

## POLICY & PRACTICE

### AACE Defends Patient Release Rule

The American Association of Clinical Endocrinologists is defending a rule by the Nuclear Regulatory Commission that permits outpatient treatment using high doses of radioactive iodine. "We believe that the current rule has improved health care delivery by allowing more timely and convenient treatment of patients with thyroid cancer," AACE President Bill Law Jr. wrote in a letter to the NRC. "In the past, the majority of patients ... were hospitalized for therapy. ... Unanticipated competition and conflicts in scheduling [the few beds available] often arose—leading to prolonged profound hypothyroidism in some patients. Outpatient scheduling has provided the flexibility to treat patients at an optimal time of their choosing." AACE was responding to a petition by Peter G. Crane, a former NRC employee, to revoke the current rule, which allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their systems. Mr. Crane, himself a former thyroid cancer patient, argued that letting patients receive outpatient radioactive iodine treatment exposes their families to harmful amounts of radiation. Outpatient therapy "means that patients who are sick, stressed, deeply hypothyroid, potentially nauseous, and highly radioactive are being sent out the door, where they may or may not come into close contact with loved ones and members of the public," Mr. Crane wrote.

### New Thyroid Trials Web Site

The American Thyroid Association has launched a Web site that lists ongoing clinical trials of treatments for thyroid diseases. The association is inviting patients to use the search engine at the site, [www.thyroidtrials.org](http://www.thyroidtrials.org), to locate trials; it is also soliciting researchers to register their trials with the site. Trial information can be submitted online and will be reviewed for posting by the ATA Web Site Committee. The committee hopes to have a 2-week turnaround from submission to posting. Studies will be removed from the site on the closing date listed. The new site

says it "aims to be the most complete, up to date, and easiest to navigate compendium of clinical trials for clinicians and patients with thyroid diseases on the Internet. The ATA Trial finder is your one-stop site to search multiple information sources at the same time—including well-known public and private information sources and trials screened by experts from the American Thyroid Association."

### Enrollees Happy With Part D

A new survey of Medicare beneficiaries who are receiving Part D drug benefits

finds them to be largely satisfied. The survey—conducted 10 weeks into the new coverage—was paid for by America's Health Insurance Plans, and conducted by Ayres, McHenry & Associates Inc., a Republican polling firm. The poll surveyed 408 of the 5.2 million people over age 65 years who have self-enrolled in Part D, and 401 of the 6.5 million "dual eligibles," who were automatically enrolled because they had Medicaid drug coverage. Of those who self-enrolled, 66% said it had been worth the time and effort to enroll, and four-fifths (84%) said they had no problem signing up. The majority—85%-90% of both groups—

said they had no problem using the new benefit. "This is a dramatic departure from the conventional wisdom about this program," said Whitfield Ayres, a principal in the polling firm. But Ron Pollack, executive director of the advocacy group Families USA, said it was not surprising that beneficiaries who went to the trouble to sign up were happy. Shockingly few have signed up, however, said Mr. Pollack. "America's seniors are clearly voting with their feet," he said.

### Bill Seeks Consent for Off-Label Rx

A new bill in the California assembly would require doctors to get informed



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### Important Safety Information:

- Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Cymbalta is not approved for use in pediatric patients.

Cymbalta should not be used concomitantly with monoamine oxidase inhibitors (MAOIs) or thioridazine and not in patients with a known hypersensitivity or with uncontrolled narrow-angle glaucoma.

**Clinical worsening and suicide risk:** All adult and pediatric patients being treated with an antidepressant for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially when initiating drug therapy and when increasing or decreasing the dose. A health professional should be immediately notified if the depression is persistently worse or there are symptoms that

\*Cymbalta vs placebo ( $P \leq .001$ ) by MMRM on 24-hr average pain severity score  
Cymbalta vs placebo ( $P \leq .009$ ) by MMRM on 24-hr night pain severity score

Reference: 1. Data on file, Lilly Research Laboratories: CYM20050314A, B&D.

consent from their patients before “prescribing, administering, or furnishing” a prescription for off-label use. A failure to adhere to the requirement would be considered a violation of the Medical Practice Act, which means physicians could be charged with a crime. The California Medical Association opposes the legislation. In a statement, the CMA said existing law is enough because physicians can be held liable for not disclosing risks. AB 2856 was introduced by Assemblywoman Loni Hancock (D-Berkeley). It would require physicians to specify that a medication is not approved by the Food and Drug Administration for the use that the doctor is

recommending, that the risks are unknown, and that there is not a consensus on the efficacy. A patient could withdraw consent at any time.

#### Patient/Doctor Decision Making

Decisions about medical treatment should be made by physicians and patients, according to a survey of 1,029 adults for the National Consumers League. More than 90% of respondents agreed that “all medications, both over-the-counter and prescription, offer benefits but also carry some risk of side effects. It should be up to physicians and patients to weigh benefits against the risks and to make decisions

that are right for them.” The poll also found that the public strongly supports broader access to treatments—even those carrying additional risks—for chronic diseases such as multiple sclerosis, Parkinson’s disease, and Alzheimer’s disease. “Everything in life carries risks, but in the case of chronic, debilitating conditions, the greatest risk is a lack of new and improved treatment options,” said Linda Golodner, the league’s president.

#### All Groups at Risk for Poor Care

Although disparities exist in health care, those gaps are small compared with the health care everyone receives and what

they should be receiving, according to a report from the RAND Corporation. “Differences exist. But they pale in comparison to the chasm between where we are today and where we should be,” said Dr. Steven M. Asch of the University of California, Los Angeles, the study’s lead author. The study assessed preventive services and care for 30 acute and chronic conditions that constitute the leading causes of death and disability. Overall, participants received about 55% of recommended care, despite the fact that the recommendations for the conditions involved were widely known and accepted.

—Joyce Frieden

Waking after a night with less pain.  
That’s a beautiful thing.

#### Now there’s help for your patients with diabetic peripheral neuropathic pain (DPNP).

Nighttime can be anything but restful for those suffering from the stabbing, shooting pains associated with DPNP. That’s where Cymbalta can help. As early as week one, Cymbalta significantly reduces the pain,<sup>1\*</sup> so many patients may feel more comfortable and have fewer interruptions to their days and nights. For some, that’s a dream come true.

To learn more, please visit  
[www.insideCymbalta.com/DPNP](http://www.insideCymbalta.com/DPNP)



**Cymbalta**<sup>®</sup> DELAYED  
RELEASE  
duloxetine HCl CAPSULES

are severe, sudden, or were not part of the patient’s presentation. If discontinuing treatment, taper the medication. Cymbalta should not be administered to patients with any hepatic insufficiency or patients with end-stage renal disease (requiring dialysis) or severe renal impairment (CrCl <30 mL/min). Postmarketing, severe elevations of liver enzymes or liver injury with a hepatocellular, cholestatic, or mixed pattern have been reported.

Cymbalta should generally not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Most common adverse events (≥5% and at least twice placebo) in MDD premarketing clinical trials were: nausea, dry mouth, constipation, fatigue, decreased appetite, somnolence, and increased sweating. Most common adverse events in diabetic peripheral neuropathic pain (DPNP) premarketing clinical trials were: nausea, somnolence, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and asthenia.

See Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent page.