



pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

Testimony of Frederick S. Mayer, R.Ph., M.P.H.
Dietary Supplement Stakeholder Meeting
July 20, 1999; 2 p.m. - 3 p.m.
Oakland Federal Building (Roybal Auditorium)
1301 Clay Street, Oakland

My name is Frederick S. Mayer, R.Ph., M.P.H. I am the President of Pharmacists Planning Service, Inc. (PPSI), a 501 C (3) non-profit consumer, public health, pharmacy education organization. I am also a practicing pharmacist, having been registered in the State of California for over forty-five years. I am also Past President of the California Public Health Association and a member of the Marin County Unit of the Gray Panthers along with the Northern California Gray Panthers Health Care Coalition.

The National Gray Panthers in conjunction with PPSI have formed a coalition to educate seniors on prescription medications, drug interactions, nutritionals and in general have had eight meetings regarding FDA and prescription drug issues. These meetings have taken place in Washington, D.C., Sacramento, Walnut Creek (Rossmoor), Marin County (San Rafael), Sonoma County (Oakmont) and Berkeley, California.

Of the many problems seniors have articulated in our meetings I would like to point out some of the major issues which stood out in all of our eight meetings.

1. Failure to properly label alternative medicines, herbs and natural products with side effects, drug interactions, allergy issues, pregnancy warnings (for grandkids), and a basic understanding of the use of these types of medications.

2. The issue of 107,000 deaths reported last year due to the mixing of these drugs along with over-the-counter (OTC) and prescription drugs.

3. Failure for health care professionals to give adequate warnings or to even ask about these alternative medicines and to counsel seniors on these side effects.

In March of 1998 PPSI petitioned the Food and Drug Administration (FDA) regarding the fact that the Agency has not instituted standards for the labeling of botanicals, nutritionals and natural products that would be similar to the labeling requirement for over-the-counter (OTC) drugs.

99N-1174

TSB

Page Two

I am enclosing a copy of this document which is listed under FDA Docket No. 98P-0169/CP1 with the response from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA.

I will not go into the various concerns which are listed including deaths of kids and seniors who have taken Ephedrine as a weight reduction product and stimulant along with the Oakland A's former player, Mark McGwire (now with the St. Louis Cardinals) who is taking Androstenedione which causes all kinds of side effects and a precursor which is converted into testosterone.

Also I would like to leave with you a March 26, 1999 News Release from the Canadian Government on how Canada is handling this major problem by accepting and agreeing to 53 recommendations including a labeling recommendation to have sufficient, relevant information on products' labels and that labeling should be standardized to provide clear and consistent information for consumers.

I will not go into the 53 recommendations but what we need from FDA is more science in the natural health products field, less unscientific claims and more proof of efficacy.

The third item I would like to submit for your review and comments is the American Pharmaceutical Association (APhA) Chart for clinical consideration and adverse drug reactions with twenty-one commonly used natural products. In the chart I have given you please note the four G's: Gingko, Garlic, Ginseng and Ginger - four of the most popular drugs sold. **THEY ALL HAVE PROBLEMS WITH EITHER ANTICOAGULATION THERAPY OR PLATELET AGGREGATION ISSUES.**

If there are seven million seniors who are stroking out each year or have stroked out and are on some type of anticoagulation or anti-platelet medication, shouldn't the FDA mandate warnings on labeling such as the Canadians are proposing to do? This is no more than what FDA is doing for OTC medications.

Some of our other concerns which include the Gray Panthers and consumers' issues are the issue of echinacea, for example, which impacts on the auto-immune disease systems such as asthma, arthritis, lupus, leukemia, AIDS, etc.

Page Three

Seniors are very concerned about another dangerous drug which is being sold in nutritional stores which are classified as Ma Huang (Ephedrine type compounds) which many seniors and kids take for pep and energy. There have been nine deaths in Fresno County, California from these types of products. In Canada these types of products are not sold over-the-counter but on prescription only under the supervision of a physician.

I would like to propose the following solutions to these issues from a senior's perspective:

1. Labeling requirement from our Citizens Petition be implemented and mandated by FDA or some regulatory body who oversees these natural health products.
2. Seniors be given adequate warnings on adverse drug reactions (ADRs) which is killing 107,000 per year and that the manufacturers educate the seniors similar to what they need to do with OTCs and prescription drugs.
3. FDA working along with PPSI and United States Pharmacopeia (USP) by putting out education, information and literature in the form of brochures and leaflets with the enclosed goals and objectives to better inform seniors and consumers on these very important issues. I have been a member of USP's Health Education/Consumer Interest Advisory Panel for ten years.
4. FDA adopt and accept the 53 recommendations from the Canadian government on natural health products including educating consumers and proper labeling of these products.
5. All ephedrine-type products be relegated to prescription-only under supervision of a physician and removed from the OTC/natural health product market place.
6. Standards be adopted in manufacturing natural health products with the elimination of shotgun-type preparations such as the weight reduction products with Guarana (caffeine alkaloid) and Ephedrine.

Page Four

In closing the four criteria and priority issues which FDA must address are:

1. Improving consumer safety.
2. Develop readable and understandable labeling similar to OTC.
3. Increase FDA inspections of these unregulated companies.
4. Eliminate dangerous products from the market place.

Thank you for allowing me to testify before you. As a senior and a Gray Panther, I stand ready to answer any questions which you may have.

Frederick S. Mayer, R.Ph., M.P.H.
President