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## CONGRESS MAY ADDRESS DTC ADS IN PDUFA REAUTHORIZATION

As Congress weighs reauthorization of the Prescription Drug User Fee Act (PDUFA), some observers are concerned that the legislation may attract amendments that have nothing to do with user fees, like provisions affecting how drug makers may use direct-to-consumer (DTC) advertising.

"The PDUFA III bill likely becomes an attractive target for amendments such as Hatch-Waxman reform and DTC advertising restrictions," forecast a research note by investment firm Saloman Smith Barney. Several House members in the past have expressed interest in enacting DTC restrictions, including Rep. Pete Stark (D-Calif.), who has introduced a bill to deny tax deductions for unbalanced DTC ads (*Drug Marketing*, 1/30, Page 2).

However, officials from industry and the FDA, as well as a key member of Congress, have urged legislators not to use PDUFA reauthorization as a means to address such issues. For instance, House Energy and Commerce Committee Chairman Billy Tauzin (R-La.) told his fellow lawmak-

(*See* **PDUFA,** *Page 8)*

## GENOTROPIN DIRECT MAIL EFFORT FEATURED ATYPICAL PACKAGING

Creatively packaged mailers may catch physicians' eyes and avoid the "unread" fate to which direct mail often is doomed.

The DeLor Group, Louisville, Ky., a brand identity firm, recently completed a direct mail campaign for Pharmacia's Genotropin. The three-piece campaign focused on informing physicians of the growth hormone replacement therapy's new indication for the long-term treatment of growth failure in children who were born small for gestational age (SGA).

(*See* **PHARMACIA,** *Page 2)*

**PHARMACIA,** *from Page 1*

SGA is ill-defined in the U.S., where the condition is referred to by a variety of names, such as "intrauterine growth retardation." The first piece in DeLor's package was intended to clear up this confusion and establish SGA as the proper term.

DeLor designed a mailer and furled it inside a transparent tube. The tube stuck out in comparison to the "typical flat mailers" drug makers usually send to physicians, according to marketing director Patrick Blair.

When physicians opened the tube and unfurled the mailer, they saw various names for the condition written in a small font and a question mark looming in the background. Meanwhile, the term "small for gestation" was written in a large font, as if to answer the question.

**Physician Education**

The first piece was unbranded and mailed prior to launch of the new indication in July 2001, followed by a second piece that hit physicians' offices immediately following launch. Intended to educate physicians, the second piece took the form of a folder. Inside the folder was a letter from Pharmacia's medical director discussing SGA and its treatment with Genotropin.

The third piece was more plainly promotional, Blair told *Drug Marketing*. The piece featured a visual image of a common child's toy, a stack of colorful rings with one ring missing. The image communicated to physicians "there may be something missing in your patients," Blair said.

DeLor now is designing a follow-up campaign, a major goal of which is to inform physicians that SGA is easy to diagnose. Another objective is to link more closely the condition with Pharmacia and Genotropin.

Genotropin is the only growth hormone replacement therapy with an indication for SGA, yet other brands may be substituted off-label for Genotropin. Since Pharmacia made the investment to study SGA and get orphan drug exclusivity, the campaign will try to highlight the company as a leader in the field and minimize what is known as "rotational prescribing."

DeLor also recently added as clients Lilly, Novartis and Abbott. *For more information on the firm, visit http://www.delor.com.*

**COMPARISON OF SALES BY CLASS OF TRADE FOR 2000-2001**

Clinics became a larger avenue of script purchases in 2001, comprising 5.5 percent of sales versus 5.1 percent in 2000. Meanwhile, independent pharmacies continue to decline in importance, with their percentage of sales dropping by 0.5 percent, according to year-in-review data compiled by NDCHealth.

| Class of Trade | 2000 WAC | 2001 WAC | Change | 2000 % of Sales | 2001 % of Sales | Change |
|---|---|---|---|---|---|---|
| *Chains* | 66.5 | 78.2 | 17.6% | 37.7 | 37.6 | 0.1% |
| *Independents* | 22.9 | 26.0 | 13.5% | 13.0 | 12.5 | (0.5)% |
| *Food Stores* | 15.3 | 17.7 | 15.7% | 8.7 | 8.5 | (0.2)% |
| *Mass Merchandisers* | 6.2 | 7.7 | 24.2% | 3.5 | 3.7 | 0.2% |
| *Mail Order* | 19.8 | 24.1 | 21.7% | 11.2 | 11.6 | 0.4% |
| *Hospitals* | 24.9 | 28.5 | 14.5% | 14.1 | 13.7 | (0.4)% |
| *Clinics* | 9.0 | 11.5 | 27.8% | 5.1 | 5.5 | 0.4% |
| *LTC Providers* | 5.2 | 6.1 | 17.3% | 2.9 | 2.9 | 0.1% |
| *Pharma Wholesalers* | 2.5 | 3.6 | 44.0% | 1.4 | 1.7 | 0.3% |
| *Home Health* | 1.4 | 1.7 | 21.4% | 0.8 | 0.8 | 0.0% |
| *Managed Care* | 1.0 | 0.9 | -10.0% | 0.6 | 0.4 | (0.2)% |
| *All Others* | 1.7 | 1.8 | 5.9% | 1.0 | 0.9 | (0.1)% |

*Source: NDC Health*

**WAC** = Wholesale Acquistion Cost
**LTC** = Long-Term Care

## SALES TERRITORY ALIGNMENT KEY TO MARKETING SUCCESS

With the average drug maker targeting approximately 200,000 out of 800,000 total prescribers in the U.S. and employing a sales force of between 500 and 600 reps, divvying up territories is crucial to ensuring maximum market coverage.

Territory alignment becomes an issue whenever companies merge or expand their sales forces. It is important to divvy up territories not based upon workload alone, but to consider "time size" and "disruption" as well, according to Jean-Patrick Tsang, president of Bayser Consulting.

Time size factors in how much time reps must spend in transit between details. In other words, if two territories have an equal number of prescribers but one territory is less compact than the other, that rep will have a more difficult job. When calculating time size, take into account the size of the geographic area, but also other variables such as traffic congestion, Tsang advised.

Reps' success hinges, to a large extent, on their relationships with prescribers, relationships that often require years to develop. Thus, "disruption" is another key consideration.

Before assigning a new rep to a prescriber, consider the relationship that already exists with the rep currently servicing that prescriber. In many cases, it is not worth it to disrupt that relationship, even if a change would seem logical for other reasons, Tsang told *Drug Marketing*. He offered other tips, as well, such as:

◆ *Include in the target audience prescribers who are marginally inexpensive to visit*. In other words, if an account is small, but it's located right across the street from a large account, it may be worth servicing because the costs are minimal. Conversely, "this may also lead to dropping mid-size accounts that would cost the rep a special trip to get there," Tsang said.

◆ *The optimal alignment is not necessarily the ideal alignment*. Sometimes, an alignment is optimal in theory, yet flawed in practice. This is because there is a value to inertia, according to Tsang. The fewer changes you make, the fewer disruptions you create. Therefore, "the optimal must be defined in relationship to where your alignment is at currently."

◆ *Give strong reps a larger workload and a larger proportion of tough accounts*. Tsang illustrated this point by drawing an analogy to sports teams. On a sports team, you don't expect each player on the team to contribute equally in all areas of the game, such as scoring, passing and defense. Rather, "the role and importance of each team player depends on his/her relative strengths and weaknesses," he said. "Why are the expectations from every team member all of a sudden equal when it comes to territory alignment?"

◆ *Remember the half-third rule*. When splitting a territory into two, split the business potential equally between the current rep and the new rep, Tsang advised. "However, split sales two-thirds to one-third, with two-thirds of the sales staying with the current rep." A 50-50 sales split is unfair to current reps, who "worked hard to build their territories. New reps have to earn their stripes."

◆ *Target nationally, but adjust locally*. Your research may suggest targeting the top 3,000 prescribers in the U.S. Yet in areas with a dense concentration of prescribers, reps may have to drop the bottom accounts in their territory even though these accounts rank among the top 3,000 nationally. Conversely, in more rural areas, the rep may have to pick up accounts ranking below the top 3,000 nationally. "This makes perfect sense as soon as you consider the opportunity cost of the rep," Tsang said.

◆ *Automatic alignment is the way to go*. Traditionally, territory alignment has been done manually. However, using technology to perform automatic alignment will allow drug makers to analyze wider scenarios much more quickly, Tsang said. That said, "human intervention is still necessary because many 'soft issues' are not captured in the data." Soft issues include knowing which rep is about to go on maternity leave, or be promoted or

(*See* **TERRITORY ALIGNMENT,** *Page 4)*

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fired. "This is why it is imperative that the alignment generated by an automatic process be checked and adjusted by a business-savvy sales person."

Bayser Consulting was founded in 1996 and specializes in sales and marketing for pharmaceutical, medical device and diagnostics manufacturers. *For more information, contact Jean-Patrick Tsang at (847) 920-1000 or bayser@bayser.com.*

## CALENDAR

**March 24-26 Medical Research Summit**
Washington, D.C.
International Association of Privacy Officers
(800) 546-3750 or (215) 545-3864
http://www.researchsummit.com/

**March 25-26 Biologics Development**
Chelsea, Mass.
Barnett International
(800) 856-2556, ext. 2200
http://www.barnettinternational.com/clintraining/BioT0302.pdf

**March 25-27 Drug Master File Workshop**
Washington, D.C.
Michigan State University School of Packaging
(517) 355-3603
http://www.DMFWorkshop.msu.edu

**March 25-27 Electronic IND Submissions and Global Issues**
Irvine, Calif.
Drug Information Association
(215) 628-2288
http://www1.diahome.org/Content/Events/02018.pdf

**March 25-27 Rx and Biotech Portfolio Management**
Philadelphia
Strategic Research Institute
(888) 666-8514 or (646) 336-7030
http://www.srinstitute.com/part_iter_site_page.cfm?iteration_id=262

## CLARITIN SWITCH TO OTC MAY RAISE MARKET QUESTIONS

Schering-Plough's decision to try to switch Claritin to over-the-counter (OTC) status raises a giant question mark over the non-sedating antihistamines market: If Claritin (loratidine) goes OTC, what sales potential remains for Rx allergy products like Aventis' Allegra and Pfizer's Zyrtec, as well as Schering's own Clarinex?

Some observers have forecast that the Rx allergy market will shrink significantly. As soon as a non-sedating antihistamine becomes available OTC, managed care providers likely will stop covering Rx products, Francesco International President Steve Francesco told *Drug Marketing*.

Also, there may be competition in the OTC marketplace, as Johnson & Johnson and American Home Products have filed generic loratidine OTC applications (*Drug Marketing*, 2/13, Page 1). Competition may bring prices down to a level below the average co-pay for Rx allergy treatments, Francesco said.

Just days before announcing its plan to switch Claritin, Schering-Plough had launched an aggressive ad blitz for Clarinex, the would-be successor to Claritin. Yet now the "potential for Clarinex has dramatically decreased, as has the potential for Allegra and Zyrtec," he added.

### 'Marginal Advantages'

If these three products were significantly better than Claritin, doctors would continue to prescribe them, even if they cost patients more money, according to Francesco. However, any advantages Clarinex, Allegra and Zyrtec may offer are marginal at best, he said.

Sepracor's Soltara had been heralded as a breakthrough product – investment firm Morgan Stanley praised its "best in class characteristics" – and may have flourished even if faced with competition from OTC loratidine. However, the FDA March 7 issued Soltara a non-approvable letter.

"The Soltara non-approvable letter means one less competitor this year" for Clarinex, a Salomon Smith Barney report noted. Forecasting the market beyond this year, however, becomes extremely difficult due to a number of unanswered questions, the firm added. For example (and assuming the FDA sanctions the OTC switch):

- Will Schering's OTC Claritin get three years of marketing exclusivity, or will the drug maker have to compete with J&J and AHP, both of whom have larger consumer health operations?
- Will the switch preclude generic copies of Claritin from the Rx market?
- How much exclusivity will Clarinex get before the FDA pushes it OTC, too?

An FDA committee will review Schering-Plough's application in April, and an action date is set for November 2002.

"With the market introduction of Clarinex as the first and only prescription non-sedating antihistamine approved for the treatment of indoor and outdoor allergies, moving Claritin to OTC status would give Schering-Plough an opportunity to establish brand leadership in both the prescription and OTC categories," said Richard Zahn, president of Schering Laboratories. Schering-Plough said the switch is intended to:

- Address potential changes in the regulatory, health and legal environments.
- Introduce a safe, non-sedating antihistamine into the OTC marketplace.
- Position Clarinex and Claritin as the premier brands in the Rx and OTC allergy categories, respectively.
- Maximize the combined value of the Clarinex and Claritin brands.

Allergies affect an estimated 45 million people in the U.S., according to the drug maker. Seventy-seven percent use either an Rx or OTC treatment. Among treatment users, approximately 37 percent only use an Rx product; 32 percent use a combination of Rx and OTC products; and 31 percent rely solely on OTC products.

## ONE IN THREE PATIENTS DISCUSS DTC ADS WITH MDs, POLL SHOWS

Direct-to-consumer (DTC) advertising works for drug makers and consumers alike, according to a survey by *Prevention* magazine, conducted with technical assistance from the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC).

The *Prevention* study underscored the marketing benefit to drug makers of advertising Rxs directly to patients. Results showed that 99 percent of those surveyed "have seen a DTC ad on television," and 32 percent have talked to their doctors about a drug they saw advertised. Of those consumers discussing drug ads, 50 percent said they got a script for the medication.

Other data showed that 79 percent of those questioned said their doctors were "very" willing to talk to them about the advertised medicine, and 27 percent said their relationships with their doctors improved because of the conversation they had about the advertised drug.

The latest findings support many of the conclusions of the three other studies released so far this year, including two Pfizer-sponsored surveys released last month (*Drug Marketing*, 2/20, Page 5). The combined data from the studies "show clearly that consumers appreciate DTC advertising and that companies get the biggest advertising bang for the buck." American Enterprise Institute (AEI) resident scholar John Calfee told *Drug Marketing*. AEI has analyzed statistics from a variety of studies, dating to 1999, Calfee said.

DDMAC offered advice to *Prevention* for its survey because "it is one of the few studies available that tracks consumer reactions to DTC ads prior to and following the 1997 guidance for broadcast advertising," said Deputy Director Nancy Ostrove.

That guidance eased Rx advertising rules, an action healthcare providers have argued contributed to soaring drug costs. DDMAC is using survey results to support its contention that DTC ads inform consumers about drug benefits and risks.

"Although there is room for improvement, giving consumers information in a balanced way should help them participate in their own care and serve the public health," Ostrove said.

She told *Drug Marketing* that the study supports the concept that DTC ads might help patients stay compliant with prescribing instructions. Data show that 57 percent of Americans who take an Rx drug have seen advertising for the medicine they take, with 40 percent of those saying the ads make them feel better about the drug's safety and benefits.

Nearly one in five consumers who see "their" drug advertised said the television commercials made them more likely to take their medicine, Ostrove said. "While the results are not 100-percent conclusive, data seem to suggest a positive association between consumer advertising and consumer compliance [with drug use instructions]." That relationship is important because increased compliance "should prove to reduce long-term healthcare costs."

Other key findings showed that 81 percent of Americans said DTC advertising informs them about new treatments for a condition they may be suffering from; 64 percent said DTC ads help them be more involved in decisions about which drug to take.

*Prevention* surveyed 1,601 adults age 18 or older living in the U.S. Interviews were conducted by Princeton Survey Research from Sept. 19 to Nov. 7. The survey was funded solely by the magazine.

## PEOPLE

### Stiefel Names National Sales Manager

Dermatology drug maker Stiefel, Suwanee, Ga., named Tom Weider its national sales manager. Weider will be in charge of all field reps in the U.S. and Puerto Rico, as well as administrative sales support staff. He formerly worked at Aventis, Boehringer Mannheim and Beecham Labs.

### Blaug Joins Regeneron As Marketing VP

Regeneron, Tarrytown, N.Y., appointed Suzanne Blaug its vice president of marketing and sales. Blaug joins Regeneron from Bristol-Myers Squibb, where she served as vice president and brand champion for the Worldwide Medicines Group.

# ANTIDEPRESSANTS

## DE-STIGMATIZING DEPRESSION HAS HELPED GROW MARKET

Eli Lilly's direct-to-consumer (DTC) advertising campaign for the anti-depression drug Prozac spurred positive media coverage of the product and helped to make depression a more socially acceptable, even trendy, condition, thus opening doors for drug makers marketing anti-depressants.

"Clever marketing by Prozac, in addition to media coverage of an avalanche of celebrities reportedly suffering from depression, have all helped to de-stigmatize the condition in recent years," said Datamonitor's Nick Alcock, senior psychiatry analyst.

Lilly's DTC campaign featured the sun – a symbol of happiness – in a series of ads for the drug. In one ad, a smiling sun replaced the letter 'o' in Prozac. This symbol created a strong brand image of the drug as a "happy pill," Alcock told *Drug Marketing*. Consequently, the media picked up on this image and fed the public "a constant diet" of stories about depression and its treatment.

Alcock recalled "its familiar green and white capsule gracing the coveted covers of *Time* and *ID* magazines." He added, "It is undeniable that media hype has given this drug cult status and made Prozac a household name."

Even so, some critics have derided Lilly's efforts to brand Prozac, claiming the company's DTC ads set unrealistic expectations for people suffering with depression. For example, Adbusters Media Foundation, a non-profit network of social activists based in Vancouver, British Columbia, has published a parody of a Prozac ad (*http://adbusters. org/spoofads/misc/prozac*).

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## NEW MEXICO PSYCHOLOGISTS GET PRESCRIBING AUTHORITY

A bill signed March 6 by New Mexico Gov. Gary Johnson (R) will allow psychologists to prescribe psychotropic drugs to patients. New Mexico thus becomes the first state in the U.S. to institute such a law and open a new market for anti-depressants and other drugs to treat mental illness.

Makers of anti-depression drugs now are likely to target psychologists in the state, forecast Nick Alcock, senior psychiatry analyst at Datamonitor. Furthermore, widening the pool of prescribers may result in an increase in the number of scripts written for depression.

In every other state, psychiatrists prescribe the majority of psychotropic drugs. Yet in New Mexico, there are long waiting times to see the few psychiatrists with practices outside of the major cities of Albuquerque and Santa Fe. The new law, therefore, is intended to ensure rural residents have timely access to anti-depression drugs.

Because psychologists lack a medical degree, they will have to receive training and certification before being given prescribing authority. Four other states – Georgia, Illinois, Hawaii and Tennessee – have pending legislation on prescription privileges for psychologists.

"Statistics show that there is a public health need in large rural areas with mental health service gaps, and it is our understanding that this is particularly true in New Mexico," said Russ Newman, American Psychological Association executive director for professional practice.

"Increasing the number of mental health professionals trained to prescribe will improve access to quality mental healthcare," Newman said.

**PDUFA,** *from Page 1*

ers, "We cannot allow reauthorization of PDUFA to be turned into a Christmas tree."

While acknowledging that both Republicans and Democrats have ideas for FDA reform, "this is not the vehicle for consideration of those matters," Tauzin said at a March 6 hearing.

Others speaking at that hearing echoed the call for clean, swift passage of new PDUFA. As Les Crawford, the new FDA deputy commissioner, explained, "Any hesitation or delay in the reauthorization of this program could trigger sudden erosion in our work force, particularly among senior reviewers whose skills are in very high demand."

"Congress needs to act with all due speed to reauthorize this program, assuring these employees of the shared commitment of all parties to continue the program for another five years," said Eli Lilly's Timothy Franson, vice president of clinical research and regulatory affairs. Elan's Mary Pendergast, executive vice president, added, "Timing is critical in this reauthorization process."

Industry and the FDA reportedly have reached an agreement on various aspects of the user fees program. However, this does not mean Congress won't have a say in the final outcome. The committee aims to move the PDUFA III bill to a House floor vote by April. The current PDUFA sunsets in late September.

Reed Smith attorney Marc Scheineson, head of his firm's food and drug practice, said it's likely "a pipe dream" to believe PDUFA III will pass through Congress without any amendments added. A number of concepts contained in the FDA Modernization Act of 1997 never have been fully implemented, he said, and may be addressed again now.

# BRIEFS

### Group Launches Anti-Industry Campaign

The American Medical Student Association (AMSA) in April will launch a new educational initiative to encourage medical students to abstain from accepting gifts from drug makers.

"It's important to communicate strong ethical behaviors to the medical student community before they are indoctrinated into the habits of accepting free lunches," said Jaya Agrawal, AMSA's national president and a fourth-year medical student at Brown University.

### Survivor Leads Campaign For J&J

Tina Wesson, winner of the reality-TV series "Survivor: The Australian Outback," will serve as official spokesperson for a rheumatoid arthritis (RA) awareness campaign co-sponsored by Centecor, a unit of Johnson & Johnson, and the Arthritis Foundation. Wesson herself suffers from RA. Meanwhile, FamilyPractice.com added a J&J-sponsored video lecture series to its online continuing medical education offerings. The series is titled, "Management of Symptoms and Behavior Associated With Psychosis." The web site is designed to meet the needs of family practice physicians. *For more information, visit http://www.FamilyPractice.com.*

### Hispanic Consumers Prefer Spanish

Seventy-four percent of Hispanic consumers prefer to receive healthcare information in Spanish, while only 6 percent indicated a preference for English, according to a study by multicultural marketing agency Tapestry, Chicago. *For more information, contact Cristal Mendlen at (312) 220-4470.*

### SoftWatch Offers New Web Site Service

SoftWatch just released its Quick Launch portal deployment program for the drug industry. The program is intended to shave time off the process of implementing and deploying a targeted web site. *For more information, visit http://www.softwatch.com.*