Eli Lilly to Start Disclosing Physician Payments

If you receive honoraria for speaking about the efficacy of Cymbalta, Zyprexa or any other product for Eli Lilly, your payments will soon become a matter of public record. The company announced last month they would initiate an industry-first policy of disclosing payments of more than $500 to doctors for their advisory roles and speaking gigs at educational seminars. Disclosure will begin in the second half of 2009 and will include payments made in the first six months of the year. Reporting of travel, entertainment, and gifts will be included in the future.

Congress has pushed for disclosures bills in recent years, and by moving first, Eli Lilly may be hoping to set the tone for future federal regulations much in the same way automakers introduced their own proposals of CAFE standards in hopes of countering higher, government-mandated fuel economies in automobiles. The latest congressional proposal, laid out in the Physician Payment Sunshine Act, called for doctors to report any payment of more than $25. The Eli Lilly plan will eventually expand to cover all payments included in the PPSA. The bill reads as follows:

"A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as:

(A) compensation;

(B) food, entertainment, or gifts;

(C) trips or travel;

(D) a product or other item provided for less than market value;

(E) participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar;

(F) product rebates or discounts;

(G) consulting fees or honoraria; or

(H) any other economic benefit, as defined by the Secretary."

In March 2008, Rep. Peter DeFazio (D-OR) and Rep. Pete Stark (D-CA) introduced a slightly different companion bill in the House of Representatives, (HR 5605).

Penalties for noncompliance with the PPSA are stiff. "Any manufacturer of a covered drug, device, or medical supply that fails to submit information required under subsection (a) or (b) in accordance with regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each such failure."

A small pack of states made up of Minnesota, Vermont, West Virginia, Maine and the District of Columbia already have disclosure laws on the books, though none of them covers medical device makers. **PN**

SHORTTAKES

■ **One and Done.** Patients who are candidates for therapy with levetiracetam can simplify their therapeutic regimen with the recently approved extended release formulation, Keppra XR (UCB). The FDA approved Keppra XR as an adjunctive treatment for patients with partial-onset seizures who are 16 years of age or older. Side effects that may be seen in patients taking Keppra XR are expected to be similar to those seen in patients on immediate-release Keppra tablets, according to the company. The most common side effects seen when paired with other AEDs were somnolence and irritability.

■ **Prophylactic Botox.** Top-line results from two Phase III Botox trials for the prophylactic treatment of headache in adults suffering from chronic migraine are positive, Allergan reports. In the Phase III clinical trials, patients were randomly assigned to treatment with Botox or placebo injections every 12 weeks. At week 24, following two treatment cycles, researchers evaluated change from baseline in the number of headache episodes as well as the number of headache days in weeks 20 through 24. In the first Phase III clinical trial, although both Botox and placebo groups showed a statistically significant improvement from baseline, there was no significant drop in the number of headache episodes between the groups. However, the company notes, the study showed a decrease in number of headache days, the FDA's preferred efficacy measure, that was significantly greater in patients receiving Botox vs. patients receiving placebo (p=0.006). Reduction in number of migraine/probable migraine days was also significantly greater in patients treated with Botox vs. patients receiving placebo (p=0.002).

■ **AD Drug Trial Comes Up Short.** The 12-week, placebo-controlled, phase IIb Sirocco trial, testing the potential new drug AZD3480, as well as donepezil, failed to meet the trial's statistical significance on the primary outcome measure—change from baseline on ADAS-Cog. At two of the three doses tested, AZD3480 showed an improvement on the secondary outcome measures: ADCS-CGIC and MMSE. Of the three AZD3480 doses, the middle dose performed best on both measures (0.5 point improvement, ADCS-CGIC and 0.9 point improvement, MMSE). Donepezil also showed an improvement on ADCS-CGIC (0.2 point improvement) and the MMSE (1.0 point improvement). Neither donepezil nor AZD3480 showed improvement in any domain of the Cognitive Drug Research computerized test battery in the pooled dataset of all the 567 subjects, who were between 60 and 85 years old and diagnosed with probable AD that was classified on a quantitative scale as mild or moderate.

PQRI Gets Poor Report from Practices

Results from a new study of physicians' happiness with the Physician Quality Reporting Initiative (PQRI) are in, and the results don't give high marks to program. Published by the Medical Group Management Association (MGMA, mgma.com), the study found that doctors cite as problematic the lack of data for improving patient outcomes, the administrative burden of participation, difficulty accessing and downloading the 2007 feedback reports, and the delay from the time data were submitted to the time reports were available.

Of practices able to get hold of their PQRI reports, almost 70 percent reported "low" or "no" satisfaction with the document's guidance in improving patient care outcomes. An overwhelming percentage (almost 93 percent) of respondents reported that they had difficulty accessing their reports. Responding practices spent five hours downloading their final 2007 PQRI feedback reports from the CMS website, on average. In addition, 63 percent of respondents reported they had difficulty capturing and submitting data.

When asked how important were individual reasons in a practice's decision to participate in the 2007 PQRI, "To earn more practice revenue" was considered extremely or considerably important by about 65 percent of respondents, "To obtain new insights on how to improve quality of care" was considered extremely or considerably important by slightly less than half of respondents. "To prepare for a future where quality reporting might be a more significant factor in the Medicare reimbursement model" was considered extremely or considerably important by about 93 percent of the group.

CMS has proposed a set of PQRI quality measures for 2009 and notes funding for PQRI incentive payments was approved through the passage of Medicare Improvement for Patients and Providers Act (MIPPA) on July 15, 2008 and includes an increase in the bonus payment amount from 1.5 percent to 2 percent. CMS proposes to select from among 175 measures, including 111 current 2008 PQRI measures. Of these proposals, 19 can be broadly applied to neurology. For more on PQRI and its impact on neurologists, see the article in our September 2008 issue, available online at practicalneurology.net. **PN**

Respondents' Reporting Difficulty of 2007 PQRI Data Capture and Submission

No difficulty	3.2%
Low difficulty	33.8%
Moderate difficulty	37.8%
Considerable difficulty	20.9%
Extreme difficulty	4.3%

— Medical Group Management Association, Legislative and Executive Advocacy Response Network Physician Quality Reporting Initiative

SHORTTAKES

■ **Stroke Survivors, Shun Supine Sleep.** Stroke patients spend most of their sleeping time on their backs, and this may contribute to sleep apnea, according to a study published in the September issue of *Stroke*. Researchers performed full sleep testing on 30 stroke survivors that included tracking their sleep positions. The average patient age was 67 years. Patients spent the "vast majority" of their sleep time in the supine position, and the study authors reported that 63 percent of patients slept exclusively on their backs. Further, sleeping supine was more common as the severity of the stroke worsened.

■ **Long-term Assurance.** Using Avonex (interferon beta-1a IM) therapy in patients with relapsing multiple sclerosis (MS) for up to 15 years reduces disability progress and improves quality of life, according to results from the ASSURANCE study, which was presented at the World Congress on Treatment and Research in MS. Data from the open-label, retrospective, patient-reported, multicenter, 15-year follow-up study that included patients with relapsing MS who received two years of treatment in the Phase III trial (n=172) found there was significantly lower disability progression as measured by a mean change in EDSS of 2.3 vs. 3.3 (p=0.011) from MSCRG baseline. Researchers also reported lower disability progression to EDSS milestones four (64% vs. 83%, p=0.06), six (32% vs. 62%, p=0.008) and seven (9% vs. 33%, p=0.008.)

■ **Hep, Hep, Hooray for MS Kids.** Vaccinating children against hepatitis B does not increase their risk of developing MS, according to new a study in *Neurology*. The French study of 349 children with MS and 2,941 children without the disease found that a total of 24.4 percent of the MS patients were vaccinated for hepatitis B in the three years before the study in comparison 27.3 percent of children without MS. Despite this, researchers found that children with MS were 1.74 times more likely to have received Engerix B, a hepatitis B vaccine.

■ **Headaches Weigh Heavily in Kids.** The more the scales tip forward for overweight children and teenagers, the more numerous and severe their headaches, according to a study published in the October issue of *Headache* and conducted at seven pediatric headache centers. Investigators studied data on 913 patients at baseline, three months, and six months and found evidence of a connection between weight and headaches. However, they also saw evidence that losing weight lessens the frequency and severity of headaches. Researchers say they couldn't claim a casual link between weight and headaches. **PN**