

IMPLEMENTING HEALTH REFORM

The Independent Payment Advisory Board

Tucked within the Affordable Care Act is a provision aimed at reining in health care spending. The provision creates the Independent Payment Advisory Board (IPAB), a panel of 15 experts charged with slowing the growth of Medicare and private health care spending, as well as improving health care quality. By law, the board's recommendations will automatically take effect un-

less Congress enacts its own cost-cutting plan that achieves the same level of savings. The board isn't expected to submit its first recommendations to Congress until 2014, but already the medical community is crying foul.

Dr. J. Fred Ralston Jr., president of the American College of Physicians, explains some of the issues with the new board.

RHEUMATOLOGY NEWS: Everyone agrees that something needs to be done to control health care spending, so why is the IPAB so unpopular with physicians?

Dr. Ralston: The ACP is supportive of the general concept of an entity such as the IPAB. We believe that making complex Medicare payment and budgetary decisions is very difficult within a polit-

ical process with substantial lobbying pressures, and that a knowledgeable, independent board serving this role would have some protection from this undue influence.

Many physician and other provider groups are opposed to this provision because a significant amount of influence is removed from the accessible, elected congressional body by the legislation. The sense is that too much congressional authority is removed, resulting in a situation in which there will be inadequate opportunity for physicians and other health care providers to express their point of view and influence the actions taken.

RN: How does the IPAB differ from other bodies like the Medicare Payment Advisory Commission (MedPAC)?

Dr. Ralston: The IPAB, a body whose members must be appointed by the president and confirmed by the Senate, is provided with the authority to have changes made by the Secretary [of Health and Human Services] to the Medicare system to reach a budgetary target. The IPAB-recommended changes will take effect unless Congress passes legislation that meets the same budgetary target. Even if Congress passes such legislation, that legislation can be vetoed by the president and the IPAB recommendation would still take effect.

MedPAC, as an advisory commission, can only make recommendations, which Congress can choose to enact or not. It has no direct authority to implement change, which differs significantly from the IPAB.

RN: The ACP and other medical societies have called for changes to how the IPAB is structured. What changes would the ACP like to see?

Dr. Ralston: The College would like to see the following changes:

- ▶ A requirement for inclusion of a primary care physician on the IPAB—the perspective of those physicians that provide first-contact, comprehensive, and continuous care to the population must be a part of the process.

- ▶ Stronger protections to ensure that the recommendations to decrease cost do not result in decreased quality of care.

- ▶ The authority for Congress to reject the implementation of IPAB recommendations with a majority vote, which maintains a reasonable influence in the hands of the elected body.

- ▶ Equal distribution of risk for budgetary reductions among all health care providers. Hospitals and certain other provider groups, for example, hospices, are protected from budgetary reductions over the first several years of the legislation, placing physicians at increased risk of being required to take reductions. ■

DR. RALSTON is president of the American College of Physicians and a general internist in Fayetteville, Tenn.

Postmarketing Experience—The following adverse reactions have been identified during postapproval use of FORTEO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- **Osteosarcoma:** Cases of bone tumor and osteosarcoma have been reported rarely in the postmarketing period. The causality to FORTEO use is unclear. Long term osteosarcoma surveillance studies are ongoing.
- **Hypercalcemia:** Hypercalcemia greater than 13.0 mg/dL has been reported with FORTEO use.

Adverse events reported since market introduction that were temporally (but not necessarily causally) related to FORTEO therapy include the following:

- **Allergic Reactions:** Anaphylactic reactions, drug hypersensitivity, angioedema, urticaria;
- **Investigations:** Hyperuricemia;
- **Respiratory System:** Acute dyspnea, chest pain;
- **Musculoskeletal:** Muscle spasms of the leg or back;
- **Other:** Injection site reactions including injection site pain, swelling and bruising; oro-facial edema.

USE IN SPECIFIC POPULATIONS: Pregnancy Category C—There are no adequate and well-controlled studies of FORTEO in pregnant women. In animal studies, teriparatide increased skeletal deviations and variations in mouse offspring at doses more than 60 times the equivalent human dose and produced mild growth retardation and reduced motor activity in rat offspring at doses more than 120 times the equivalent human dose. FORTEO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In animal studies, pregnant mice received teriparatide during organogenesis at subcutaneous doses 8 to 267 times the human dose. At doses ≥ 60 times the human dose, the fetuses showed an increased incidence of skeletal deviations or variations (interrupted rib, extra vertebra or rib). When pregnant rats received subcutaneous teriparatide during organogenesis at doses 16 to 540 times the human dose, the fetuses showed no abnormal findings.

In a perinatal/postnatal study, pregnant rats received subcutaneous teriparatide from organogenesis through lactation. Mild growth retardation in female offspring at doses ≥ 120 times the human dose (based on surface area, mcg/m²). Mild growth retardation in male offspring and reduced motor activity in both male and female offspring occurred at maternal doses 540 times the human dose. There were no developmental or reproductive effects in mice or rats at doses 8 or 16 times the human dose, respectively.

Exposure multiples were normalized based on body surface area (mcg/m²). Actual animal doses: mice (30 to 1000 mcg/kg/day); rats (30 to 1000 mcg/kg/day).

Nursing Mothers—It is not known whether teriparatide is excreted in human milk. Because of the potential for tumorigenicity shown for teriparatide in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use—The safety and efficacy of FORTEO have not been established in any pediatric population. FORTEO should not be prescribed in patients at an increased baseline risk of osteosarcoma which include pediatric and young adult patients with open epiphyses. Therefore, FORTEO is not indicated for use in pediatric or young adult patients with open epiphyses.

Geriatric Use—Of the patients receiving FORTEO in the osteoporosis trial of 1637 postmenopausal women, 75% were 65 years of age and over and 23% were 75 years of age and over. Of the patients receiving FORTEO in the osteoporosis trial of 437 men, 39% were 65 years of age and over and 13% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment—No studies have been performed in patients with hepatic impairment.

Renal Impairment—In 5 patients with severe renal impairment (CrCl $<$ 30 mL/min), the AUC and T_{1/2} of teriparatide were increased by 73% and 77%, respectively. Maximum serum concentration of teriparatide was not increased.

OVERDOSAGE: Incidents of overdose in humans have not been reported in clinical trials. Teriparatide has been administered in single doses of up to 100 mcg and in repeated doses of up to 60 mcg/day for 6 weeks. The effects of overdose that might be expected include a delayed hypercalcemic effect and risk of orthostatic hypotension. Nausea, vomiting, dizziness, and headache might also occur.

FORTEO® (teriparatide [rDNA origin] injection)

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In postmarketing spontaneous reports, there have been cases of medication errors in which the entire contents (up to 800 mcg) of the FORTEO delivery device (pen) have been administered as a single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose have been reported.

Overdose Management—There is no specific antidote for teriparatide. Treatment of suspected overdose should include discontinuation of FORTEO, monitoring of serum calcium and phosphorus, and implementation of appropriate supportive measures, such as hydration.

DOSAGE FORMS AND STRENGTHS: Multi-dose prefilled delivery device (pen) for subcutaneous injection containing 28 daily doses of 20 mcg.

PATIENT COUNSELING INFORMATION: Patients should read the FDA-approved *Medication Guide* and delivery device (pen) *User Manual* before starting therapy with FORTEO and re-read them each time the prescription is renewed. Patients need to understand and follow the instructions in the FORTEO delivery device *User Manual*. Failure to do so may result in inaccurate dosing.

PLEASE SEE FULL PRESCRIBING INFORMATION FOR ADDITIONAL INFORMATION.

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