Will Vioxx fallout affect medical device industry?

As physicians and pharmaceutical companies exchanged verbal bullets with each other about drug safety, medical device manufacturers crouched low to avoid getting hit by the crossfire.

In the wake of the withdrawal from the market of the painkiller Vioxx in September, some physicians and members of Congress were calling for a better system to monitor the safety and effectiveness of pharmaceuticals after the Food and Drug Administration has cleared them for marketing. A potential problem for medical device manufacturers is that some of the most vocal critics of the current system suggest that regulators revise the way medical devices are monitored as well.

The clamor stemmed from a number of well-publicized incidents involving big-name drugs, the most recent being Vioxx, the painkiller from Merck & Co. that’s been linked to heart attacks. Two previous incidents were also cited:

- The withdrawal from the market in 2001 of the cholesterol drug Baycol (cerivastatin) by Bayer AG over concerns that the drug caused serious muscle conditions. Critics charge that Bayer knew of a possible link between the drug and the muscle condition soon after the drug was introduced in January 1998, but that the company failed to confirm it or notify doctors of the potential link until much later.
- The failure of GlaxoSmithKline to report studies linking its anti-depressant Paxil with incidences of suicide among children and teenagers.

Conflicts of interest


The editors said that the current postmarketing surveillance (which relies on field reports of adverse drug reactions) is laden with shortcomings, including:

- The withdrawal from the market in 2001 of the cholesterol drug Baycol (cerivastatin) by Bayer AG over concerns that the drug caused serious muscle conditions. Critics charge that Bayer knew of a possible link between the drug and the muscle condition soon after the drug was introduced in January 1998, but that the company failed to confirm it or notify doctors of the potential link until much later.
- The failure of GlaxoSmithKline to report studies linking its anti-depressant Paxil with incidences of suicide among children and teenagers.
‘It’s frustrating that medical devices got thrown in almost as an afterthought.’ —ADVAMED

‘It’s frustrating that medical devices got thrown in almost as an afterthought,” says Mark Brager, spokesman for the Advanced Medical Technology Association (AdvaMed), speaking with IMDA Update. “All of the case studies [JAMA] mentioned are pharmaceutical-related. There has been no evidence of any parallel problem in the medical technology industry.” In fact, says Brager, more than 99 percent of medical technology recalls are done voluntarily by manufacturers — a statistic to which the FDA often points as proof that the current system works.

Brager also points out many problems with medical devices — such as manufacturing or sterilization problems with particular lots — can be addressed relatively easily. Even user errors and design flaws can be addressed without pulling a product from the market. “But if a drug is causing adverse events, you can’t change its formula and make the problem go away.” That’s why standards for postmarketing surveillance of drugs should be separate from those of medical devices, he says.

Finally, Brager believes that medical devices simply don’t lend themselves to the same kind of postmarketing surveillance as pharmaceuticals. “A drug is a compound; it’s static; it doesn’t change. But on average, a new model or iteration of a device comes on the market every 18 months, because technology is constantly improving.” Chances are, by the time a postmarket study of a medical device were to be completed, the device itself would already have been modified, making the study irrelevant.

“We’re monitoring the situation to ensure that anything arising from the Vioxx fallout isn't painted with a broad brush to affect medical device manufacturers.”

Medical devices thrown in

JAMA proposed that an independent board be created to track the safety of drugs after they have been put on the market. (Indeed, the FDA has asked the Institute of Medicine of the National Academy of Science to study the current system of postmarketing surveillance.) But the editors went one step further, suggesting that this agency be charged with overseeing postmarketing surveillance for drugs and devices.

Device oversight unnecessary

“This agency should be given full authority to ensure compliance with regulations and sufficient funding to establish an effective national active surveillance system with a prospective, comprehensive, and systematic approach for monitoring, collecting, analyzing, and reporting data on adverse events. Above all, the agency must be completely independent of influence from the pharmaceutical industry, biotechnology firms, and medical device manufacturers.”

‘It’s frustrating that medical devices got thrown in almost as an afterthought.” —ADVAMED

San Diego

outdoor pools, jogging trails and volleyball.
That’s not to mention the nearby attractions, such as SeaWorld, Scripps Institute of Oceanography, Palomar Observatory, San Diego Zoo and the Temecula wineries. It’s a great place to bring your kids.

Details of the Conference agenda were being worked out at press time. However, attendees can expect expanded hours for the Manufacturers Forum, plenty of time for formal and informal networking, first-class education, a warm and friendly banquet (Friday evening) and, of course, the annual Golf Tournament.

IMDA headquarters will be sending out information about the Conference shortly. In the meantime, check out the Rancho Bernardo website at www.ranchobernardoinn.com.
C HICAGO — Discrimination lawsuits may be an employer's worst nightmare. They're also pretty bad for employees who have been unfairly discriminated against.

By improving their employment practices, you can minimize the likelihood of getting sued by employees for alleged discrimination. But to do so, you must communicate with your people well and often, devise well-thought-out employment policies, and practice a lot of patience.

Jerry Coker, J.D., a partner in the Atlanta office of Ford & Harrison LLP and a specialist in employment law, addressed the topic at the 2004 Fall Conference of HMMC, an association of senior-level sales and marketing executives for medical products manufacturers.

In the Public's Eye

Employment discrimination is a big issue right now, said Coker. More than 40,000 civil rights complaints were filed in 2000 — a 200 percent increase from 1990. Employment discrimination cases accounted for 65 percent of the increase.

Much of the increase is due to new and expanded federal laws, including:

- The Civil Rights Restoration Act of 1991, which increased damages and allowed for discrimination cases to be heard by juries.
- The Family and Medical Leave Act of 1993, which entitles employees a total of up to 12 work weeks of unpaid leave during any 12-month period following the birth of a child; a serious health condition; the care of a child, parent or spouse; and certain other circumstances.
- The Americans with Disabilities Act of 1990, which prohibits discrimination because of a disability or perceived disability, or because of a person's relationship with a disabled person (such as someone with AIDS).

A sobering fact for employers to keep in mind is this: When such cases go to trial, juries find in favor of the worker more than 50 percent of the time. What's more, defending discrimination claims is expensive. Companies can spend as much as $8,000 merely responding to a complaint lodged with the Equal Employment Opportunity Commission. Going to trial can cost another $100,000 — not including the judgment. Reinstating a person whom the courts have found to be unfairly fired calls for back pay.

Then there's the toll such claims take on the company in terms of poor morale, adverse publicity and lost management time and attention. Add to that the loss of the management's credibility with its employees.

What is Discrimination?

Title VII of the Civil Rights Act prohibits discrimination on the basis of a person's race, sex, religion, color or national origin.

Sex discrimination can take many forms. For example, an employer may refuse to hire a woman for what it considers to be a "man's job," or because she is pregnant. Sexual harassment is another form of discrimination, and it includes unwelcome sexual advances,
Stretch a little. Get yourself or someone in your company a good business book for Christmas. Following are ten of the Best Business Books of 2004, selected by the editors of strategy+business (www.strategy-business.com), an electronic publication of management and technology firm Booz Allen Hamilton. Reviews were written by the publishers and amazon.com.

**Confronting Reality: Doing What Matters to Get Things Right**  
*By Larry Bossidy and Ram Charan.*  
Bossidy and Charan (authors of the 2002 bestseller *Execution: The Discipline of Getting Things Done*) attempt to show that companies can succeed if they return to reality and examine every part of their business. They point out that many companies fail to apply the simplest of measurement methods correctly, such as the business model.

**Strategy Maps: Converting Intangible Assets into Tangible Outcomes**  
*By Robert S. Kaplan and David P. Norton.*  
Kaplan and Norton — authors of *The Strategy-Focused Organization* — argue that the most critical aspect of strategy — implementing it in a way that ensures sustained value creation — depends on managing four key internal processes: operations, customer relationships, innovation, and regulatory and social processes. The authors show how companies can use strategy maps to link those processes to desired outcomes; evaluate, measure, and improve the processes most critical to success; and target investments in human, informational, and organizational capital.

**A Bias for Action: How Effective Managers Harness Their Willpower, Achieve Results, and Stop Wasting Time**  
*By Heike Bruch and Sumantra Ghoshal.*  
Why do most managers work so hard but accomplish so little? Bruch and Ghoshal suggest that many managers confuse action with accomplishment, and motivation with leading. Their research has revealed that 90 percent of managers spin their wheels by procrastinating, detaching emotionally, and distracting themselves with busywork. The authors explore ways to marshal the willpower of others to encourage collective action.

**Predictable Surprises: The Disasters You Should Have Seen Coming, and How to Prevent Them**  
*By Max H. Bazerman and Michael D. Watkins.*  
Bazerman and Watkins show that many disasters are preceded by clear warning signals that leaders either miss or ignore. They explain the biases that make predictable surprises so common in business and society, and outline six danger signals that suggest a predictable surprise may be imminent. They also provide a systematic framework that leaders can use to recognize and prioritize brewing disasters and mobilize their organizations to prevent them.

**The Seven-Day Weekend: Changing the Way Work Works**  
*By Ricardo Semler.*  
(Portfolio, 2004)  
Imagine a company where employees set their own hours; where there are no offices, no job titles or business plans; where employees get to endorse or veto any new venture; where kids are encouraged to run the halls; and where the CEO lets other people make nearly all the decisions. This company — Semco — actually exists, and despite a seeming recipe for chaos, its revenues have grown from $35 million to $160 million in the last six years. The author shows that for those willing to take a chance, there are new and better ways to run a workplace.

**The U.S. Army Leadership Field Manual: Battle-Tested Wisdom for Leaders in Any Organization**  
*By the Center for Army Leadership.*  
For more than 50 years, The U.S. Army Leadership Field Manual has provided leadership training for every officer training program in the U.S. Army. This trade edition brings the manual’s leadership principles and practices to today’s business world. More than 60 vignettes and stories illustrate historical and contemporary examples of army leaders who made a difference. The Manual also provides (1) a leader-
Medex Inc. (Carlsbad, CA) announced that its Medfusion™ 3500 syringe pumps with safety software infusion technology were implemented at Children’s Hospital Boston. The syringe pump features PharmGuard™ Medication Safety Software, designed to reduce medical errors by offering programmable upper and lower dose limits. When the limits are exceeded, device alerts the clinician and provides an electronic record of the event.

Insightec Image Guided Treatment Ltd. (Haifa, Israel) introduced its ExAblate® 2000 magnetic resonance-guided focused ultrasound system (MRgFUS) at RSNA in Chicago in November. The system was exhibited by GE Healthcare (Milwaukee, WI) and GE Women’s Healthcare. ExAblate uses a magnetic resonance imaging scanner to identify tissues in the body and assist in planning treatment. During the noninvasive procedure, delivery of high intensity focused ultrasound energy is guided and controlled using MR thermal imaging. This allows the physician to monitor and adjust the treatment, ensuring that the targeted tumor is fully treated without damage to non-targeted tissue.

MedicalCV Inc. (Minneapolis), a cardiovascular surgery device manufacturer, announced plans to withdraw from the mechanical heart valve and pyrolytic carbon businesses. The company said its primary objective will be to develop cardiovascular products for improved patient outcomes by early treatment of cardiovascular disorders. MedicalCV also plans to develop products targeting treatment of atrial fibrillation.

LeMaitre Vascular (Burlington, MA) introduced the AnastoClip Vessel Closure System at the VEITH Symposium in New York City in November. The system is designed to replace traditional sutures by providing rapid and precise vascular anastomosis. Titanium AnastoClips may be used in a variety of vascular procedures, particularly vascular access. The company says that the product results in a 20 percent increase in primary patency and reduced OR time, while providing immediate hemostasis.

Vascular surgeons at the recent VIETH Symposium supported the formation of an independent board for vascular surgery to improve patient care. The board of directors for the Society for Vascular Surgery cited the failure of the American Board of Surgery and the American Board of Medical Specialties to respond to the evolution of new medical specialties by altering training paradigms and certification criteria, the result being a decline in the number of graduates enrolling in surgical residencies and an increase in medical errors.

Quinton Cardiology Systems Inc. (Bothell, WA), a manufacturer of cardiology products, announced that it has begun shipping the Q-Stress® version 3.5 cardiac stress testing system. This software features FreezeFrame, which enables clinicians to perform in-test ECG analysis by continuously storing and displaying vital information for analysis and archiving during the test. Another feature is Cardiac Risk Scoring, which employs clinical and patient demographic information to help predict the likelihood of future heart attacks, and which compares a patient’s performance with widely accepted standards.

Boston Scientific Corp. (Natick, MA) announced that it has made an equity investment in — and secured an exclusive option to purchase — REVA see “Tech Briefs” page 6 or click HERE to continue.
Tech Briefs
...continued from page 5

Medical Inc. (San Diego), a privately held company that develops ultra-thin, radially strong vascular stents using tiny ratchet-like elements to lock the stent open. Presently, REVA is developing a balloon-expandable, bioresorbable drug-eluting stent, which is said to combine distinctive geometry with resorbable polymer properties. The REVA stent is designed to perform comparably to metallic drug-eluting stents and then be resorbed by the body once the artery has healed.

www.bostonscientific.com

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Artromick International Inc. (Columbus, OH), a developer and marketer of medication and medical carts, announced the release of its new line of anesthesia carts. The Avalo AC Anesthesia Carts are available in two models and feature Artromick’s exclusive Auto-Lock™ Keyless Security System, cart user audit, badge ID security access and remote cart security control.

www.artromick.com

Dale Medical Products Inc. (Plainville, MA) introduced its Dale® Naso-Gastric Tube Holder, designed to keep naso-gastric feeding and aspiration tubes from advancing or retracting during therapy. The tube holder features dual interlocking tabs, which spiral around the tubes for improved tube security. Non-adherent plastic tips on both tabs reportedly facilitate easy removal without scissors. The nose pad stretches and conforms to the patient’s anatomy, while the holder helps reduce the likelihood of skin irritation. Dale Medical Products also introduced the Dale® Transducer Holder, designed to secure up to three transducers on the patient’s arm, in line with the phlebo-static axis. The transducer holder stays with the patient during transport, reducing the need for re-seroing and re-leveling.

www.dalemed.com

SuperDimension Ltd. (Tel Aviv, Israel), a company focused on minimally invasive diagnosis and treatment of lung disease via CT-guided bronchoscopy, announced that the U.S. Food and Drug Administration has cleared its superDimension/Bronchus™ for marketing and distribution in the United States. The superDimension/Bronchus, reportedly the only FDA-approved navigation system for guiding endoscopic instruments in the pulmonary tract, is designed to facilitate the minimally invasive diagnosis of lung cancer, emphysema, asthma and tuberculosis. When traditional bronchoscopy is performed in peripheral areas of the lungs, endoscopic vision of the targeted area is restricted, leading to unreliable results, according to the company.

www.superdimension.com

ATS Medical Inc. (Minneapolis), a medical device company specializing in mechanical heart valves, aortic graft prostheses and related cardiovascular surgery accessories, entered into a global partnership agreement with CyroCath Technologies (Montreal, Canada), a manufacturer of cryotherapy solutions. The agreement entitles ATS to co-promotion rights in the United States, as well as exclusive distribution rights in the rest of the world.

www.atsmedical.com
www.cryocath.com

dj Orthopedics Inc. (San Diego), a medical device company that specializes in rehabilitation and regeneration products for the non-operative orthopedic and spine markets, announced that it has signed a three-year contract with MedAssets Supply Chain Systems (Atlanta), a group purchasing organization serving 22,000 healthcare providers nationwide. Under the agreement, dj Orthopedics will sell its line of functional (rigid) knee bracing products, post-operative knee and shoulder bracing products and its entire line of cold therapy products, including the Motorized IceMan® and Manual AirFlow™ cold therapy circulation units and DuraKold® ice wraps.

www.djortho.com
www.medassets.com

Omnicell (Mountain View, CA) introduced new features for its Anesthesia Workstation designed to help hospitals meet JCAHO and CMS requirements.

see “Tech Briefs” page 7 or click HERE to continue
The workstation operates as a mobile unit for the management of anesthesia supplies and medications, while helping facilities meet regulatory requirements for medication management. Some key features include the ability to: automate government-required documentation of controlled substance use and pharmacy replenishment; document the withdrawal of any item not contained in the controlled access medication drawers; provide a continuous running list of all medications used during the case, including all items withdrawn for a patient; and allow the anesthesia provider to electronically document wastes and the total amount issued for controlled substances and other user-defined medications at the end of a surgical case. [www.omnicell.com]

The Hospital of the University of Pennsylvania (Philadelphia) is participating in a nationwide clinical trial of a new valve repair device that could replace major heart surgery in some patients. The device consists of a tiny clip manufactured by Evalve Inc., Redwood City, CA. The clip is delivered by a catheter and deployed in the heart to repair a malfunctioning and leaking mitral valve. It is designed to secure the valve's leaflets near the center of the valve, minimizing blood leakage and helping the heart pump more efficiently. Severe mitral valve regurgitation is a debilitating condition that causes shortness of breath, fatigue and palpitations, and often necessitates surgery. The new valve device could decrease a patient's stay in the hospital, limit complications, and speed up recovery time. [www.evalveinc.com]

Exactech Inc. (Gainesville, FL), announced that its Equinoxe™ Shoulder System has received 510(k) clearance from the U.S. FDA. The system includes primary implants designed to provide surgeons with anatomic precision. The system is also said to offer maximized intraoperative flexibility. The company's orthopedic products are used in the restoration of bones and joints that have deteriorated as a result of injury or disease, such as arthritis. [www.exac.com]
Fair Work  
...continued from page 3

sexual comments, inappropriate use of terms of endearment, touching in a manner that has sexual overtones, or sex- or gender-based epithets.

Other forms of discrimination — as defined by federal and state laws — include age-based discrimination, discrimination on the basis of marital status or sexual orientation, discrimination because of a person’s disability and discrimination on the basis of national origin. (With the growth of Hispanics in the workplace, claims by Hispanics are increasing, Coker said.)

What’s more, discrimination should be the concern of everyone in the company, not just senior management. According to Coker, immediate supervisors can be — and often are — held personally liable for discrimination. “You have to make people understand the impact on their career if they engage in sexual discrimination — and it’s often the first-line supervisor who is guilty of it,” he said.

Effective Discipline

An employee in a so-called protected class — such as a racial minority or a disabled person — can prove unlawful discrimination by showing that an employee in a similar situation who is not in a protected group was treated more favorably than they. Here’s a classic example: Without warning, a company fires a black employee for poor performance, but gives a white employee repeated warnings before firing him.

Employers should have written policies in place to ensure that all employees are treated equally. In addition, they should document all warnings and disciplinary actions taken against any worker.

Because so many discrimination claims arise from people getting fired, companies should focus on instituting what Coker called “progressive discipline.” Effective disciplinary procedures do the following:

- Provide for fair and consistent treatment of employees.
- Give employees an opportunity for “rehabilitation.”
- Provide for equal employment opportunity.

Perhaps most important, a good disciplinary system helps keep a business running smoothly and allows everyone to focus on one thing — getting the job done, said Coker.

A good disciplinary process begins with detailed job descriptions. Without them, no one knows what is expected of them. Supervisors should document that they have reviewed the job description with their employees.

At the first sign of a problem — whether it’s a quality-related problem, low productivity, absenteeism or something else — the supervisor should go into a “coaching” mode. He or she should tell the employee about the problem, spell out how he or she can resolve it, and clearly explain what will happen if the employee fails to do so. (Perhaps the employee is entitled to one more warning before termination.) All of this should be documented.

One caveat: Employers must follow similar procedures for all their employees, not just those in a so-called protected class.

Representation Needed

The following manufacturer is seeking representation by specialty sales and marketing organizations.

Medex-HSMG
Contact: Jeremy Kraus  
(713) 838-1989 • Fax: (713) 838-8070  
2616 South Loop West, Suite 610 • Houston, TX 77054  
E-mail: jkraus@valesc.com

Product: SmartInfuser PainPump

Product Description:
Regional anesthesia delivery system — “Pain Pump” — used post-operatively by surgeons of all specialties to reduce pain and promote healing and faster rehabilitation. The SmartInfuser PainPump features a unique mechanical design, variable flow-rate, and compelling cost advantages over existing systems.

Marketed to: Orthopedic, general, and plastic surgeons.

Territories: U.S. and Canada.
Facing a $413 billion budget deficit, Congress and the Bush administration are looking for savings — big savings — anywhere they can find them. And with an annual budget of $473 billion, the Medicare and Medicaid programs are prime targets.

Together, the two programs account for almost one-quarter of U.S. government spending, and their share is growing, according to a recent article in The Wall Street Journal (Dec. 3). And it’s pretty much a lock that the Medicare drug benefit, scheduled to take effect in 2006, will only accelerate the pace of government healthcare spending.

Hospitals could face the brunt of cutbacks, according to the article. Under last year’s budget, hospitals were to have received $25 billion in payment increases over the next 10 years. But if the government were to rescind some of those increases, it would not be the first time it has done so.

Nor is it likely that Medicaid will escape unscathed. Some experts predict that the administration may once again propose capping federal contributions — something it has unsuccessfully sought in the past. The nation’s governors won’t like it, but there may not be much they can do about it.

The only ones who might come out okay are physicians. Under existing law, physicians are slated to undergo eight years of payment cuts starting in 2006. But doctors have argued that the formula used to calculate the cutbacks was flawed. Congress will be listening to those arguments in the months ahead.

Health insurance premiums keep going up. For that reason, the IMDA board is investigating whether the association can help its members obtain health insurance for themselves, their employees and their families at a favorable rate.

On Nov. 8 and again on Dec. 1, you should have received via e-mail a survey about your health insurance needs and preferences. Twenty-two members have responded to the survey, but responses from at least 50 are needed.

Filling out the survey does NOT obligate you to participate in a health insurance program, should IMDA pursue one. And the information you provide will be confidential. Once the data is compiled by staff, it will be shared as a compilation with the board of directors and an insurance professional.

We all know that obtaining health benefits for our employees and ourselves is getting tougher and tougher. Please take a few minutes to help us see whether, by working together, we can do anything about it.

If you need another survey or have any questions, contact Carole Kulinski at IMDA headquarters at (866) IMDA-YES (866-463-2937). Thanks.