From: Tatum, Chandler [/O=CEPHALON/OU=US01 ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CTATUM]
Sent: 11/22/2006 2:34:51 PM
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Subject: FW: End-of-day WSJ Pick-up

From: Sarah Handza [mailto:SHandza@cooneywaters.com]
Sent: Wednesday, November 22, 2006 1:04 PM
To: Narayana, Arvind; Sehgal, Arpana; bshahbel@cephalon.com; Simmons, Betsy; Anderson, Candace; Catherine Collier; Condodina, Cynthia; DeWildt, Charles; Tatum, Chandler; Connelly, Denise; Winkelman, Dan; Del Ricci, Francine; Snyder, Heather; Yeh, Helen; Datin, Joseph; Duarte, Joseph; Messina, John; Thatcher, Jerri Ann; Kohl, Kevin; klee@bluediesel.com; Lisa Weiss; lmccue@cephalon.com; Thibodeau, Laurie; DE-LA-SALLE Marie-Dominique; Felker, Matthew; Geandreau, Matthew; Napoletano, Matthew; Patel, Mina; Richardson, Michael; Riotto, Mark; MSL-CNS; MSL-Oncology Pain; Solomon, Mark; Castagno, Paula; Levin, Penny; Bennett, Rosanne; DeChristopher, Robin; rkhankar@cephalon.com; Spokane, Randy; Beckhardt, Stacey; Diaz, Simon; Hedgepeth, Sueann; Larijani, Susan; McGaurn, Susan; Johnson, Tracey; Terifay, Terrence; Grupp, Robert; Clements, Sean; andria.arena@bm.com; swiliams@cephalon.com
Cc: Lisa Weiss; Catherine Collier; Jacqueline Davis
Subject: End-of-day WSJ Pick-up

Wall Street Journal Coverage

Compiled by Cooney/Waters Group

As of 2:00 pm, November 22, 2006

Since this morning, one more media outlet covered yesterday's *Wall Street Journal* article.

We will continue to monitor coverage of this.

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http://www.fool.com/news/commentary/2006/commentary06112206.htm

The Motley Fool
To Educate, Amuse & Enrich

The Motley Fool
How to Market a Drug Too Well
By Brian Lawler
November 22, 2006

Getting a drug through the clinical trial process is a daunting and complex task, but the rules and regulations for pharmaceutical companies don't end once a drug receives regulatory approval for marketing. Companies are only allowed to market a drug for indications it was approved to treat, and oftentimes they have to develop what is known as a risk-management plan as a way of limiting off-label usage and to ensure that the drug is being used in the proper settings.

Pharmaceutical companies are perpetually engaged in this balancing act, trying to get their drugs used as much as possible but also being careful not to go overboard in their marketing and bring on the wrath of regulators. Besides the constant television and magazine commercials, pharma companies promote their drugs in other ways, such as paying doctors to sponsor seminars on the drugs or handing out promotional knickknacks at hospitals. Yesterday, it was reported in *The Wall Street Journal* that biopharmaceutical company Cephalon (Nasdaq: CEPH) might have gone a step too far in this delicate balancing act and excessively promoted its pain drug Actiq for indications it wasn't approved to treat.

How off-label usage of a drug works
The reason pharmaceutical companies try to promote their drugs to as wide an audience as possible is obvious: It will result in more sales of the drug. Sales of a drug for indications it wasn't approved to treat, called off-label sales, are

sometimes much higher than sales for the drug's approved indication. There is nothing wrong with this, and it can be a way of circumventing years of clinical trials and getting a drug into the hands of patients before it receives formal approval for a particular use.

A good example of this is Genentech's (NYSE: DNA) Avastin, which has the same mechanism of action as the company's age-related macular degeneration (AMD) treatment, Lucentis, but was already approved to treat various unrelated disorders years before Lucentis came on the market as a treatment for AMD. While waiting for Lucentis to go through the clinical trial process and finally receive regulatory approval to treat AMD, which happened this year, ophthalmologists had been using Avastin off-label as a treatment for AMD, saving the eyesight of thousands of people. So off-label usage of a drug can clearly be a good thing sometimes.

Cephalon's Actiq, though, is a powerful opioid narcotic, similar to heroin or morphine. With many other types of pain medications on the market, off-label usage of the drug was bound to come under much more scrutiny, and such use is much less necessary than that of an eyesight-saving therapy like Avastin, for example.

How a drug might be over-promoted

Cephalon is being accused by the Connecticut attorney general and is under investigation by the FDA for promoting Actiq to physicians it wasn't supposed to, such as neurologists, who rarely treat patients with cancer-related pain. Medical practitioners who don't treat cancer-related pain fall outside the scope of the types of doctors the drug is supposed to be marketed to in accordance with the risk-management plan the company made with the FDA when Actiq was approved.

The probable reason that the FDA made Cephalon write up a risk-management plan for Actiq was to prevent rampant off-label usage of the drug because of its addictiveness and potential for abuse, similar to what has happened with the pain drug Oxycontin. The Actiq risk-management plan stated that the drug was only to be marketed to pain specialists and oncologists. Risk-management plans are almost always associated with drugs that the FDA expects will have strong off-label demand from patients or doctors but that the agency doesn't want used outside its approved treatments.

The probable outcome of the investigations

The investigations are still ongoing, but by far the most likely outcome of all this is that Cephalon pays a large fine and agrees to abide by an even stricter marketing agreement for Actiq. This is exactly what happened to *Rule Breakers* pick **InterMune** (Nasdaq: ITMN) last month. InterMune agreed to pay a fine of $37 million to settle government investigations of its overaggressive sales practices for its only marketed drug, which is used primarily off-label as well.

Since Actiq started to face generic competition from **Barr Pharmaceuticals** (NYSE: BRL) last quarter and Cephalon just introduced a follow-up product for the drug, the impact of this investigation on the company's bottom line will most likely be minimal, aside from the one-time hit of the fines from the FDA and the attorney general. But there's a larger issue raised by all this. There needs to be a better system in place to inform doctors and patients of the treatment options available to them, so that they can make impartial decisions on which drug or treatment will provide the most therapeutic benefit -- so that it's not simply the most-promoted drug that ends up being used.

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