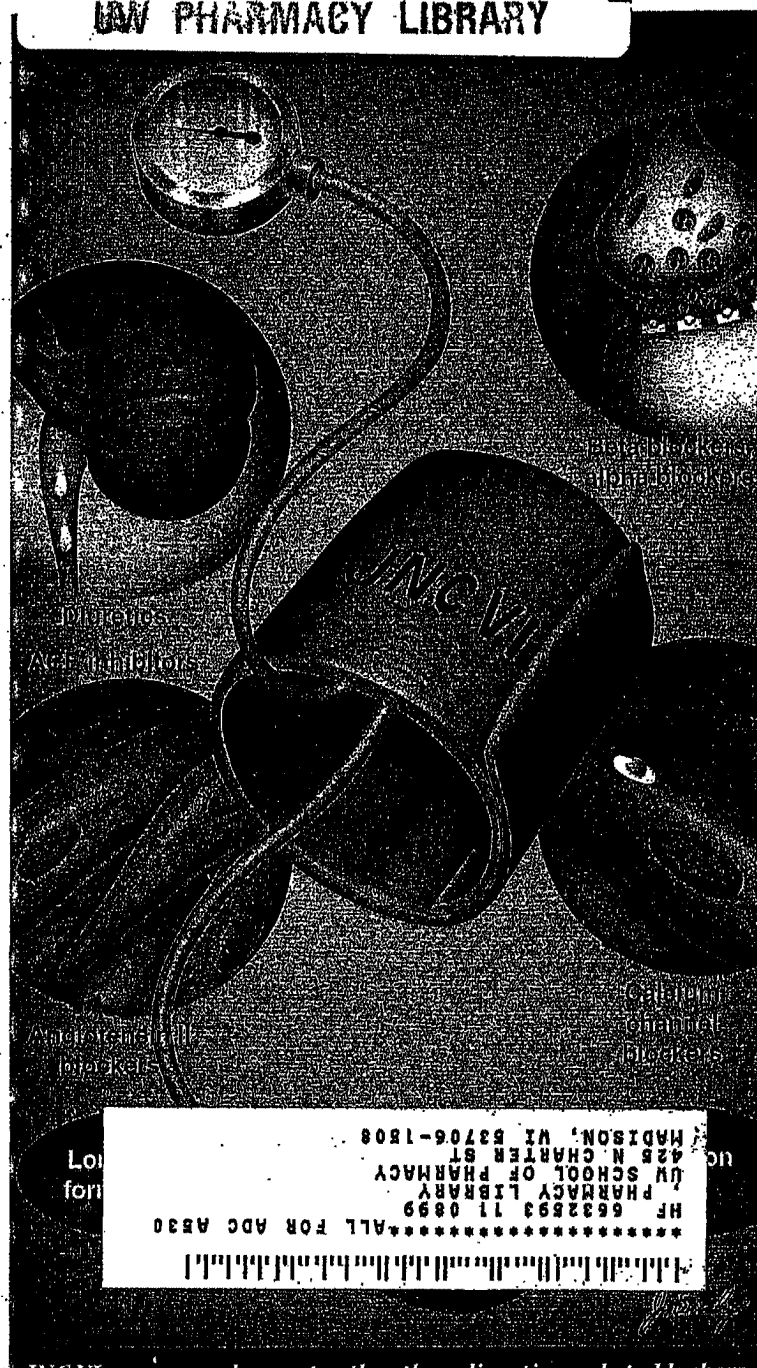


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Final reform bill 'modernizes' FDA, permits dissemination of off-label and economic data

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FOCUS

Danaparoid: A heparinoid for DVT prophylaxis with potential for use in HIT 1211

MARLA J. CAMPBELL, BS PHARM, PHARM D

Danaparoid (Orgaran), approved in the United States for the prophylaxis of deep venous thrombosis in patients undergoing elective hip replacement surgery, is under study or already approved in other countries for use in heparin-induced thrombocytopenia. This *Focus* article considers danaparoid's use and formulary role in the United States for both approved and unapproved indications.

COVER ARTICLE

Perspectives on the new JNC VI guidelines for the treatment of hypertension 1224

NORMAN M. KAPLAN, MD

The just-published sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) is expected to be a widely used guidance for hypertension management. Dr. Kaplan—who served as chair of the section on treatment for JNC VI—reviews the report's drug therapy recommendations, noting changes from the JNC V report. The report's new risk-stratification guidance, considerations for individualizing drug therapy, and advice on use of long-acting formulations and combination therapy are presented.

ORIGINAL ARTICLE

Developing systematic, information-driven disease management interventions: A model 1232

DONALD KENNERLY, MD, PhD, CHRIS HATWIG, MS, RPH, AND VICKI S. CRANE, MBA, RPH

This article presents a conceptual model for disease management development, highlighting seven general steps to ensure a comprehensive and properly ordered approach. The model is illustrated in a step-by-step case study of a population-based asthma management program developed at the authors' hospital system. In addition to reporting the outcomes they've achieved and ongoing program improvements, the authors offer their insights on ways to integrate disease management and P & T Committee functions.

DEPARTMENTS

FDA news and product notes 1196

- News on eight new molecular entities (Anzemet, Avapro, Corlopan, Gabitril, GenESA, Infergen, Requip, Seroquel), four new indications, and three drugs nearing approval

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On a scale of 1 (low) to 10 (high), HMOs gave their PBMs an overall score of 6.2, down from 6.3 in 1996. That follows a drop from 7.2 to 6.3 the previous year.

Especially noteworthy is that just 50% of HMOs gave their PBM an overall rating of 7 or higher in 1997, whereas 61% did in 1996.

Moreover, HMOs rated PBMs lower than almost all of the 21 specific PBM functions evaluated. Many of

the highest-rated functions were operational or administrative in nature, such as pharmacy network administration (rated 8.3) and claims processing (rated 7.1), whereas more clinical functions (disease management, DUR, formulary management) fared less well. The figure (see previous page) presents average ratings for selected PBM functions.

In a separate survey of 561 HMOs conducted in early 1997, PBMI

found that just 45 of them (mostly staff- and group-model plans) do not contract with a PBM for any service. Of those that do use PBMs, however, only 17% said they use a PBM to manage their formulary.

The results of the satisfaction survey are published in PBMI's 1997 *Pharmacy Benefit Manager Customer Satisfaction Survey Report*, which also includes findings on large employers' satisfaction with PBMs.

New acetylcholinesterase inhibitor shows promise in largest Alzheimer's trial to date

■ The investigational brain-selective acetylcholinesterase inhibitor ENA-713 improves cognition, global functioning, and activities of daily living in patients with Alzheimer's disease, according to results reported at the 16th World Congress of Neurology, held recently in Buenos Aires.

"The development of drugs like ENA-713 should help break down the nihilism that surrounds the progressive degenerative process of this disease," said Howard Feldman, MD, clinical associate professor of neurology, University of British Columbia, Vancouver, Canada, and an investigator in trials involving the drug.

The reported findings are based on 6-month follow-up in 2,096 patients with symptomatic mild to moderate Alzheimer's disease who were randomized to treatment with high-dose (6 to 12 mg/day) or low-dose (1 to 4 mg/day) ENA-713 or placebo.

The mean age of study participants was 73 years, and 94% had other illnesses requiring medication. All patients were participants in the 3,300-patient ongoing Alzheimer's Disease with ENA-713 (ADENA) program, the largest global trial of an Alzheimer's medication to date, and will be followed for up to 2 years.

Placebo recipients worsened on the three primary efficacy measures, while patients assigned to ENA-713, particularly the high-dose group, either improved or showed less decline compared with placebo.

Placebo group scores worsened by 4.15 points on the cognitive scale of the Alzheimer's Disease Assessment Scale (ADAS-cog). By contrast, ADAS-cog scores improved by 0.79 points in patients receiving ENA-713.

"An annual 7- to 8-point deterioration on the ADAS-cog scale is characteristic in mild to moderate Alzheimer's disease," Dr. Feldman said. "Thus, the nearly 5-point difference in scores between the treatment and placebo groups indicates a clinically relevant postponement in deterioration of roughly 6 months."

He added that this magnitude of effect on ADAS-cog scores is the largest that has been reported for an acetylcholinesterase inhibitor.

Benefit was also observed on the Clinician's Interview-Based Impression of Change (CIBIC) measure, which provides a global assessment of the patient's condition. Placebo group scores decreased by a mean of 0.48 points while scores for the high- and low-dose ENA-713 groups decreased by 0.13 and 0.16 points, respectively (both significantly lower than the decrease with placebo).

Scores on the third efficacy measure, the caregiver-rated Progressive Deterioration Scale (PDS), were significantly better in the high-dose ENA-713 group than in the placebo group at 6 months. "This finding is extremely important, because it concerns the aspect of the patients' condition that affects caregivers most,"

Dr. Feldman said. The PDS evaluates quality-of-life changes.

"These results mean that about 30% of patients receiving ENA-713 treatment will improve in terms of cognition, global functioning, and performance of routine activities," Dr. Feldman said. The study also found that benefits were greater in patients with more severe disease.

The most common side effects seen with ENA-713 in the trial were gastrointestinal in nature and were generally mild and transient, rarely requiring treatment.

Dr. Feldman noted that studies have recently been launched to explore the use of ENA-713 with available medications frequently used to treat patients with Alzheimer's disease, including antipsychotics, benzodiazepines, and antidepressants.

Novartis Pharmaceuticals filed an NDA for ENA-713 (under the proprietary name Exelon) in April for the treatment of mild to moderate Alzheimer's disease.

Donepezil HCl (Aricept), also a second-generation acetylcholinesterase inhibitor, was recently approved for this indication. ENA-713 is given twice daily, while donepezil is taken once a day. To date, there have been no head-to-head comparisons of the two drugs; however, both have been shown to be significantly safer and more effective than the first-generation acetylcholinesterase inhibitor tacrine HCl. ■