

Monday, March 03, 2008

Mr. David Schmickel
Senator Enzi's Office
Senate
United States Government
David_schmickel@help.senate.gov

Dear Mr. Schmickel:

I am writing to ask that a hold be placed on the Senate Bill S. 877 to place human growth hormone (hGH) on the Schedule III list of the FDA.

I represent (as Secretary) the Board of Directors of the Lawson Wilkins Pediatric Endocrine Society, the largest pediatric endocrine society in North America with more than 1,000 members.

The reason that I write is quite clear—there would be a major disruption in our ability to prescribe hGH for legitimate indications in infancy, childhood and adolescence. The following conditions are FDA-approved for the prescription of hGH:

- Growth hormone deficiency
- Chronic kidney disease
- Turner syndrome
- Prader-Willi syndrome
- Small-for-gestational age with failure to catch-up to the normal growth curves
- Idiopathic short stature
- SHOX gene haplo-insufficiency
- Noonan syndrome

In addition a number of severely growth hormone deficient children have hypoglycemia (low blood sugar) that is appropriately treated with hGH. This is a medical emergency, for hypoglycemia can lead to permanent brain injury. These children cannot tolerate a disruption in their supply of hGH.

I realize that the impetus for this re-scheduling of hGH comes from its abuse potential in the anti-aging market and from its use in athletes. In fact, I was one of the scientists who provided testimony to Mr. Waxman's committee in the House of Representatives the day before the Clemmen's hearing. The unintended consequences for children are too great to rush into rescheduling this drug; for its legitimate uses far outweigh those of the potential misuses.

I am prepared to come to Washington on Thursday March 6th to meet with anyone on Mr. Enzi's subcommittee or staff, if you think that that might prove useful.

Thank you for your consideration in this matter of great import to the children who require hGH therapy and, by reflection, to those of us pediatric endocrinologists who prescribe it.

Yours sincerely,

ADR

Alan D. Rogol, MD, Ph.D
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Professor of Clinical Pediatrics, Indiana University School of Medicine
Secretary, Lawson Wilkins Pediatric Endocrine Society