POLICY & PRACTICE

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Ads Misled on Metozolv ODT

Salix Pharmaceuticals Inc. misled physicians and consumers in promotional materials for its drug Metozolv ODT (metoclopramide), which was approved in September 2009 for diabetic gastroparesis and gastroesophageal reflux disease, the Food and Drug Administration said in a warning letter to the company. Metozolv ODT is approved for short-term therapy in adults with diabetic gastroparesis, and for short-term therapy in adults who have GERD that does not respond to other medications. The FDA warning letter said Salix downplayed and omitted risk information and broadened the indications for Metozolv ODT in advertising materials and in a display at a clinical meeting. Salix failed to submit some of the materials to the FDA, as required, at the time of their initial use. The FDA specifically flagged the term "ideal for all patients," which it said was untrue due to Metozolv ODT's "numerous contraindications and limitations of indications for use." The warning letter told Salix to immediately stop using the questionable promotional materials and to ensure that all other materials comply with FDA regulations.

Calif. County Sues Over Avandia

A California county has sued GlaxoSmithKline, saying the pharmaceutical giant falsely promoted its diabetes drug Avandia as safe and effective while suppressing evidence of serious cardiovascular problems. The complaint, filed by Santa Clara County in U.S. District Court for the Northern California District, asserts that GSK ignored or concealed early data and studies revealing Avandia's hazards. The company also engaged in "an aggressive and highly successful marketing strategy designed to persuade patients, doctors, and insurers to use Avandia instead of less expensive and far safer diabetes drugs already on the market," the complaint said. The lawsuit seeks monetary restitution for all Avandia purchasers and users in California, and notes that Santa Clara County spent $2 million on Avandia purchases between 1999 and 2007.

GSK Ties Underreported

Many researchers who published articles supporting rosiglitazone (Avandia) after it was linked to cardiovascular disease in 2007 had financial ties to GlaxoSmithKline, an analysis published in the British Medical Journal found. The authors examined 202 articles, including 108 that contained a financial conflict-of-interest statement, and found that researchers who had a favorable view of Avandia's cardiovascular risks were more likely to have financial conflicts of interest. Disclosure rates overall were "unexpectedly low," the BMJ analysis said. "There was a clear and strong link between the orientation of authors' expressed views on the rosiglitazone controversy and their financial conflicts of interest with pharmaceutical companies," the analysis said, adding that although this does not prove cause and effect, it shows the need for better disclosure practices.

HbA_{1c} Test Sales Increasing

Hemoglobin A_{1c} testing will increase more than other tests performed at the point of care as a result of expert recommendations, new diabetes cases, and booming mail-in test sales, according to a report from marketing research company Kalorama Information. Kalorama estimated that the global market for point-of-care HbA_{1c} tests reached $230 million in 2009 and will rise to $350 million by 2013, a growth rate that is 50% higher than the average point-of-care testing product. The mail-in self-tests, performed by mail-in laboratory services, represents a small percentage of those revenues now, but is showing faster sales growth than lab-based tests and should grow at 25% annually over the next 5 years, Kalorama said. At least 30 companies offer HbA_{1c} assays for automated systems, the report said.

FDA Warns on Food Labels

The Food and Drug Administration has notified 17 food manufacturers, including Gorton's Inc. and Nestle, that labeling for some of their food products violates the Federal Food, Drug, and Cosmetic Act. Violations cited in the warning letters include unauthorized health claims, unauthorized nutrient-content claims, and the unauthorized use of terms such as "healthy." Nestle, for example, was warned about using "100% juice" to describe a product that had added flavors, while the FDA told Gorton's in its letter that its fish fillet packages need to disclose high levels of sodium, saturated fat, and total fat to accompany the claim of zero trans fats.

—Jane Anderson

BUSINESS BRIEFS

Baxter Acquires ApaTech

Baxter International Inc. will enter the bone fusion market through its acquisition of ApaTech, maker of the bone graft Actifuse, for up to $330 million, in a deal announced last month. Baxter will pay $240 million up front, plus up to $90 million in milestone payments. The total is worth up to 5.5 times ApaTech's sales of $60 million last year. Actifuse "will allow us to immediately enter the emerging bone fusion category, and ApaTech's product pipeline is highly complementary to our existing commercial and technical capabilities in biosurgery," said Ron Lloyd, vice president and general manager of Baxter's BioTherapeutics and Regenerative Medicine. Actifuse is a silicate-substituted, calcium-phosphate synthetic bone graft material that combines a biostimulative scaffold with chemical properties that accelerate bone formation, according to ApaTech. Actifuse formulations include microgranules for small graft areas and E-Z Prep, which forms a cohesive graft in 20 minutes when mixed with blood or bone marrow aspirate. According to Andrew Lewis, a spokesperson for Baxter, the overall U.S. bone growth substitutes market is worth $1.5 billion, and the synthetic bone growth substitutes segment reached $145 million in 2009. The deal also will allow Baxter to gain access to ApaTech's global sales force, half of which is based in the United States.

Envoy, Merck Team for Research

Envoy Therapeutics Inc. has entered into a multiyear research collaboration agreement with an affiliate of Merck and Co. to explore novel diabetes and obesity drug targets. Envoy will use its bacTRAP technology to identify proteins expressed specifically in certain cell types, and Merck, which will provide an upfront fee and research funding, will develop compounds that modulate protein targets with therapeutic potential for the treatment of metabolic disorders. "Obesity and diabetes have become epidemics with horrific mortality rates and devastating social stigmas," said Brad Margus, cofounder and CEO of Envoy. "We're thrilled that our technology will be applied toward discovering drug candidates for the growing millions of patients who suffer from these conditions." Envoy will be eligible to receive payments at certain milestones associated with drug candidate development and royalties on any products resulting from the collaboration. "Partnering with companies developing innovative drug discovery technologies … is an essential part of our diabetes and obesity portfolio discovery strategy," said Nancy A. Thornberry, senior vice president and franchise head for diabetes and obesity at Merck Research Laboratories.

Atherotech Taps Heart Experts

Atherotech Inc., maker of the VAP cholesterol test, which identifies markers for the metabolic syndrome, has added eight cardiovascular experts to its medical advisory board to guide the development of the company's disease management program. The new team comprises Dr. Eliot A. Brintman, director of the metabolism section of cardiovascular genetics and the LDL apheresis center at the University of Utah, Salt Lake City; Dr. Michael H. Davidson, director of preventive cardiology at the University of Chicago; Prakash C. Deedwania, chief of cardiology for the VA Central California Health-Care System, Fresno; Dr. Gary H. Gibbons, endowed director of Morehouse School of Medicine's Cardiovascular Research Institute, Atlanta; Dr. Peter H. Jones, medical director of the Methodist Weight Management Center in Houston; Dr. Richard B. Lanman, chief medical officer of Veracyte Inc., a molecular diagnostics company in South San Francisco, Calif.; Dr. Charles A. Reasner II, medical director of the Texas Diabetes Institute in San Antonio; and Dr. Peter B. Toth, chief of medicine at CGH Medical Center in Sterling, Ill. "Collectively, [they] have more than 150 years of clinical research, nearly 1,000 publications, and over 200 years of clinical patient care," said Dr. Michael E. Cobble, Atherotech's chief medical officer. In addition to the VAP cholesterol test, Atherotech has more than a dozen cardiovascular and metabolic tests, including those for high-sensitivity C-reactive protein, lipoprotein-associated phospholipase A2, apoE genotype, N-terminal–pro brain natriuretic peptide, cystatin C, T3 and T4, and gamma-glutamyl transferase.

Unigene Restructures to Meet Debts

Unigene Laboratories, maker of Fortical, a nasal calcitonin treatment for postmenopausal osteoporosis, has restructured its debt financing agreement with Victory Park Capital Advisors, its primary shareholder and lender. The deal buys time for Unigene to pay off its debt and adds $13.6 million to its balance sheet. The family-owned biopharmaceutical company agreed to major management change and gave Victory two seats, including chairmanship, on its board of directors. Unigene's chairman, Jay Levy, relinquished his board seat and Ronald S. Levy, secretary, left that position but stayed on as executive vice president, according to the terms of the agreement filed with the Securities and Exchange Commission. The regulatory filing also states that Unigene "is obligated to use its reasonable best efforts to identify, interview, and negotiate with candidates for, and, subject to the board's approval, hire a new chief executive officer as successor to Warren Levy as soon as reasonably practicable." Victory Park Capital's principal and founder, Richard N. Levy (no relation to the Levy family that runs Unigene), stepped in as chairman. Unigene reported a 2009 net loss of $13.4 million, more than double its 2008 net loss of $6.1 million. Unigene is currently focused on the development of salmon calcitonin in nasal and oral formulations for postmenopausal osteoporosis, Paget's disease, and hypercalcemia.

—From staff reports

Reporters and editors from Elsevier's "The Pink Sheet" contributed to this column.

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