An important overarching question concerns the true clinical value of fenofibrate products in improving patient health outcomes rather than surrogate markers like lipid fractions and triglycerides.[2] The Action to Control Cardiovascular Risk in Diabetes (ACCORD) study authors[3(p1572)] concluded that their findings

> . . . do not support the use of combination [feno]fibrate-statin therapy, rather than statin therapy alone, to reduce cardiovascular risk in the majority of patients with type 2 diabetes who are at high risk for cardiovascular disease.

We still have enormous gaps in the medical evidence on how various drugs actually contribute to hard clinical end points rather than to the surrogate measures often used in clinical trials used by the Food and Drug Administration for drug-marketing approval. This leads to unnecessary spending on drugs and medical procedures that is orders of magnitude larger than the potential gains from enhanced generic drug competition.

Joel W. Hay, PhD

Author Affiliation: Department of Pharmaceutical Economics and Policy, University of Southern California, Los Angeles.
Correspondence: Dr Hay, Department of Pharmaceutical Economics and Policy, University of Southern California, UGW-Unit A, Los Angeles, CA 90089-7273 (jhay@usc.edu).
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Generic Competition in a Flawed System: Pill Them, Bill Them

Psaty and Redberg[1] explained to us Abbott Laboratories' trick to avoid generic drug competition. In 2000, Abbott Laboratories reformulated fenofibrate at a slightly different dose to avoid competition because the minor differences in dose prohibited generic substitution.

The license of some corporations to manipulate the system to suit their interests requires an enduring complacency of the system. Recently, the US Food and Drug Administration, despite the lack of evidence for benefit, granted a new marketing authorization for the 23-mg dose of donepezil hydrochloride in the treatment of Alzheimer disease.[2] This allows Pfizer to avoid generic competitors, since the patent for donepezil, first approved in 1996, expired in November 2010. Lastly, could this be a reason why so many physicians prescribe their patients with costly medicines when less expensive ones are available?

The US Senate Finance Committee must investigate this situation that allows potential fraud, waste, and abuse.

Alain Braillon, MD, PhD

Author Affiliation: Department of Public Health, Gres, Amiens, France.
Correspondence: Dr Braillon, Department of Public Heath, Gres, 27 rue Voiture Amiens 80000, France (braillon.alain@gmail.com).
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In reply

Hay questions whether consumers were actually harmed by Abbott's branded reformulations of fenofibrate, suggesting that Abbott likely offered rebates and discounts to payers in an effort to improve formulary position. Our article included an analysis of wholesale prices for fenofibrate that showed that Abbott's branded reformulations were twice as costly as generics.[1] Given this difference in price, generic fenofibrate almost certainly would be listed on a more favorable formulary tier than branded versions, even if Abbott was offering significant rebates or discounts. Thus, patients who continued to use branded fenofibrate likely faced higher copayments than those using generic formulations. In addition, the continued use of branded formulations likely increased overall health care costs, which impose indirect costs on patients through higher insurance premiums. Hay also draws attention to the findings of the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, which showed that fenofibrate did not reduce cardiovascular risk when added to statin therapy.[1] We agree that the broad use of fenofibrate, especially the more costly branded reformulations, should be re-evaluated in light of this study.

Braillon highlights similarities between Abbott's fenofibrate switching strategy and the launch of a new 23-mg dose of donepezil hydrochloride soon after its patents expired. There are many similarities between these 2 examples; however, an important difference should be noted. The new drug application submitted to the Food and Drug Administration for the approval of the 23-mg dose of donepezil hydrochloride included results from clinical trials that compared the safety and efficacy of this dose with the original 5-mg and 10-mg doses. Although the incremental benefit of the 23-mg dose is being debated,[2] the inclusion of new clinical trial data in its application means that the 23-mg formulation enjoys a statutory 3-year exclusivity period, in which the Food and Drug Administration cannot approve generic versions of the drug. In contrast, Abbott's fenofibrate reformulations were subject to generic competition as soon as they were launched because they were approved on the basis of bioequivalence, not clinical trial, data. Abbott was able to limit the effect of these generic approvals by repeatedly