The value of orlistat for weight maintenance has been documented (5, 6, 8) as follows: 1) at 2 y of follow-up, 19% of orlistat-treated and 8% of placebo-treated subjects maintain a weight loss of 10% of initial body weight, and 2) weight regain at 1 and 2 y in orlistat-treated subjects is less than half that of placebo-treated subjects (15). Sustaining weight reductions of this magnitude is associated with significant reductions in cardiovascular disease risk factors. In addition, enabling persons to maintain lower weights is usually associated with improved lifestyles (ie, decreased fat intake). Because the side effects related to orlistat use are exaggerated with high fat intakes, it seems likely that orlistat use will have adjunctive value in decreasing fat intake (15). Thus, in our assessment, the potential benefits of orlistat use as an adjunct to weight maintenance exceed the hypothetical risks.

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REFERENCES

Blockade of pancreatic lipase

Dear Sir:

Despite the fact that Xenical (orlistat; Hoffmann–La Roche, Nutley, NJ) has been evaluated in >17000 individuals worldwide, and is now being prescribed to >100000 patients, you (1) question the safety of pancreatic lipase blockade in the treatment of obesity. In doing so, you contradict the findings of the Journal’s invited editorial writer (2)—a fellow gastroenterologist who, after careful review of the submitted scientific article and several previously published clinical trials, failed to identify a safety risk secondary to fat malabsorption when orlistat is used as directed. Similarly, your stance runs counter to decisions by the Food and Drug Administration and drug control authorities in many other nations to approve orlistat for prolonged use.

That the safety and efficacy of obesity medications are held to a higher standard of proof than that applied to other drugs used for treating chronic conditions is perplexing. In particular, I question why the Editor-in-Chief has not cited medications with known adverse effects on the gastrointestinal tract, eg, insulin sensitizers for the treatment of diabetes and antiinflammatory drugs for the treatment of arthritis, to name only 2. Clinical trials for drugs such as these typically run for just a few months.

No obesity medication approved for prolonged use has resulted in death or organ failure, even in instances of voluntary recall. For editorializing of this kind to thus be credible, the standard of evidence for doubt must exceed that used to establish safety. It took but a brief review of Moran et al’s (3) article to dismiss it as a rationale for questioning orlistat’s safety in obesity treatment. Perhaps a more pertinent study would be one that investigates why editors feel compelled to challenge not only the management of obesity but the very existence of the disease itself (4–7).

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