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November 1, 1999

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Jane Henney, M.D., Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

RE: Label information on SUPPLEMENTS

Dear Commissioner Henney:

I'm writing because I am appalled at the thinking processes of the FDA, from field representatives to the product investigators to the lawyers to, it seems, the whole bureaucracy.

Specific claims for four specific products have been filed for approval by the FDA by Dr. Julian Whitaker, M.D., which are now pending before your organization. They involve Folic Acid, Palmetto Extract, Psyllium Husk Seeds and Vitamin E.

Folic acid studies were done by the Texas Department of Health. Recommendations to citizens in the Rio Grande Valley, troubled by neural tube defects, to use this simple substance, which has long been known to prevent neural tube defects in the fetus, were delayed FOUR YEARS by bureaucrats in your FDA. The result: there are numerous children in the valley with neural tube defects, affecting their lives and the lives of their families and local communities, which did not have to happen.

Your people should be ashamed! How can they, and you, sleep easily with the knowledge that the FDA, deliberately withholding health information about the detriments to pregnant women and their babies of not having adequate supplies of folic acid in early pregnancy, has created crippled children in significant numbers?

The claims filed, mentioned above, each involve substances about which much is known supporting the claims as truthful. These claims should all have been approved forthwith. The delay is unconscionable.

Herbal supplements are used by thinking people to a greater and greater extent. They are as efficient as most of the patent medication and have none or fewer side effects and cross medication complications.

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The recent publication in English of the complete 254 monographs on herbal supplements by the German Commission E (American Botanical Council, Austin, Texas, 512 926-4900) has been of great interest to citizens such as I, who want truthful, accurate and unbiased information about what herbal supplements work.

The FDA should long ago have taken the lead in this country to provide similar information to the American people. It would not be a bad idea to start with adopting these monographs and publishing them with FDA approval.

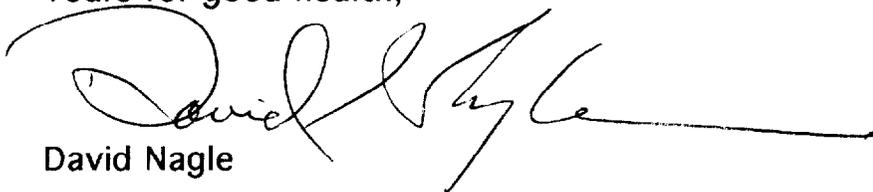
The Congress, particularly the Senate of the United States, is in thrall to the drug companies and their generous "political contributions". Most of us who think about it, are aware of the revolving door between the FDA and the patent drug industry.

We all feel beset by "GREED". There is no other word to describe the mendacity of those senators and congressmen who do the drug companies' bidding. Or of the FDA administrators who suppress health information because of their drug company connections. Or, worse, because of rules set up to benefit drug company profits.

It is time to hose out the stygean stables at the FDA. The whole place stinks.

Change the rules! Change the rulers! Work for the people for a change!

Yours for good health,

A handwritten signature in black ink, appearing to read "David Nagle", with a long horizontal flourish extending to the right.

David Nagle

cc: Congressman Lloyd Doggett
Senator Kaye Bailey Hutcheson
Dr. Julian Whitaker

CROSS FILE SHEET

File Number: 99P-3029/C *189*

See File Number: 99P-3030/C *188*