as quickly and thoroughly as possible." Again, the procedure provides no further instructions, simply leaving it up to the individual employee to judge the meaning of "as quickly and thoroughly as possible." If an employee is under pressure to get complaint files closed, a complaint file may be closed out too early under the premise that it was as "quick and as thorough as possible" under the given time constraints. These instructions clearly do not ensure uniform and timely handling of complaint issues.

Moreover, the defendants' complaint handling procedures also fail to define how far back into the firm's historical data an employee should look when reviewing a product complaint.

According to complaint files collected at the 2004 inspection, complaint reviewers "looked back" at historical data on similar complaints anywhere from 0 to 3 years. The defendants have failed to explain the discrepancies between how far back complaint reviewers have looked at historical data in reviewing individual complaints. Without proper instructions on how to review complaints in a uniform and timely manner, as is required by 21 C.F.R. § 820.198(a)(1), the defendants risk overlooking significant data that is necessary in establishing an effective CAPA system.

II. The Government Is Entitled To A Permanent Injunction.

Based on the violations of the Act discussed above, the government seeks permanent injunctive relief under 21 U.S.C. § 332(a), which expressly authorizes injunctive relief to restrain such violations. When a statute authorizes an injunction to enforce Congressional policy, the court applies a different standard to consider the propriety of an injunction than that applied to private litigants. The Supreme Court has held that the government does not need to show that irreparable harm will result to obtain an injunction authorized by statute. United States v. City and County of San Francisco, 310 U.S. 16, 30-31 (1940). The Tenth Circuit has followed this rule: "When the evidence shows that the defendants are engaged in, or about to be engaged in, the act or practices prohibited by a statute which provides for injunctive relief to prevent such violations, irreparable harm to the plaintiffs need not be shown." Atchison, Topeka and Santa Fe Ry. Co. v. Lennen, 640 F.2d 255, 259 (10th Cir. 1981), rev'd in part on other grounds, 732 F.2d 1495 (10th Cir. 1984); accord Mical Communications v. Sprint Telemedia, 1 F.3d 1031, 1035 (10th Cir. 1993). Instead, the government must show only that the defendants have violated the statute and there is some "cognizable danger of recurrent violations" to obtain a statutory injunction. United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953). See also Shadid v.

Fleming, 160 F.2d 752, 753 (10th Cir. 1947) ("it is enough if the requirements of the statute are satisfied."); United States v. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. 1159, 1167 (D. Utah 1989) ("Here, it is sufficient to warrant an injunction under section 332(a) if it is established that the defendants violated section 331 and that such violations likely will continue.").

The Court enjoys the full scope of its equitable authority under the Act. See United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 761 (6th Cir. 1999). Further, the Court's equitable powers "should be exercised in harmony with the overall objectives of the legislation." CFTC v. Hunt, 591 F.2d 1211, 1219 (7th Cir. 1979). The Act's "overriding purpose [is] to protect the public health." United States v. An Article of Drug, Bacto-Unidisk, 394 U.S. 784, 798 (1969). By keeping adulterated medical devices from reaching consumers, an injunction serves that important purpose.

A. Absent Injunctive Relief, The Defendants Are Likely To Continue Violating The Act.

As explained above, the requirements for injunctive relief are met when the government shows that the defendants have violated the statute and that there is some likelihood that the violations may recur. The probability of future violations may be inferred from past unlawful conduct. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. at 1167 ("In determining the defendants' likely future conduct, the court need look no further than defendants' past record with the FDA."). See also CFTC v. British Am. Commodity Options Corp., 560 F.2d 135, 142 (2d Cir. 1977). As set forth in detail in the discussion above, the defendants have violated, and continue to violate, the Act by distributing adulterated medical devices. Thus, there is not merely a reasonable likelihood of recurrence. Rather, based on the

defendants' history of violative inspections, repeated assertions of compliance with the QS regulation, and continued distribution of adulterated medical devices, the defendants' future noncompliance is clear. See United States v. Diapulse Corp., 457 F.2d 25, 29 (2d Cir. 1972) ("The company's persistence in marketing the [violative product] makes it highly likely that the prohibited activity will cease only on the issuance of [an injunction]").

In addition, the law is clear that the "court's power to grant injunctive relief survives discontinuance of the illegal conduct" and that all the government need prove in addition to past violations is "some cognizable danger of recurrent violation." United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953) (emphasis added). Although the defendants may attempt to defend against this litigation by arguing that they are currently operating in compliance with the Act and the QS requirements, even if such contention were true, which it is not, injunctive relief is still necessary and appropriate. Any of the defendants' corrective actions would have occurred only after FDA and the Department of Justice notified the defendants that this enforcement action was being filed. Prior to that time, the defendants repeatedly claimed that they were in compliance with the Act and the QS regulation, notwithstanding that FDA investigators consistently found the defendants to be out of compliance with the Act. In any event, the defendants' temporary cessation of violative conduct does not foreclose injunctive relief or moot a lawsuit. See 22 Rectangular or Cylindrical Devices, 714 F. Supp. at 1167 ("Moreover, . . . claims that the illegal activities have been discontinued do not, standing alone, provide a defense to a statutory injunction."). See also City of Mesquite v. Aladdin's Castle, Inc., 455 U.S. 283, 289 (1982) ("It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice."); United States v. Parke, Davis and Co., 362 U.S. 29, 48 (1960) ("A trial court's wide discretion in fashioning remedies is

not to be exercised to deny relief altogether by lightly inferring an abandonment of the unlawful activities from a cessation which seems timed to anticipate suit."); Lyons Partnership v. Morris Costumes, Inc., 243 F.3d 789, 800 (4th Cir. 2001); United States v. Odessa Union Warehouse Co-op, 833 F.2d 172, 176 (9th Cir. 1987) ("cessation of violations does not itself foreclose issuance of an injunction."); United States v. Article of Drug . . . B-Complex Cholinols Capsules, 362 F.2d 923, 928 (3d Cir. 1966); United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970, 981 (S.D. Fla. 1979); United States v. Medwick Labs., Inc., 416 F. Supp. 832, 833 (N.D. Ill. 1976) ("Not even the complete cessation of the alleged violative acts will, of itself, afford grounds for denying injunctive relief under the Food, Drug and Cosmetic Act.").

Courts must also be wary of attempts to stop injunctions through remedial efforts and promises of reform that appear to take place in anticipation of legal action. United States v. Oregon State Med. Soc'y, 343 U.S. 326, 333 (1952). Such circumstances place a heavy burden on the defendants to establish mootness; otherwise they would simply be free to return to their old behavior once the threat of a lawsuit has passed. Iron Arrow Honor Soc'y v. Heckler, 464 U.S. 67, 72 (1983). The defendants must establish that "there is *no* reasonable expectation that the wrong will be repeated." W.T. Grant Co., 345 U.S. at 633 (quoting United States v. Aluminum Co. of America, 148 F.2d 416, 448 (2d Cir. 1945)) (emphasis added).

The evidence will show that the defendants have not taken remedial actions sufficient to remedy their ongoing violations of the QS regulation. Even if the Court finds that the defendants have taken steps to correct their violative behavior, the defendants' activities have only been taken in the face of pending litigation. Thus, given the defendants' lengthy history of violating the Act despite FDA's repeated warnings, it is clear that, absent injunctive relief, the defendants'

conduct is reasonably likely to continue. Accordingly, an injunction is necessary and appropriate.

B. The Government Is Entitled To Injunctive Relief That Allows Future Shut-Down And Recall Authority.

The government seeks injunctive relief that includes requiring the defendants to cease distributing product until they are inspected by FDA and determined by FDA to be in compliance with the QS regulation and the Act. Once the defendants are determined to be in compliance by FDA, the defendants would be free to resume distributing their products as long as they continue to comply with the law. There is a real concern on the government's part that, after resuming product distribution, the defendants may again violate the QS regulation or the Act. Given the defendants' past history of noncompliance, additional safeguards are required. Accordingly, the government is entitled to injunctive relief that permits FDA to issue a cessation and/or recall letter to the defendants upon a finding of future violations, without further action by this Court. This provision is intended to allow swift and appropriate action to prevent adulterated devices from reaching consumers. If the defendants take appropriate measures to conform with the QS regulation from the outset and these procedures are properly implemented, there should not be future violative conditions. If, however, FDA finds that serious violative conditions have returned, then immediate steps must be taken to prevent adulterated devices from being distributed. Requiring the defendants to shut down operations and/or initiate a product recall immediately when serious violative conditions have been observed by FDA is a more effective remedy than allowing the defendants' products, already found to be unlawful, to be marketed to consumers while new court proceedings are prepared and instituted.² Similar

² Decisions conferred to FDA in an order of injunctive relief are subject to review by the Court pursuant to the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). United States

provisions have been recognized as necessary and appropriate in FDA cases. See, e.g., Syntrax, 149 F. Supp. 2d at 885 ("I also find it necessary to permit the government to shut down the defendants' operations upon a finding of a violation of this Order without further action by this Court. Once again, this relief is routinely ordered by other courts to ensure compliance with the terms of the injunction."); United States v. Universal Mgmt. Servs., Inc., 999 F. Supp. 974, 983 (N.D. Ohio 1997) (paragraph 7 of court's order), aff'd, 191 F.3d 750 (6th Cir. 1999); United States v. Union Cheese Co., 902 F. Supp. 778, 789 (N.D. Ohio 1995) (paragraph VI of court's order); United States v. Richlyn Labs., Inc., 822 F. Supp. 268, 275 (E.D. Pa. 1993) (paragraph F of court's order); United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 39-40 (E.D.N.Y. 2001), aff'd, 2003 WL 193719 (2d Cir. Jan. 28, 2003).³

The government's request for future shut-down and recall authority is not punitive, but forward-looking and prophylactic, seeking to ensure compliance with the QS regulation at the defendants' firm and ensuring that no adulterated devices are introduced into interstate commerce. The proposed order will enjoin the defendants from selling their products until they take important steps to come into compliance with the QS regulation. After these crucial steps

v. Syntrax Innovations, Inc., 149 F. Supp. 2d 880, 885 (E.D. Mo. 2001).

³ The government is prepared to submit a proposed Order of Injunctive Relief upon the Court's request. The provisions that will be sought in the government's proposed order are necessary to protect the public health. Such provisions are routinely entered by the courts. See, e.g., Syntrax, 149 F. Supp. 2d at 882-91 (granting government's motion for permanent injunction on summary judgment, and imposing terms similar to those to be proposed in this case); Universal Mgmt., 999 F. Supp. at 981-86 (same); Union Cheese, 902 F. Supp. at 787-91 (granting injunction similar to that proposed here); Richlyn Labs., 822 F. Supp. at 274-75 (granting government's motion for permanent injunction on summary judgment, and imposing terms similar to those to be proposed here); United States v. Vital Health Prods., Ltd., 786 F. Supp. 761, 779-80 (E.D. Wis. 1992) (granting government's motion for permanent injunction on summary judgment, and imposing terms similar to those to be proposed here), aff'd sub nom. United States v. LeBeau, 985 F.2d 563 (7th Cir. 1993).

are completed and approved by FDA, the defendants would be free to resume distributing their products as long as they continually operate in conformance with the law.

III. Full Compliance With The QS Regulation Is Required As A Matter Of Law.

The defendants have argued throughout this litigation that they are in "substantial compliance" with the QS regulation, and that FDA is trying to impose additional requirements upon them that go above and beyond the plain language of the QS regulation. Courts have accorded deference to FDA's determination that a firm is in violation of the QS regulation. Indeed, the Court in Latex Surgeons' Gloves held that "whether a manufacturer is, in the Court's estimation, in substantial compliance with GMP regulations is immaterial if the FDA, in its discretion, determines that *full* compliance with the regulation is necessary." 799 F. Supp. at 1287 (emphasis in original)(internal quotations omitted). Likewise, in Western Serum, 498 F. Supp. at 867-68, although the court found only four CGMP violations, it nevertheless held:

Whether full compliance with the CGMPs is either possible or necessary is an issue that is not within this Court's competence. Rather, this is a matter properly left to determination by the FDA.

498 F. Supp. 867-68 (emphasis added), aff'd 666 F.2d 335 (9th Cir. 1982). Therefore, so long as the government has proven a single violation of the QS regulation, the articles are adulterated as a matter of law. Here, there are numerous violations, indisputably demonstrating that the defendants' products are adulterated.

Moreover, the law does not permit a medical device manufacturer to weigh the relative importance of one CGMP regulation against another CGMP regulation. Congress entrusted these decisions to FDA. See Nat'l Ass'n of Pharm. Mfrs., 637 F.2d at 879. Were this Court to accept a "best efforts" approach to compliance with the QS regulation, affording complete discretion to the manufacturer regarding the degree of implementation, the regulations would not

be binding and each manufacturer would be able to pick and choose unilaterally which regulations it could conveniently and economically obey, and which it could ignore. Such an interpretation would completely undermine the purpose of the QS regulation, for each manufacturer could, in effect, establish its own standard for safe and effective medical devices.

Furthermore, FDA's interpretation of the extent of implementation required under the QS regulation is entitled to substantial deference. Latex Surgeons' Gloves, 799 F. Supp. at 1288. Compliance with the QS regulation is required, regardless of any cost or hardship alleged by the defendants, and without respect to the nature of the defendants' operation. Id. A manufacturer has no right to conduct a business regulated by the Act in an unlawful manner. Diapulse, 457 F.2d at 29; United States v. Ellis Research Labs., Inc., 300 F.2d 550, 554 (7th Cir. 1962). As the Supreme Court has clearly and repeatedly recognized in cases arising under the Act, the difficulties or hardships of a manufacturer who voluntarily enters a regulated industry cannot outweigh the interests of the public in protection from products that violate the law:

The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products effect the health and well-being of the public.

United States v. Park, 421 U.S. 658, 671-72 (1975). See also Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 601 (1950) (potential injury to a regulated business because of seizures under the Act cannot outweigh the public interest in being protected from defective products); United States v. Dotterweich, 320 U.S. 277, 285 (1943) (in balancing hardships under the Act, the interests of a regulated business cannot outweigh those of "the innocent public who are wholly helpless"). The Act

does not provide that parties shall avoid doing such things if it is possible, it provides that it shall not be done at all. A party who cannot prepare proper . . . products under [proper] conditions must cease putting such products into interstate commerce.

United States v. Lazare, 56 F. Supp. 730, 733 (N.D. Iowa 1944).

CONCLUSION

The evidence will show that the defendants have violated the Act, and that, without permanent injunctive relief, a very real danger exists that further violations will occur and that the public safety will continue to be put at risk. Accordingly, injunctive relief is necessary and proper.

Respectfully submitted,

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