United States v. Utah Medical Products, Inc.: FDA Violates its Own Quality System Regulation Policy in an Enforcement Trial

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United States v. Utah Medical Products, Inc. is the first reported FDA enforcement action in which a medical device manufacturer chose to go to trial to contest the agency's request for an injunction—instead of sign a consent decree—to resolve alleged violations of the Quality System Regulation (QSR). The QSR governs good manufacturing practice requirements for medical devices.[2] The court in *Utah Medical* exhaustively examined the technical facts relating to the agency's claims throughout numerous pretrial conferences and during the trial. After all of the evidence was in, the court ruled against FDA on each of its QSR claims, held that Utah Medical is in full compliance with the QSR, and denied the agency's request for an injunction.[3] This article examines how FDA's violation of its own QSR policy affected the result in the *Utah Medical* case.

The Agency's QSR Policy

The QSR governs the manufacturing processes for an extraordinarily broad range of medical devices—from complex implantable electronic devices like pacemakers to relatively simple products like surgeon's gloves. Because the QSR regulates such disparate manufacturing processes, FDA has repeatedly emphasized that the QSR is a flexible "umbrella" regulation that permits a wide variety of methods to achieve compliance. The regulation's preamble explains that by following an "umbrella" approach, the QSR establishes *what* must be done without defining *how* it must be done:

> 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*.[4]

FDA has used different phraseology at different times to make this same point. For example, FDA has stated that the "Quality System Regulation specifies *general objectives* (e.g. calibrated equipment, training, management responsibility, process and design controls) *rather than methods*, since one method would not be applicable to all manufacturers."[5] The agency also has emphasized that "[t]he Quality System (QS) regulation indicates the required *end result* rather than specifically prescribing *how* a manufacturer is to comply with this regulation."[6]

The flexibility given manufacturers under FDA's "umbrella" QSR policy is wholly consistent with the congressional purpose in the underlying statute, which includes ensuring that medical device development and manufacture are not burdened by bureaucratic red tape. When Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA") in 1976 (establishing comprehensive federal regulation of medical devices for the first time), Congress recognized that medical devices "hold the promise of improving the health and longevity of the American people."[7] As a result, Congress sought to incentivize the development of "sophisticated, critically important medical devices."[8] Congress regarded the Medical Device Amendments as "a balanced regulatory proposal" that would protect innovations in device technology from being "stifled by unnecessary

restrictions" at the same time that it would protect the public from unsafe and ineffective devices.[9] The "umbrella" approach under the QSR embodies the "balanced" purpose of the statute — promoting safe and effective devices through broadly worded requirements while giving manufacturers the "breathing room" necessary to develop and manufacture their products without needless bureaucratic meddling in their operations.

FDA's Violation of its Policy

In the *Utah Medical case*, the agency took an entirely different approach to the QSR that violated its own "umbrella regulation" policy. Instead of focusing on the regulation's objectives rather than methods, FDA did the opposite, focusing on the methods rather than the objectives. Instead of examining the end result of the company's quality system and acknowledging that the company had flexibility in determining the means of compliance, FDA criticized the means of compliance without assessing the end result. The consequence was a trial in which the undisputed evidence showed that the quality system was consistently meeting its objective of assuring safe and effective high-quality products, and in which FDA simply tried to second-guess the methods used, without presenting any evidence that the company's chosen methods were inadequate to meet their objective.

The agency's failure of proof extended both to the specific objectives of particular QSR provisions (e.g., complaint handling) and to the overall objectives of the QSR—assurance that devices are safe and effective.[10] Thus, for example, FDA never tried to demonstrate that Utah Medical's quality system failed to meet its intended purpose, never claimed that there was any problem with unsafe, ineffective, or defective devices, and never undertook a risk assessment to evaluate the potential that there could be real-world problems from the methods critiqued by the agency. The court rejected FDA's approach as a "nitpicking" case.[11]

The agency's process validation claim, which challenged the company's plastic component manufacturing process, is a case in point. The objective of the process validation regulation, 21 C.F.R. § 820.75, is for the manufacturer to confirm with objective evidence that a manufacturing process consistently produces products that meet predetermined specifications, with a high degree of assurance.[12] During the trial, the company presented extensive evidence that this objective is consistently met. The evidence showed that Utah Medical's full range of product and process testing, comprehensive procedures and skilled engineers establish a carefully controlled component manufacturing process that consistently meets specifications at an extraordinarily high rate—more than 99.7% of the time. The agency's witnesses admitted that even a 95% probability of meeting specifications constituted a "high degree of assurance." And the agency did not contest the company's evidence that it has consistently met specifications more than 99.7% of the time. In fact, the agency's witnesses conceded that they had *never even analyzed* whether the company was consistently meeting specifications. They also admitted that the company's rate of compliance with specifications was not relevant to FDA's analysis. Why not? Because the purpose of these witnesses' testimony was to

challenge the company's methods—and not to address whether the company's methods met the objectives of the regulation.

The Language of the QSR and "Industry Standards"

The text of the QSR says nothing about the particular methods the agency's witnesses testified about at trial. What, then, was the agency's claimed legal basis for questioning the methods used by Utah Medical in its quality system? FDA argued that the QSR incorporates industry standards, relying on its witnesses to attempt to establish that such standards had been violated. The court never reached the question whether any industry standards even existed, because it concluded that any such standards would not be not incorporated into the regulations. The court stated that "[t]he regulations were promulgated in 1997 with no express incorporation of industry standards,"[13] and held that "it is fundamental that the regulations state the applicable law."[14]

The court's ruling rejecting the process validation claim described above well illustrates its analysis of the "industry standards" issue. The agency's witnesses had relied exclusively on two written references—*The Quality System Compendium* and the Global Harmonization Task Force's *Process Validation Guidance*—in attempting to establish "industry standards" for process validation. The court rejected FDA's arguments that these publications established binding legal requirements for manufacturers such as Utah Medical:

> The suggestion found in *The Quality System Compendium* and [the Global Harmonization Task Force's] *Quality Management Systems—Process Validation Guidance* may be of value as evidence of some standards suitable for some manufacturers, but in no sense are specifically embraced by the regulations, nor have changes been made in the regulations to incorporate them."[15]

The court echoed FDA policy that the QSR specifies objectives, not methods, when it noted that "'[v]alidation' is the key word, and has often been noted, 'many roads led to Rome.'"[16] The court then underscored that FDA's simple questioning of a method did not prove a violation of the regulations:

> 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.[17]

The court's ruling draws strong support from the FFDCA and the QSR, which indicate that the text of the regulations states all applicable legal requirements. The provision of the FFDCA authorizing the QSR indicates that binding good manufacturing practice requirements are to be "prescribed in . . . regulations."[18] Similarly, in the QSR preamble, FDA indicated that there are no regulatory requirements that are not stated in the text of the QSR. In response to a comment received during the notice and comment rulemaking process, FDA stated that the

language of the regulation was changed to make clear that unstated requirements do not exist:

> [T]he agency does not believe that FDA investigators will cite deviations from requirements not contained in this part. However, as noted above, FDA has altered the language of the scope to make clear that *additional, unstated requirements do not exist*.[19]

The regulatory language referred to by the FDA is set forth in the very first sentence of the QSR:

> Current good manufacturing practice (CGMP) requirements *are set forth in this quality system regulation*.[20]

In the *Utah Medical* case, the court properly held that the company was in full compliance with those requirements.[21]

The QSR's "Virtue of Generality" and "Vice of Imprecision"

The judge who presided over the *Utah Medical* trial perceptively observed that the QSR has "the virtue of generality and the vice of imprecision."[22] From FDA's vantage point, the QSR's generality is a virtue, because the agency has been able to regulate an extraordinarily broad spectrum of medical devices under a single set of regulations, thereby avoiding the burden of adopting specific regulations for each device type. However, the *Utah Medical* case demonstrates that the QSR's generality quickly becomes a "vice of imprecision" for the agency during a contested injunction action when FDA seeks to assert requirements that are not stated in the regulation's text. That is because the agency is unable to prove that its criticisms of a quality system constitute legal violations.

The hurdle that regulatory imprecision creates for the agency in contested medical device injunction actions is nothing new. Although *Utah Medical* is the first reported QSR injunction case to go to trial, there are three reported injunction cases that went to trial under the predecessor medical device Good Manufacturing Practice ("GMP") regulation, which followed the same "umbrella" approach as the QSR. FDA failed to prove any GMP violations in any of the cases, largely because it did not prove that broadly worded "umbrella" regulations required quality system changes demanded by FDA.[23]

In the future, FDA should avoid these results and return to its own first principles. The agency should stop challenging quality system methods when the objectives of the QSR are being met. And it should base QSR enforcement actions on violations of requirements stated in the text of the regulations.

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[2] *See* 21 C.F.R. pt. 820.

[3] *United States v. Utah Medical Products, Inc.,* 2005 WL 2716299 (D. Utah Oct. 21, 2005).

[4] 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996).
[5] FDA, Guide to Inspections of Medical Device Manufacturers (Dec. 1997) at 2, http://www.fda.gov/ora/inspect_ref/igs/med_dev_mnfct/meddev2.html (emphasis added).
[6] FDA, Center for Devices and Radiological Health, Medical Device Quality Systems Manual: A Small Entity Compliance Guide (Dec. 1996), Note to Manufacturers of Medical Devices, http://www.fda.gov/cdrh/qsr/intro.html.
[7] S. Rep. No. 94-33, at 2 (1976).
[8] *Id.*
[9] H.R. Rep. No. 94-853, at 12 (1976).
[10] *See* 21 C.F.R. § 820.1(a) ("The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act)."
[11] 2005 WL 2716299 at *8.
[12] *See* 21 C.F.R. §§ 820.3(z)(1), 820.75(a).
[13] 2005 WL 2716299 at *8.
[14] *Id.* at *3.
[15] *Id.* at *8.
[16] *Id.*
[17] *Id.*
[18] 21 U.S.C. § 360j(f)(1)(A).
[19] 61 Fed. Reg. at 52,605 (emphasis added).
[20] 21 C.F.R. § 820.1(a) (emphasis added)
[21] 2005 WL 2716299 at *5-8.
[22] *Id.* at *8.
[23] *See United States v. H.W. Andersen Prod., Inc.*, 1997 U.S. Dist. LEXIS 3080 (M.D.N.C. Jan. 24, 1997) at *14; *United States v. Laerdal Mfg. Corp.*, 853 F. Supp. 1219, 1227, 1229-33 (D. Or. 1994) *aff'd on other grounds,*73 F.3d 852 (9th Cir. 1995)*; United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 84 (D. Md. 1987).