Panel Opposes Separate Drug Testing in the Elderly

BY JANE SALODOF MACNEIL
Southwest Bureau

PARIS — A consensus panel convened by the European College of Neuropsychopharmacology has drafted a report opposing separate clinical trials of central nervous system drugs in elderly patients.

The panel calls instead for dropping age cutoffs from clinical trials testing the efficacy of new CNS drugs. It favors inclusion of elderly patients in trial populations and use of the same placebo-controlled trial designs in studies across age ranges.

"We are of the opinion in the consensus meeting that specific studies in the elderly, while very interesting, are not worth doing," said Dr. Stuart A. Montgomery, the panel's cochair, in a presentation of its preliminary findings at the annual congress of the college.

More than 200 experts participated when the panel on investigating CNS disorders in the elderly met in Nice, France, in March 2006, according to Dr. Montgomery, professor emeritus of psychiatry at the University of London. The written draft, currently under review, will be published in a journal when the process is completed.

He said a review of clinical trials in the elderly determined that elderly patients, whether 60 or 65 years of age or older, responded much the same as younger patients to CNS drugs. The widespread belief that older patients respond more slowly is a myth, Dr. Montgomery said; changes in physiologic function occur on a continuum throughout life rather than in response to an arbitrary age cutoff.

"There is such a paucity of data at the upper end—above 75 and above 80—it is really not possible to comment on what goes on at that point," he said. "There is such substantial individual variation … that the effect of age becomes minimal by comparison."

European regulatory agencies usually do ask drug companies to conduct separate studies in the elderly, said Dr. Montgomery. If these studies are not done, and often they are not, he said, a drug may not be approved for use in patients aged 65 and older. Therefore, the panel concluded that requiring separate studies in the elderly serves only to limit the availability of treatments in older patients.

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DR. MONTGOMERY

"Excluding patients over 60 or 65 is inappropriate and unhelpful and in some ways regarded as counterproductive," Dr. Montgomery said.

The panel focused on efficacy in its deliberations, but it agreed that safety can be an issue in older patients. Dr. Montgomery cited concerns about delays in elimination of CNS drugs in the elderly, who also tend to have more comorbidity and take more medications than younger patients.

Accordingly, the panel recommended that safety issues be addressed in subgroup analyses of older patients enrolled in placebo-controlled clinical trials with broad populations as well as in separate studies identified explicitly as safety studies.

"There are potentially more drug-drug interactions, more safety problems, and they should be the focus with increasing age, not efficacy," Dr. Montgomery said.

He also summarized the panel's findings on age relative to the following disorders:

► **Depression.** Major depressive disorder is no different in the elderly; antidepressants that help younger people are just as effective in older people

► **Bipolar disorder.** Mania is an early-onset disorder affecting younger patients, but the elderly are more likely to present with depression. The efficacy of drugs for bipolar depression does not change with age.

► **Anxiety.** Generalized anxiety disorder is the most common late-onset anxiety disorder in the elderly. Response to treatment is not age related.

► **Insomnia.** Age has no effect on the efficacy of licensed treatments for insomnia, which is common in the elderly.

► **Schizophrenia.** Chronic schizophrenia patients who reach old age have more negative, cognitive, and depressive symptoms, possibly as a result of chronicity. The experts found no evidence of age-related changes in response to treatments for negative or positive symptoms. ■

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