in patients with prostate cancer who receive androgen deprivation therapy, according to the company. Amgen is reviewing both letters "and will work with the FDA to determine the appropriate next steps regarding these applications," the company indicated.

At a meeting in August, an FDA advisory committee voted that the benefits of denosumab for treating postmenopausal osteoporosis outweighed its risks, but did not support use of the drug for other indications, including osteoporosis prevention, primarily because of concerns about its long-term safety. Denosumab, a human IgG2 monoclonal antibody, targets "an essential regulator" of osteoclasts, according to Amgen. It is also being studied for other conditions associated with bone loss, including rheumatoid arthritis, and for its potential to delay bone metastases. If approved, its trade name would be Prolia. ■

Pretherapy Spinal Fractures Seen In Pediatric Rheumatic Disorders

BY AMY ROTHMAN SCHONFELD

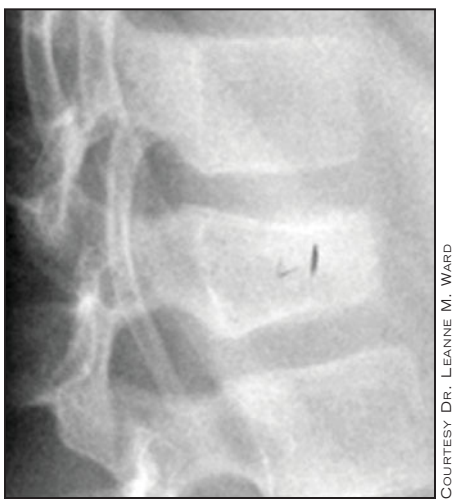
PHILADELPHIA — Vertebral fractures are present in a significant percentage of children with rheumatic diseases, and these fractures appear prior to prolonged glucocorticoid exposure, according to Dr. Leanne M. Ward.

"Vertebral fractures are an underrecognized complication of steroid-treated rheumatic disorders," said Dr. Ward, director of the Pediatric Bone Health Clinical and Research Programs at University of Ottawa. "The question is when the fractures first occur—in the course of the disease or steroid treatment."

Investigators from the Canadian STOPP (Steroid-Associated Osteoporosis in the Pediatric Population) Consortium evaluated the spine health of 134 children (89 girls; median age, 10 years) with rheumatic conditions.

In all, 30 children had juvenile dermatomyositis (JDM), 28 had juvenile idiopathic arthritis excluding systemic JIA, and 76 were diagnosed with other rheumatic disorders (systemic lupus erythematosus, systemic vasculitides, systemic JIA, and others).

The children underwent thoracolumbar spine x-rays and lumbar spine areal bone mineral density (LS aBMD) evaluation within 30 days of beginning glucocorticoid therapy.



COURTESY DR. LEANNE M. WARD

This image shows a fracture at L1 in a girl with JDM who takes glucocorticoids.

A total of 7% of the group (9 of 134) had vertebral fractures. In these nine children, six patients had a single vertebral fracture and three patients had 2-5 fractures, for a total of 13 fractures. Three of the fractures (23%) were moderate and the rest were mild. Most fractures were located in the midthoracic and upper lumbar regions, said Dr. Ward at the annual meeting of the American College of Rheumatology. Although the mean LS aBMD scores for the group were lower than the norm (–0.6 plus or minus 1.22; *P* less than .001), LS aBMD did not predict the development of vertebral fractures. The odds for fracture were increased 10-fold if the child reported back pain.

The STOPP Consortium was founded in 2003 as a Canadian national pediatric bone health working group of investigators from 12 tertiary children's hospitals.

Dr. Ward recommends that children with rheumatic diseases undergo baseline spine radiographs at diagnosis and then annually, or more frequently if they have new-onset back pain. Children with vertebral fractures who have back pain may be candidates for bisphosphonate therapy, said Dr. Ward.

Dr. Ward reported having a business relationship with Novartis. ■