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Society Releases Position Statement on Bioidentical Hormones

At its October 21 meeting, The Endocrine Society's Council approved a position statement on the use and regulation of bioidentical hormones (BH). This is one of a series of statements that the Society is developing to communicate its official position on a range of existing and emerging issues to policy makers and the media. This particular statement was developed by the Society's Clinical Affairs Committee's FDA Issues Task Force, chaired by Loren Greene, MD.

While proponents of BH claim that they are safe and effective, few clinical studies have been done to measure long-term outcomes to support such claims. There are also those that assert that customization of hormone therapy can be achieved by testing a patient's saliva and compounding a hormone treatment to exactly match the patient's needs. However, the accurate and precise determination of hormone levels is no small feat, and consistency of dose in compounded hormone preparations is not guaranteed.

As the practice of compounding is becoming more widespread for hormones, it has become necessary to examine the regulation of compounding pharmacies. Furthermore, as more patients are requesting bioidentical hormone preparations, it is critical that patients be properly informed of the potential risks as well as the current data in the scientific literature on the effects of bioidentical hormones.

According to its recently adopted position statement, The Endocrine Society supports FDA regulation of all hormone preparations, including but not limited to:

- Surveys for purity and dosage accuracy
- Mandatory reporting by drug manufacturers of adverse events
- A registry of adverse events related to the use of hormone preparations
- Inclusion of uniform information for patients, such as warnings and precautions, in packaging of hormone products

To read the full position statement, go to <http://www.endo-society.org/publicpolicy/policy/index.cfm>.

Society Approves Two More Clinical Practice Guidelines

During its recent October meeting, the Society's Council approved the latest clinical practice guidelines (CPGs) from The Endocrine Society. The new guidelines are titled *Prevention and Treatment of Pediatric Obesity* and *Management of Thyroid Dysfunction during Pregnancy and Postpartum*. The task forces that developed the guidelines were chaired by Drs. Gilbert August and Leslie

DeGroot, respectively. The next stage of development is submission to the *Journal of Clinical Endocrinology & Metabolism (JCE&M)* for peer review. Once approved, the guidelines will be published in *JCE&M* and mailed with *Endocrine News*. Patient guides (companion pieces to the CPGs) will also be developed by The Hormone Foundation for physicians to distribute to their patients.

As was the case for the other guidelines, these new guidelines have gone through a rigorous multi-step development and review process. For each document, the level of scientific evidence is rated and the recommendations are graded using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system.

Current CPGs available from the Society are *Evaluation and Treatment of Adult Growth Hormone Deficiency* and *Testosterone Therapy in Adult Men with Androgen Deficiency*. The most recent guideline from the Society on *Androgen Therapy in Women* is currently available on the Society's Web site.

The Society has five other guidelines nearing completion and coming soon: *Diagnosis and Evaluation of Women with Hirsutism*, *Lipids* (with an endocrine focus), *Primary Aldosteronism*, *Primary Prevention of Cardiovascular Disease in Patients at Metabolic Risk*, and *Vitamin D & Bone*.

Guidelines are available for purchase at <http://www.endo-society.org/quickcontent/clinicalpractice/clinical-guidelines/>. Please contact the Society's Government & Public Affairs department at govt-prof@endo-society.org for more information.

NIH Announces Long-Term Strategy for Type 1 Diabetes Research

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has released a long-term strategic plan to guide the future of research into type 1 diabetes. The plan comprises six discrete goals intended to further knowledge of and improve treatments for the disease.

Two of the goals apply directly to increasing our knowledge of type 1 diabetes. The first goal outlined in the plan is to identify the genetic and environmental causes of type 1 diabetes. The sixth goal of the plan is to attract new talent and apply new technologies to research on type 1 diabetes. The work directed toward these two goals should contribute greatly to our knowledge of the disease. Furthermore, new talent and technologies could help in finding new treatments and avenues of research.

Three of the goals have direct implications in the treatment and management of the disease. These goals are to develop cell replacement therapy, prevent or reduce hypoglycemia in type 1 diabetes, and to prevent or reduce the complications of type 1 diabetes.

The second goal outlined in NIDDK's plan is to prevent or reverse type 1 diabetes. While described as a specific goal in the strategy, this must also be considered the overarching purpose of the plan.

In addition to outlining the direction of research that the institute will support, the development and implementation of the plan has resulted in an accessible central location on NIDDK's Web site that contains useful information for researchers, patients, and family members of those suffering from type 1 diabetes. A patient or family member can access information on the Web site on health services and clinical research studies in which a patient may enroll. Researchers will also find information on research funding opportunities and research resources.

For more information, please visit:

<http://www.niddk.nih.gov/fund/diabetesspecialfunds/plan/>

TES Comments on CMS Proposed Rule for Physician Payment Schedule

The Endocrine Society provided comments on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the Medicare payment policies under the Physician Payment Schedule for calendar year 2007. The Society's comments focused mainly on the congressionally mandated imaging cuts as directed by the Deficit Reduction Act, most specifically payment rates for Dual energy X-ray absorptiometry (DXA).

The Society requested that CMS exempt code 76075—DXA bone density, axial—from the proposed list of codes to be reduced to the outpatient perspective payment system (OPPS) payment rate. While other osteoporosis screening procedures are scheduled to be cut by the proposed rule, no other single procedure is as important as 76075, or will see as dramatic a cut, about 41 percent. The Society also showed its support for expanding the number of beneficiaries who qualify for bone mass measurement (BMM) tests by reducing the dosage requirements for steroid therapy in order to meet the eligibility requirements. The Society will continue to advocate for a positive payment update for FY 2007 when Congress returns after the November 7 election.

Society Experts Weigh in on Breaking News

In the October 22, 2006, *Boston Herald* story "Docs: Beware of 'Quackery' on the Web," Society Past-President Dr. Andrea Dunaif discussed the hazards of human growth hormone (hGH) and other hormone replacement schemes promoted on and available through the Internet. The story was part of a larger feature critical of unsupported claims about bioidentical hormones, particularly in light of recent books in the popular press. Dr. Dunaif stated that unsupported anti-aging claims are at best harmless and people are wasting their money, but at worst things like hGH or estrogen could have serious effects.

The full story can be viewed at:

<http://theedge.bostonherald.com/healthNews/view.bg?articleid=163511>.

Recently quoted on ABC News was Society member Dr. Linn Goldberg who discussed the lack of government regulation of dehydroepiandrosterone (DHEA) and other dietary supplements. The ABC story summarized findings from a new study published in the *New England Journal of Medicine (NEJM)*, which concluded that DHEA, when used as a dietary supplement, has no effect on aging markers such as muscle strength, peak endurance, muscle mass, fat mass, and glucose tolerance in elderly men and women. The accompanying editorial in *NEJM* was authored by Society Council member Dr. Paul Stewart who stated

that DHEA should no longer be accepted as a food supplement and should instead be treated as a regulated drug to “dispel much of the quackery associated with this elusive hormone.”

The ABC News story can be viewed at:

<http://abcnews.go.com/Health/story?id=2583419&page=1>.

Also in the news was Society member Dr. Mitch Lazar, who was elected to the Institute of Medicine (IOM). Established in 1970 by the National Academy of Sciences, the IOM is recognized as a national resource for independent, scientifically informed analysis and recommendations on issues related to human health. Elected members volunteer a significant amount of time to work on IOM study committees.

Pay-for-Performance Continues to Gain Momentum

The development of a wide-reaching pay-for-performance (P4P) system is being supported through a number of initiatives, including a CMS demonstration project, CMS’ Physician Voluntary Reporting Program (PVRP), and the Institute of Medicine (IOM) report, *Rewarding Provider Performance: Aligning Incentives in Medicare*, released on September 21.

The report raises concerns that Medicare’s current payment system does not take into account whether the clinical quality of care provided is of a high standard or even if the care provided is appropriate, and does nothing to encourage coordinated preventive care. The report claims that P4P systems can reward higher value and better outcomes. Components of a well-designed P4P program, according to the IOM report, include:

- Defining quality care and optimal health outcomes through the use of performance measures.
- Rewarding care that is of high clinical quality, patient centered, and efficient, and that fosters care coordination among providers.
- Rewarding both those providers who make significant improvement and those who achieve excellence.
- Rewarding data collection and reporting functions, and encouraging adoption of improved information technologies.
- Maximizing provider participation through the structure of performance measures and rewards.

CMS has taken several steps toward the development of a P4P system and has moved one step closer with an announcement on October 16 that physicians in solo or small group practices will have the opportunity to participate in a demonstration project that will pay up to \$10,000 per physician and up to a total of \$50,000 per practice annually for reporting and following quality measures for chronically ill patients. Funded jointly by CMS and the Agency for Healthcare Research and Quality, the project will reward up to 2,800 physicians in Arkansas, California, Massachusetts, and Utah that are the main provider of primary care to at least 50 Medicare fee-for-service beneficiaries and are enrolled in their state’s Doctor’s Office Quality-IT program. Qualifying Society members should contact their state’s Quality Improvement Organization for further information.

CMS also published a set of 86 quality measures that will be used in its Physician Voluntary Reporting Program, set to begin in 2007. The measures were developed in conjunction with the Physician Consortium for Performance Improvement and cover 32 of the 39 physician specialties, including endocrinology. An updated PVRP measure set will be posted in November 2006. The Endocrine Society has representatives working with the Physician Consortium in the development of measurement sets and will continue to advocate on behalf of Society members. Specific measures for endocrinology include:

- Diabetes: hemoglobin control—hemoglobin A1c control in Type 1 or 2 diabetes mellitus
- Diabetes: lipid control—low density lipoprotein control in Type 1 or 2 diabetes mellitus
- Diabetes: blood pressure control—high blood pressure control in Type 1 or 2 diabetes mellitus
- Treatment/screening dual x-ray absorptiometry (DXA) measurement—screening for women age 65 years and older.

The Endocrine Society's positions on P4P are outlined in a position statement released earlier this year.

To view the Society's position statement on P4P, go to <http://www.endo-society.org/publicpolicy/policy/index.cfm>.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within The Endocrine Society, contact the Government & Public Affairs department:

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