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THE INCREASING ROLE OF CONGRESSIONAL AND ADVOCACY STRATEGIES FOR LIFE SCIENCES PRODUCTS

In view of recent widely publicized issues regarding lobbyists' activities and ethics, many life sciences companies are taking a hard look at their congressional and advocacy strategies and Washington D.C. representatives. It is important to choose one's Washington representative carefully, to manage their activities and exercise appropriate oversight, and to choose the appropriate projects for a congressional strategy. For the FDA-regulated industry, having a congressional and advocacy strategy in place is an increasingly critical element of both an overall product strategy and maintaining a successful Washington presence. While having strong and reliable data and positive interactions with FDA staff are the preferred paths toward product approval or achieving other regulatory goals, FDA does not operate in a vacuum; external interactions can be a necessity for many sponsors of FDA-regulated drugs, biologics, medical devices and food products.

In the late 1980s, patient advocacy groups began to play a greater role in drug policy. AIDS activist groups loudly took a stance and were able to attain a place at the table in negotiating with the Agency regarding early and expanded access to AIDS treatments. In the early 1990s, as "women's health" became a term of art, and an issue, women's and reproductive health and disease-focused patient groups became more involved in the FDA process. In some areas, such as breast cancer, the groups representing the collective voices of patients achieved notably involved status, and became an integral and unavoidable force in policymaking. Congress also became more attuned to health policy and FDA decision-making—a result of the influence and activities of the patient groups in raising congressional awareness, growing patient education and awareness through the Internet and direct-to-consumer advertising, and interests of aging constituents, from the elderly to aging baby-boomers.

More recently, Capitol Hill and advocacy strategies have often become a necessity in helping to break through Agency gridlock.

The combination of having only an acting FDA Commissioner, the sudden departure of former Commissioner Crawford, and the emergence of questions concerning FDA approval of widely marketed drugs such as Vioxx, has resulted in a perception that FDA is in paralysis. Indeed, this increased scrutiny has created an environment that understandably makes ordinarily reluctant FDA officials even more fearful of taking any action for which they might be criticized later.

How can a company move forward in this environment? In addition to developing a strong science basis and sound regulatory strategy, working with external stakeholders can be a necessary third leg of an effective Washington strategy. For new technologies, this approach is critical—but it can also be useful for products that are less cutting edge as well. An external Washington strategy can involve Capitol Hill; agencies other than FDA, such as NIH or the higher levels of the Department of Health and Human Services; trade associations, such as PhRMA, BIO and AdvaMed; and medical professional, patient or other consumer organizations. Legal or governmental policy groups, such as the Washington Legal Foundation, also can play a useful role in supporting well-founded industry positions, and other less traditional supporters can emerge as allies as well. Life sciences companies can communicate with and educate these entities seeking their support or, in the instance of an entity that may be oppositional, seek to neutralize its impact. The support of the external entities can then be communicated to FDA in either formal or informal ways. While such support is not sufficient to reverse an Agency decision where science is lacking, outside support can help to focus and energize FDA efforts, provide a higher level of confidence regarding the decision and trigger action when the Agency's bureaucratic apparatus is stuck.

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U.S. v. UTAH MEDICAL PRODUCTS: LESSONS LEARNED

On October 21, 2005, the U.S. District Court for the District of Utah, Central Division, dismissed the FDA's request for a permanent injunction against Utah Medical Products (Utah Medical), stemming from alleged violations of the Quality System Regulation (QSR), 21 C.F.R. Part 820 (also referred to as Good Manufacturing Practices, or GMPs). *U.S. v. Utah Med. Prods.*, 2005 U.S. Dist. LEXIS 25993 (D. Utah 2005). The decision is surprising in that the court gave FDA almost no deference in its interpretation and application of technical QSR requirements, including those related to process validation. Moreover, in another surprise move, FDA has decided not to appeal the decision, but has stated that it does not see any effect of the court's decision beyond the facts of the case, and does not plan to make policy changes to GMP requirements in light of the ruling. Accordingly, while only time will tell whether this decision will have any lasting importance in the sphere of FDA enforcement, the case history reveals a number of important lessons for medical device and pharmaceutical companies under the threat of FDA enforcement action.

The events leading up to the district court decision (summarized in the next column) began in 2001 and were marked early on by heated disagreements between Utah Medical and FDA. Utah Medical was inspected by FDA four times in less than three years.

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- **June 4-8, 2001**—FDA inspects Utah Medical and issues FDA Form 483.
- **September 4, 2001**—FDA issues Warning Letter to Utah Medical concerning QSR violations dating back to 1995, and requests that Utah Medical (1) provide evidence from an outside expert consultant by November 30, 2001 certifying that it was in compliance with QSR requirements, and (2) conduct bimonthly certifications until all corrections are made.
- **September/October 2001**—Utah Medical declines FDA's request for outside expert consultant certification but consents to further inspection.
- **December 2001**—Utah Medical meets with FDA Denver District Office and denies noncompliance with QSR requirements.
- **March/April 2002**—FDA inspects Utah Medical and issues FDA Form 483 (13 observations).
- **February/March 2003**—FDA inspects Utah Medical and issues FDA Form 483 (19 observations).
- **Early 2003**—Utah Medical requests that FDA conduct an investigation of inspector bias.
- **May 2003**—Utah Medical meets with FDA Denver District Office and other Agency officials.
- **January 30, 2004**—Utah Medical files lawsuit in U.S. District Court for the District of Utah, Central Division, to compel FDA to issue Certificates of Foreign Governments.
- **February 2, 2004**—FDA begins fourth inspection of Utah Medical, which concludes March 3, 2004 (56 inspector days) at which time FDA Form 483 is issued (7 observations).
- **May 2004**—Utah Medical requests nonbinding mediation with FDA, which is denied.
- **August 9, 2004**—FDA files complaint against Utah Medical with the U.S. District Court for the District of Utah, Central Division, seeking a permanent injunction.
- **October 21, 2005**—District court dismisses government's case against Utah Medical.

Lesson #1: FDA Does Not Always Obtain Complete Judicial Deference

In its September 19, 2005 pretrial brief, Utah Medical framed its general position in the case as follows: "By attempting to elevate 'industry standards' to binding legal requirements, the Government posits an essentially lawless regulatory regime — one in which legal requirements have extraordinary ambiguity, and manufacturers must consult FDA-approved 'experts' instead of the Code of Federal Regulations to know what their obligations are. . . . No industry conference or committee can supersede the language of the regulations." Moreover, Utah Medical asserted that, based on the regulatory history of the QSR, the regulations were intended to establish "what must be done without defining how it must be done," and therefore "the government's attempts to require that Utah Medical pursue a very specific manner of compliance is at odds with the purpose of the QSR." The district court clearly embraced these positions, and provided no deference to FDA on its interpretations of QSR requirements, including those set forth in Agency guidance documents and industry standards. The court's analysis of Utah Medical's compliance with installation validation requirements is indicative of its overall approach in the case:

Though done years after installation, the in-house engineers checked out the installation over a period of months and documented what they did over a period of months. They determined that the machines were properly installed. To the Court, that seems perfectly adequate. It verifies the validity of what was done at installation. The movie can't be run backwards, nor the clock turned back. The current effort by Utah Medical, of course, is to ensure product safety by doing now and providing documentation of a comparable "installation" series of tests. Such complies with the regulation. So much for installation.

The courts generally give federal agencies, and particularly FDA and similar science-based agencies, reasonable deference in interpreting their statutes and regulations in order to advance such laudable goals as protecting the public health. Even under more narrow recent

Supreme Court precedent, which has clarified that rulings, guidances and similar sources “are best treated like ‘interpretations’ contained in policy statements, agency manuals, and enforcement guidelines . . . [and thus] are beyond the *Chevron* pale,” the courts will uphold an agency’s actions according to their persuasiveness. *U.S. v. Mead*, 533 U.S. 218 (2001) (citing *Christensen v. Harris County*, 529 U.S. 576, 587 [2000]). Accordingly, regulated entities generally strive to avoid litigation with FDA, as the prospects for prevailing are not promising, and this approach can prove extremely costly.

Lesson #2: There Is Precedent to Reverse the Utah Medical Decision

While Utah Medical prevailed in the district court, recent FDA-related precedent in the District of Utah and persuasive authority in other circuits involving asserted GMP violations suggest that the Agency could have prevailed on appeal. In these other cases, the courts have granted greater deference to FDA’s interpretation of its statutes and regulations.

Notably, on February 26, 1999, the U.S. District Court for the District of Utah, Central Division, set aside and held unlawful FDA’s administrative decision that Cholestin, a product marketed by Pharmanex, Inc., was a drug because it contained lovastatin (the active ingredient in Merck’s cholesterol-lowering drug Mevacor), rather than, as Pharmanex contended, a dietary supplement. *Pharmanex, Inc. v. Shalala*, 35 F. Supp. 1341 (D. Utah 1999). Based on Pharmanex’s interpretation of the prior-market clause at Section 201(ff)(2) of the Federal Food, Drug and Cosmetic Act (i.e., if an article was merely present in food, it was marketed as food), the district court ruled that Cholestin qualified as a dietary supplement because lovastatin was present in red yeast rice, oyster mushrooms, and other foods that were marketed in the United States and East Asia prior to lovastatin’s approval as a new drug in 1987. FDA appealed to the U.S. Court of Appeals for the Tenth Circuit, which reversed and remanded the district court’s ruling. *Pharmanex, Inc. v. Shalala*, 221 F.3d 1151 (10th Cir. 2000). The Tenth Circuit held that FDA’s application of the prior-market clause to the dietary ingredient lovastatin rather than to the finished dietary supplement product Cholestin was reasonable and merited deference. Accordingly, should the Tenth Circuit consider the Utah Medical case on appeal, it appears probable that the court would provide FDA with greater deference and

potentially reverse, at least in part, the district court decision.

Moreover, while there have been very few cases in which firms have litigated with FDA over asserted GMP violations, in the most notable case, *U.S. v. Barr Laboratories, Inc.*, 812 F. Supp. 458 (D.N.J. 1993), the court was far more deferential to the Agency and evenhanded in its overall approach than in the *Utah Medical* case. While the *Barr* court also determined that, in light of Barr’s remedial efforts and human and other resource improvements, it was unwilling to order a temporary shutdown, it also ordered Barr to conduct concurrent or prospective validation studies for 39 products, and to cease all distribution of 24 of these products until such studies were completed. Similarly, the court determined that of the 15 batches of 10 different products recommended by the government for recall, 13 were to be recalled. As opposed to the *Utah Medical* court’s general dismissal of FDA’s positions, the *Barr* court undertook a meticulous evaluation of and made particularized determinations concerning each asserted GMP violation. If the Tenth Circuit had considered the *Utah Medical* case on appeal, it may not have reversed the district court’s decision with respect to a permanent injunction, but it seems plausible that, like the *Barr* court, it would take a more measured approach to future compliance requirements.

Lesson #3: Dismissing FDA Concerns Will Lead to Legal Action

While the scope of FDA’s demands at different points in the foregoing compliance history are not completely known, it appears that, notwithstanding FDA assertions to the contrary, Utah Medical continually professed its compliance with all QSR requirements dating back to 2001. Otherwise stated, it does not appear that, irrespective of Utah Medical’s belief in its compliance, the firm was prepared to agree to take steps to enhance its systems to address Agency

concerns. For example, in its September 2001 Warning Letter, FDA requested that Utah Medical provide evidence from an outside expert consultant certifying that it was in compliance with QSR requirements. Utah Medical declined this request, and instead consented to further inspection. FDA obliged Utah Medical, with inspections in 2002, 2003, and 2004 that resulted in 13, 19, and 7 FDA Form 483 observations, respectively, that facilitated the Agency’s development of a case against Utah Medical.

While it is unclear whether FDA would have stopped short of judicial action had Utah Medical made concessions, taking a more pliant and measured approach with respect to FDA GMP observations and demands generally enables firms to avoid litigation with the Agency. For example, had Utah Medical agreed in 2001 to retain an outside expert consultant to certify the firm’s compliance with QSR requirements and make more significant changes to its systems, it is possible that the direction of this matter would have changed. An unwillingness to satisfy the Agency over a protracted period of time, however, often leads to more forceful FDA enforcement tactics.

Lesson #4: Taking an Aggressive Approach Toward FDA Carries Risk

Utah Medical’s longstanding aggression toward the Agency likely exacerbated the implications of its decision not to make appreciable concessions to FDA. The company filed a lawsuit against FDA in January 2004 to compel the Agency to issue Certificates of Foreign Governments, requested that FDA conduct an investigation of inspector bias in 2003, issued approximately 20 press releases since February 2004 detailing FDA improprieties, and made various derisive statements about FDA in the trade press. In its press releases, Utah Medical accused FDA of abusing the regulatory process and its authority, misrepresenting facts, covering up mistakes,

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Morgan Lewis’ Life Sciences Practice is one of the largest in the nation, with approximately 200 lawyers whose practice and experience are significantly devoted to the life sciences industry. Additionally, we have more than 200 professionals with life sciences scientific degrees, nearly a third of whom have advanced degrees. For more than two decades, we have developed our practice to “protect the complete life sciences product life cycle,” with depth and quality in all important areas: regulatory, transactional and litigation. For more information regarding Morgan Lewis’ Life Sciences Practice, please contact the group’s Chair, Stephen Paul Mahinka, at 202.739.5205 or smahinka@morganlewis.com.

EVENTS, SPEECHES & ARTICLES

MORGAN LEWIS-SPONSORED LIFE SCIENCES EVENTS

Biotechnology Council of New Jersey's Employment Law for Executives and HR Professionals in the Life Sciences Industry
February 21, 2006, Bridgewater, NJ

BIO 2006 Annual Convention
April 9–12, 2006, Chicago

New York Biotechnology Association Annual Meeting
April 17–18, 2006, New York

DRI Drug and Medical Device Litigation Seminar
May 11–12, 2006, Chicago

LIFE SCIENCES SPEECHES & ARTICLES

Antitrust

ACI In-House Counsel Forum on Pharmaceutical Antitrust
Understanding Market Power and Its Effect on Antitrust Analysis of Company Actions
Scott A. Stempel
April 25, 2006, Philadelphia

Business and Finance

BIO 2006 Annual Convention

Outsourcing Biopharmaceutical Development in a Globalized Economy: What Are the Strategic and Business Challenges of Outsourcing Across the Discovery, Development, and Manufacturing Value Chain?

Randall B. Sunberg
April 10, 2006, Chicago

New York Biotechnology Association Annual Meeting

Creative Financing for Biotech and Pharma Drug Development and Commercialization

Randall B. Sunberg
April 17, 2006, New York

IBC's Advances in Drug Discovery and Development

How to Profit from the Japanese Biopharma Investment/Venture Market and Other International Biotech Finance Opportunities

John Y. Sasaki
April 25, 2006, Tokyo

Pharmaceuticals/Biotechnology/Medical Devices

ACI's Internal Investigations

for the Pharmaceutical & Medical Device Industries

John C. Dodds
April 26, 2006, New York

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systematic corruption, misusing public funds, bias, unfairness, dishonesty, incivility, incompetence, and generally being out of control.

Utah Medical's strident posture toward FDA likely escalated the situation and contributed

to the Agency's decisions to deny mediation and file the lawsuit. While Utah Medical repeatedly acknowledged FDA's significant enforcement powers, by its actions, it challenged the Agency to wield this power.

Lesson #5: Case Revealed Concerns with Agency Behavior

Finally, while Utah Medical's regulatory strategy contributed to FDA's lawsuit, revelations from the case supported certain of the firm's contentions of Agency subjectivity. For example, an internal email from an Agency QSR decision-maker to other reviewers prior to the completion of the 2003 inspection directed: "This 483 is going to have to be dead on, for me to support an observation with all the issues surrounding the inspections. I will not be able to massage it for the complaint like some cases." While these types of statements serve to discredit the Agency's position that it enforces in a fair and evenhanded manner, Utah Medical paid a hefty price and took significant risks to obtain this information.

Given the significant costs and risks of litigation, and the possibility that the district court decision arguably could have been reversed in whole or in part on appeal, FDA-regulated companies should carefully consider the substantial risks associated with adopting the Utah Medical regulatory approach as a new template for addressing FDA enforcement concerns.

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