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National Consumers League
Founded 1899

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February 16, 1999

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Dear Mr. Cooper:

This letter is in response to your February 1, 1999 letter to me and my colleagues in the women's health and labor community, in which you question our motivation in writing to the Food and Drug Administration (FDA) regarding Duramed's estrogens product, Cenestin. Since our founding in 1899, the National Consumers League (NCL) has worked tirelessly to protect consumers from unsafe food and drugs, and we will continue to serve as a watchdog for consumers in the new millennium.

In receiving your letter, I was surprised that you would question a consumer organization's First Amendment right--indeed duty--to express its concerns to a federal regulatory agency. In fact, FDA makes a real effort to solicit the input of consumer organizations and other nonprofit groups--ranging from conducting outreach through its Offices of Consumer Affairs and Women's Health, to including consumer and patient representatives on advisory committees, to seeking public comment on proposed regulations, to requesting our participation as panelists at FDA conferences and programs.

With regard to your allegations, the League stands behind our January 27, 1999 letter to Dr. Woodcock. Contrary to your characterization of the letter, it was not intended to disparage Duramed's estrogens product, but rather to ensure that the FDA rigorously enforces the safety and efficacy standards of the Food, Drug, and Cosmetic Act in reviewing Duramed's NDA.

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Mr. Charles J. Cooper, Esq.
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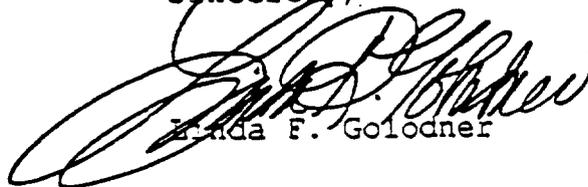
Based on an apparent lack of safety studies, NCL thought it entirely appropriate to communicate our concern that the agency review Duramed's data with a critical eye. Of course, if Duramed's drug meets the requirements of the FD&C Act, then NCL welcomes its approval as another option for the treatment of vasomotor symptoms.

Regarding your view of NCL as a "pawn," I deeply resent your implication that the National Consumers League's positions are influenced by anything other than our concern for the protection of consumers. As the President of NCL, I assure you that the League would never compromise our principles, least of all to advance some corporate interest.

Finally, I want to reiterate NCL's long history of involvement in the generic Premarin debate. Although the League is a strong supporter of generic drugs, we first registered our opposition to approval of generic versions of Premarin that did not have the same active ingredient as the brand-name product in March, 1995. The League took this position because of our concern that drugs without the same components as Premarin could not be known to have the same safety and efficacy profile as the innovator. NCL's January 27, 1999 letter to Dr. Woodcock is simply a continuation of our interest in ensuring that consumers have access to estrogen products that have been proven safe and effective.

I hope this letter helps to clarify the position of the National Consumers League on this issue.

Sincerely,



Linda F. Golodner

LFG:dm

cc: Commissioner Jane E. Henney, MD
Janet Woodcock, MD, Director, Center for Drug Evaluation and Research