

IMDA UPDATE

The nation's premier providers of specialty medical sales, service and education

MANUFACTURERS' EDITION

'Restrain GPOs' says speaker

Groups have amassed too much power and money, says MDMA's Leahey

SAN DIEGO--Are patients getting access to the best medical technologies out there? No, says Mark Leahey, executive director of the Medical Device Manufacturers Association. And he spent time at IMDA's 25th Annual Conference explaining why.

Based in Washington, DC, MDMA was founded in 1992 by a dozen manufacturers who felt their voice was not being heard by federal lawmakers. Several years after its founding, MDMA members began complaining that even though they had received 510(k) clearance for their devices from the Food and Drug Administration, they still could not penetrate the hospital market. They blamed group purchasing contracts for the problem.

"There's nothing wrong with the

GPO model," Leahey told IMDA members. "But the concern is that through massive consolidation, by 2001, you had two GPOs controlling two-thirds of the marketplace." Purchasing decisions were moving away from local and regional cooperatives (in which doctors still had a voice) to national organizations based far away from their hospital members, he said.

Safe Harbor

Fueling that consolidation was money, said Leahey. In 1986, Congress granted a Safe Harbor to GPOs, allowing them to collect administrative fees from manufacturers based on the sales of contracted items. (Without the Safe Harbor, Congress would have considered such payments to be

(See "Leahey" on page 2)

Safety pays off for anesthesiologists and their patients

Anesthesiologists have avoided horrendous rises in malpractice insurance premiums by doing one thing that many other specialists have not – improve patient safety. Technology has played a big role in the strategy, including pulse oximetry, capnography and computerized mannequins that simulate real-life surgical crises.

According to a report in *The Wall Street Journal* ("One group of doctors changes its way," June 21, 2005), anesthesiologists pay less for malpractice insurance today (in constant dollars) than they did 20 years ago. In fact, the average annual premium for malpractice insurance is less than \$21,000. "Their theory: Less harm to patients would mean fewer lawsuits," writes the article's author.

Over the past two decades, patient deaths due to anesthesia have declined to one death per 200,000 to 300,000 cases, from one for every 5,000 cases, according to studies compiled by the Institute of Medicine.

Whipped into action

In 1982, a report by the ABC news program "20/20" on anesthesia-related deaths whipped anesthesiologists into action. In response, the American Society of Anesthesiologists provided \$100,000 to launch the Anesthesia Patient Safety Foun-

(See "Safety" on page 5)

Mark Leahey (center) chats with IMDA attendees



Leahey

...continued from page 1

illegal kickbacks under the Medicare statute.) These payments were designed to cover the GPOs' administrative expenses.

"But over the past 20 years, we've seen these fees escalate to where they far exceed operating expenses," said Leahey. He cited a January 2005 report by the Department of Health and Human Services' Office of Inspector General, which found that during the audit period, three GPOs collected \$1.8 billion in fees -- \$1.3 billion more than their operating expenses. (According to the report, the GPOs invested \$415 million for venture capital investment and other business ventures.)

'We're concerned that Safe Harbor has become something other than a means to fund overhead.'

More recently, in June 2005, the OIG issued a second report on three additional GPOs, which stated that of the \$513 million they collected in administrative fees, just \$238 million was spent to cover operating expenses. Of the remaining \$275 million, \$217 million was distributed to members, and \$58 million was retained by the GPOs to provide reserves and venture capital for new business lines, according to the study. "We're concerned that Safe Harbor has become something other than a means to fund overhead," said Leahey.

Leahey pointed to other excesses, many of which were uncovered in a series of hearings by the Antitrust Subcommittee of the U.S. Senate

Judiciary Committee in 2002, 2003 and 2004, as well as in a series of articles in The New York Times and other publications. For example, one GPO executive made roughly \$4 million through stock options in a vendor with whom the GPO had a contract. And one GPO charged vendors \$1 million in return for the GPO doing an analysis and writing up a report on its technology.

Is legislation necessary?

"Small companies can't play in this game," said Leahey. Yet MDMA has felt somewhat alone in its public battle against GPOs. The reason is that large manufacturers want to retain their GPO contracts and market dominance; hospitals want to continue to get their year-end rebates from their GPOs; and GPOs themselves want to continue to collect fees, he said.

After the initial Capitol Hill hearings in April 2002, the Senate gave GPOs 90 days to write up voluntary Codes of Conduct to address the lawmakers' concerns, recounted Leahey. And the GPOs did a good job in some respects, he

said. For example, they addressed the conflicts of interest, which found GPOs and some of their executives investing in companies with whom they had contracts. But they remained silent about other things, including fees that exceeded 3 percent, the bundling of unrelated products, and long-term, sole-source contracts for clinical-preference items, said Leahey.

A second hearing was held in July 2003 and a fourth in September 2004. "By the summer of 2004, there was a recognition that the current codes of conduct didn't have the impact that the senators had hoped they would," said Leahey. "As a result, in October 2004, Antitrust Subcommittee Chairman Mike DeWine (R-OH) and ranking member Herb Kohl (D-WI) introduced the Medical Device Competition Act, which would have prohibited GPOs from receiving fees greater than 3 percent as well as the conflicts of interest, and would have called for GPOs to be certified by an outside body that they were acting in accordance with

(See "Leahey" on page 3)

IMDA Announcement

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Leahey

...Continued from page 2

the law.

But the GPOs opposed the legislation, said Leahey. Why? "Safe Harbor gives them incredible heft," he said. "Capping fees is like capping punitive damages for trial lawyers."

Still, without legislation to cap GPOs' fees, the patient is the big loser, said Leahey. "He is not getting the technology he needs."

The bill died when Congress adjourned in November 2004. But in early 2005, the Senate gave GPOs (and their trade association, the Health Industry Group Purchasing Association) until mid-March to come up with a voluntary Code of Conduct with teeth, said Leahey. That process is still going on today, he said.

"We're not saying that GPOs

aren't serving a role," said Leahey. "But based on some of the reports we've heard, we think the fees they are collecting need to be brought back to a reasonable realm, and [we need] to make sure that their decisions are being made in the best interests of patients instead of their own financial well-being. To achieve that, we think additional steps need to be taken."

Leahey urged IMDA members with concerns about GPOs to write to their lawmakers about the issue. "We need people to weigh in and make sure their voice is heard in Washington." ◀

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GPOs have their say with feds

Current antitrust laws and regulations are adequate to ensure competition in the marketplace, said Health Industry Group Purchasing Association President and CEO Robert Betz in a letter written on May 24 to Daniel Levinson, acting Inspector General of the Department of Health and Human Services. "HHS does not need to become another antitrust regulator focusing only on GPOs," wrote Betz.

Betz wrote the letter in response to the Medical Device Manufacturers Association's written request to HHS that the agency amend the GPO Safe

(See "GPOs" on page 4)

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New member

National specialty distributor Tri-anim joins IMDA

IMDA's newest member is also its largest – Sylmar, CA-based Tri-anim. At \$150+ million in sales, more than 125 outside reps, some 300 employees and 13 distribution centers around the country, 29-year-old Tri-anim focuses on the respiratory, anesthesia, critical care, EMS and, most recently, surgical markets.

The company was founded in 1975 by Bob Byers Jr. and two colleagues. Byers, a former medical equipment designer and salesman for Puritan-Bennett as well as the specialty division of the now-defunct Daylin Medical, is the company's president and CEO today.

Though some have questioned whether a national company can be a specialty sales and marketing company, Byers is not one of them.

"You can't start out with the idea of being a great national specialty distributor," he says. "You have to be a great local specialty

distributor all over the country. If you can do that, you'll be the best regionally and then nationally. It's a philosophical shift for most people. But there's no reason why you can't be a great national company in any specialty."

Three years ago, Tri-anim entered the EMS market. More recently, the company has made some acquisitions in an effort to penetrate the surgical

market. In December 2004, it acquired Charles Polo & Co. Then, in June, it purchased Norcross, GA-based Adler Instrument Com-

pany, a 25-year-old company specializing in surgical instruments, equipment and devices. Adler's 22 sales reps service customers in Ala-



Bob Byers

bama, Florida, Georgia, North Carolina, South Carolina, Tennessee, Virginia and portions of eastern Mississippi.

"Adler is a major piece in our vision of a nationwide surgical division," said Dale Clendon, Tri-anim vice president of sales and marketing, at the time of the Adler acquisition.

Byers believes his membership in IMDA will help Tri-anim keep abreast of what is occurring in the industry and how specialty companies do things differently. He said that IMDA membership is a way to help raise the importance of specialty sales and distribution, and to gain access to new specialty product lines.

Welcome Bob Byers and the Tri-anim team to IMDA by phoning the company at (818) 362-6882. Other company executives include Dan Pister, chief operating officer; Dale Clendon; and Bill DeMars, director EMS sales. ◀

GPOs

...continued from page 3

Harbor to place a cap on the level of fees paid by vendors to 3 percent of sales of contracted items. "A scheme that uses the safe harbors to regulate GPOs can only needlessly add to the administrative burden and expense of health care, not only for GPOs but for suppliers, providers, payors and ultimately the patients," he wrote.

In his letter, Betz pointed out that in a July 2004 report on group purchasing, the U.S. Justice Department and Federal Trade Commission concluded that no changes to antitrust safe harbors were necessary, that tools already exist to assure competition in the GPO industry, and that

contracting practices would continue to be examined on a case-by-case basis.

Rebuttal

Betz disputed MDMA's assertions that supplier payments to GPOs are excessive, add no value to the health care system, and create false incentives.

Are administrative fees excessive? No, said Betz in his letter. First of all, an HHS audit found few instances of payments in excess of 3 percent. Second, administrative fees fund the cost of purchasing activities that would otherwise be borne by hospitals. A good percentage of these fees are redistributed back to the hospitals, with the remainder being

spent "improving programs and operations and creating additional services to members that would be prohibitively costly for individual members to fund."

Do GPOs only sell market share to suppliers? No again, wrote Betz. "GPOs negotiate various types of discounts and rebates that benefit their members, regardless of quantities of purchases."

Do GPOs shy away from negotiating rock-bottom prices in order to earn higher administrative fees? No, said Betz. "To the contrary, higher prices mean fewer purchases under the GPO contract, and not only less money per contract, but fewer members for the GPO. MDMA ignores the marketplace realities." ◀

Safety

...continued from page 1

dation, whose members included doctors, nurses, insurers and medical products companies.

"Industry's participation initially caused angst over whether the foundation was designed merely to sell machines," according to the article. "But over the years, that concern dissipated...as company money helped the organization fund important research."

One outcome of that research was the development of high-tech mannequins to help anesthesiologists

practice responses to allergic reactions and emergency tracheotomies.

Pulse oximetry and capnography devices were far from a sure thing when they were introduced in the 1980s. But in 1986, at the urging of the foundation, pulse oximetry was incorporated into the ASA's basic standards for anesthesia care. Later, capnography was added. By 1990, almost all American hospitals had pulse oximeters and capnographs.

The foundation is credited with facilitating the introduction of other technologies and safety techniques, including blood and fluid warmers

as well as special blankets to keep patients warm during surgery.

The payoff? In 1972, anesthesiologists accounted for 7.9 percent of all medical-malpractice claims; but between 1985 and 2001, they accounted for just 3.8 percent of all claims. The median size of payments for successful malpractice suits dropped from \$332,280 during the 1970s to \$179,010 by the 1990s (expressed in 2005 dollars). And malpractice premiums have decreased 37 percent over the past 20 years (expressed in inflation-adjusted dollars). ◀



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