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Joan Claybrook, President

November 28, 2001

01N-0196 C8 01 NOV 28 A10:31

Dockets Management Branch
Mailstop HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Withdrawal of PPA, Docket No. 01N-0196: Comment

To Whom It May Concern:

This letter is a reply to the letter of November 16, 2001, submitted by American Home Products Corporation ("AHPC"). That letter responded to Public Citizen Health Research Group's ("HRG's") letter of October 12, which urged the FDA not to grant APHC's request for a liability disclaimer in conjunction with its withdrawal of PPA-containing drugs. AHPC's principal point is that it agrees with HRG "that FDA should remain neutral in state-law liability matters." APHC Nov. 16 Letter, at 1.

On September 12, AHPC requested a disclaimer in which the agency would specifically state that withdrawal of PPA-containing products does not connote state-law negligence, product defect, or breach of warranty. AHPC Sept. 21 Letter, at 8. In its most recent letter, AHPC again asks the Commissioner to "formally state" that, if the FDA withdraws approval of PPA-containing drugs, the agency's statements and actions "are not intended to – and should not – be used as evidence in product liability cases." AHPC Nov. 16 Letter, at 2.

The flaw in AHPC's position is that, in the context of a product liability case, the requested disclaimer is not one of neutrality. Rather, APHC maintains that that a drug approval has been withdrawn should not in any circumstance be admitted in state-law liability proceedings. As HRG explained in its October 12 letter, the FDA's longstanding position is that the agency should not take a position, one way or the other, on whether and how agency determinations affect state liability law. Under our system of federalism, the state-law decision makers themselves, not federal agencies, decide the admissibility and weight of all evidence. That position is consistent with state common-law tradition,

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which decides what weight, if any, to give to agency product-approval determinations. *See* Restatement (Second) of Torts, section 288C.

HRG's position is, in fact, the position of true neutrality. Under it, the FDA stays within its sphere, and makes determinations about the approval and withdrawal of drugs, and the state judicial systems stay within their spheres and set admissibility and liability rules to compensate victims of defective products. Put differently, the most clearly neutral statement would be no statement at all.

Sincerely,

AA for BW

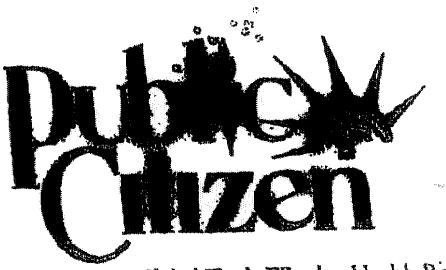
Brian Wolfman
Attorney
Public Citizen's Litigation Group

Sidney Wolfe, MD
Director
Public Citizen's Health Research Group

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group

Amer Ardati
Research Associate
Public Citizen's Health Research Group

cc: William W. Vodra, Partner
Arnold and Porter



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