www.storm.ca/~topsey/survey. Respondents will find a number of stories about interactions between physicians and patients collected from patient focus groups, face-to-face interviews with patients and responses to a patient survey posted on the Internet. Survey participants are asked to respond to 2 basic questions pertaining to each of these case studies. Patient interaction stories will be changed bimonthly at the Web site, but all stories will be available in an archive on the same site. Research for this project will end July 30, 1998. Confidentiality will be respected for all participants.

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Rule of thumb: check the dictionary

In the article "MDs have key role in bringing ugly secret of wife abuse out of closet" (*CMAJ* 1997;157[11]: 1579-81), by Nicole Baer, I was most perplexed to read the old chestnut that the expression "rule of thumb" is derived from an American law permitting a husband to thrash his wife with a "rattan no wider than his thumb." Although the derivation seems plausible, your readers can be thankful that this macabre yarn is a fabrication, first published in July 1986 in a letter to *Ms.* magazine from the creative mind of Claire Bride Cozzi. Within only 11 years even that version has evolved: Cozzi cited an undated "English common law" permitting a man to chastise his wife with a "switch" that was to be "no thicker than his thumb."

The true derivation of the term "rule of thumb" has never been in doubt. As the *Shorter Oxford English Dictionary on Historical Principles* indicates, a rule of thumb is "a method or procedure derived entirely from practice or experience, without any basis in scientific knowledge; a roughly practical method." It first appeared in 1692. In his book *Not Guilty*, D. Thomas explored the origins and significance of this persistent urban myth.[1] As Georges Braque has observed, "Truth exists — only falsehood has to be invented."

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Questions about donepezil

After the recent release of donepezil, a new drug for treating Alzheimer's disease, many of our patients and their families began to enquire about it. Their questions often focused on the drug's efficacy, in view of its high cost (about $150 a month).

A review of the literature for this product yielded only one published randomized controlled trial,[1] which involved 161 patients with mild to moderate Alzheimer's disease followed for 12 weeks. The benefits of treatment were modest,[2] and the authors stated that because of the short length of the study "in the majority of patients the condition was unchanged."[1]

Another randomized controlled trial, lasting for 24 weeks (plus a 6-week placebo washout) and involving 473 patients, is cited in the product's prescribing information (e.g., *CMAJ* 1997;157[6]:809-11). One of us tried unsuccessfully to obtain a copy of this promising study from the manufacturer and from Health Canada. At the time of writing this letter, in December 1997, the product had been on the market for 3 months in Canada and 11 months in the United States, but clinical decisions have had to be based on limited data.

When a product has been accepted by Health Canada and marketed, should not all information be made available to treating physicians, who have the responsibility to inform and guide patients and their families?

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[Dr. Bernard M. Prigent, Pfizer Canada, responds:]

The clinical evidence supporting the efficacy and safety of donepezil in patients with mild to moderate dementia of the Alzheimer's type shows a strong and consistent pattern of favourable results.

Three well-controlled clinical trials provide the core evidence. Two of these trials are phase III pivotal trials, one a 12-week study and the other a 24-week study; the third is a 14-week phase II supportive dose-finding study.

Two of the studies have now been published: the 24-week pivotal trial in January 1998[1] and the 14-week dose-finding trial in 1996.[2] (An analysis at 98 weeks of the open-label extension of the latter study has also been published.[3])

There is often a gap between the time a drug is approved and the publication of the data on which the approval is based. In the case of donepezil, the prompt acceptance of

the clinical trials for publication in respected peer-reviewed journals confirms the quality of the data gathered during the development program.

During the period between approval and publication of pivotal data, the product monograph can be relied on for information, since it provides a summary of the findings as assessed by independent reviewers from the Health Protection Branch of Health Canada. The product monograph for donepezil, which includes a lengthy section on clinical trial data, has been made available to all physicians since the start of commercialization of this drug.

Notwithstanding the information provided here, we are sorry that the request to our company for the results of the 24-week study was not fulfilled, and we apologize for the inconvenience.

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3. Rogers SL, Friedhoff LT. Long-term efficacy and safety of donepezil in the treatment of Alzheimer's disease: an interim analysis of the results of a US multicentre open label extension study. *Eur Neuropsychopharmacol* 1998;8:67-75.

[Dr. Serge Gauthier comments:]

There is indeed a lag time between completion of pivotal studies leading to regulatory approval and publication of results in peer-reviewed journals. In addition to reports on the main 24-week study[1] and open-label extension over 98 weeks,[2] 2 sets of guidelines for the proper use of the drug have been published.[3,4]

The cost-effectiveness of symptomatic anti-dementia drugs is a broad issue that is still under discussion. Pharmacoeconomic models have been proposed for tacrine, most recently from Sweden.[5] The main savings are expected to arise from delays in disease milestones (accompanied by the retention of high quality of life) and delays in the emergence of neuropsychiatric symptoms and subsequent admission to an institution.

Careful clinical observation of patients treated with such drugs will demonstrate improvement in cognition, activities of daily living and global functioning to a variable extent between individuals. This heterogeneity is inherent to Alzheimer's disease, and further research is needed on the clinical and biological predictors of response to treatment for patients with this condition.

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