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

July 23, 2003

Food and Drug Administration (FDA)
c/o Christine Bechtel (Email: BechtelC@cder.fda.gov)
Center for Drug Evaluation and Research (HFD-006)
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 03N-0168
Current Status of Useful Written Prescription Drug Information for Consumers
Public Meeting, Friday, July 31, 2003; Request for Comments

I am Fred S. Mayer, R.Ph., M.P.H., President and CEO of Pharmacists Planning Service, Inc. (PPSI), a 501 C (3) nonprofit, public health, consumer, pharmacy education organization. I also am Past President of the California Public Health Association and have served for ten years as a member of the USP Consumer Health Education Advisory Board in Washington, D.C.

The FDA wants the following questions addressed:

1. What steps are the private sector taking to improve the usefulness of written information patients receive with prescription drugs and to meet the year 2006 goals?

a. It has been over twenty years since PPSI has been studying and discussing useful written drug information for consumers. PPSI as a national pharmacy group feels that the current situation is not improving. In fact, the information should be taken over by the FDA and guidelines used by the FDA currently in its black box program should be adhered to.

b. A couple examples of why PPSI feels so strongly about the FDA's role are that currently commercial organizations put out the written prescription drug information through computers and most of the needed information and the most important part of the information is buried instead of the leaflets instead of being highlighted.

c. In the case of two new arthritis drugs, Celebrex and Bextra, both of these drugs have sulfonamide structures and patients allergic to sulfa's should be notified about this problem. Some of the patient information leaflets do not mention this at all. Although only one out of one thousand patients may be allergic to sulfa's, it is a major problem, but for some strange reason the commercial firms have not picked up this information. If they have, it is buried in the leaflet and patients never see it.

03N-0168 C5

d. With the increase of prescription drugs in 2000 at 2 billion prescriptions, to 2003, three billion, to 2004, four billion prescriptions, it is mandatory that all pharmacies have prescription drug information for consumers especially since there is a shortage of pharmacists and there is an increase in pharmacists' workload.

e. As a practicing pharmacist with fifty years of experience in the community pharmacy where I work, the second computer because of the increase of prescription volume, is hooked up to produce labels for the prescriptions instead of printing out the written prescription drug information.

f. In lieu of handing out prescription information, pharmacists counsel all patients; however, because of the workload many useful information pieces in the patient information leaflets, (PILs), which is of value is not transmitted.

g. Because of some of these problems, pharmacists have seen patient harm. As an example, a patient was not told about codeine allergies when a Vicodin prescription was dispensed and patient ended up hospitalized.

h. Again, the FDA must regulate these PILs with the most important information being imparted to the patient/consumer.

2. What barriers exist for the private sector to meet the year 2006 goal and what plans exist to overcome these barriers?

a. In 1998 Lucien Leppe, M.D., Professor, School of Public Health, Harvard University, stated in a research paper that the fourth leading cause of death in the United States after heart, cancer and stroke is adverse drug events, wrong pills for the wrong patients, and misdiagnosing of prescription drugs.

b. Barrier No. 1 is the shrinking prescription drug fees by HMOs, managed care organizations (MCOs) and pharmacy benefit manages (PBMs) for most pharmacists to do their job correctly.

c. Because of these shrinking fees, pharmacists do not have time to consult properly and look at the patient's history on the computer screen to pick up adverse drug events (ADEs), allergies, drug interactions and other side effects.

d. The barrier in this case is "time is money". It takes an average of three to five minutes to counsel the patient properly, hand out the PILs and go over some of the side effects including the ones not listed, look at the computer screen for ADRs, and do a professional job. THIS IS NOT BEING DONE AS REIMBURSEMENT IS ONLY FOR COUNTING, POURING AND TYPING, NOT FOR USING THE PHARMACISTS' BRAIN. UNTIL THIS SYSTEM IS FIXED, THE ISSUE OF PILs AND WHAT'S IN THE PILs is academic. However, PILs must be accurate and have oversight by FDA especially for off label use where PILs are not used and

compounding pharmacists where PILs are not being used.

e. In the State of California from May to October 2002, the California State Board of Pharmacy reviewed under its Cite and Fine Committee, citations against pharmacists. The number one citation was under Section 1716, Variation from Prescription, 22% of all fines. For pharmacies, the number one violation was Section 1716, Variation from Prescription, 20%.

f. The second cause of citations under Section 1707.2, Duty to Consult, 19% by pharmacists and 14%, Duty to Consult, by pharmacies.

g. The third cause of the top ten violations by license-types for pharmacists was Section 1707.3 was Duty to Review Drug Therapy with 7% violation by pharmacists and pharmacies, 6%. Over 30% of the top ten violations by licensed pharmacists and pharmacies were a variation from prescription, duty to consult and duty to review drug therapy. THIS SYSTEM MUST CHANGE IF PILs ARE TO BE UTILIZED PROPERLY.

h. The point I am making here is that the system needs to be changed if the PILs are to be of value to the pharmacist and OF COURSE THE PILs MUST BE PUT OUT BY THE FDA, NOT COMMERCIAL FIRMS.

3. What should the role of the FDA be in assuring full implementation of the action plan to meet the year 2006 goals?

a. The FDA should take over the PILs' commercial program and put out all of the written prescription drug information under their direction and guidelines.

b. Again, accuracy is one of the key issues. As in the case of Cory Christen who was given misleading, incomplete and often out of date commercially produced patient information leaflets (PILs) dispensed with prescriptions by many pharmacists, which resulted in his death.

c. Cory was treated for attention deficit hyperactivity disorder (ADHD) with Imipramine and died from a fatal cardiac arrhythmia.

d. If Cory's parents had been informed by the physician or pharmacist of the cardiac and other adverse effects of Imipramine, they would not have administered the drug to their son.

e. Cory's parents did receive a PIL from the pharmacy produced by MediSpan, Inc. of Indianapolis, who omitted the most important information and only listed the minor "nuisance" effects of the drug.

f. The scientific literature and the popular media are brimming with examples of inappropriate prescribing such as off label use as in the case of Imipramine and dispensing leading to drug induced injury and deaths MOST OF WHICH COULD HAVE BEEN PREVENTABLE.

g. Pharmacy nationally has been unable to implement counseling or the DURs with looking at patient profiles on computers on a large scale. For this reason factual PILs put out by the FDA would be a bonus.

4. What other initiatives should FDA consider for providing patients with useful information about prescription drugs as endorsed by Public Law 104-180?

a. FDA should take over the PILs similar to what they do for black box warnings for the following reasons:

1) Many of 107,000 deaths each year are due to mixing prescription drugs with OTC and herbal supplements.

2) FDA should mandate that all PILs have information on these ADRs, especially with herbal supplements, which consumers and patients have been told are safe and efficacious.

3) A good example of this: seniors who are obese using Ephedra, Ma Huang, Metabolite, which raise blood pressure, cause heart attacks and increase the risk of strokes.

4) On current package information in Coumadin it lists that herbals such as Ginseng, Garlic, Ginger and Ginkgo, may interfere with INRs and may cause stroke in patients whom are on Coumadin.

5) This type of warning on herbals needs to be in all PILs in order to reduce morbidity and mortality and to insure the public of safety.

6) In AIDS patients 9.6% in a most recent study showed resistance to at least one of the three types of retroviral drugs which suppress the virus which causes AIDS.

7) Drug resistant strains appear because the virus in AIDS patients mutates rapidly and they thrive when patients take their drugs carelessly. This type of public health warning about adherence to AIDS medication should be spelled out in all PILs and fortified by pharmacists and healthcare professionals in oral consultation. THIS IS NOT BEING DONE.

In summation, the current PILs program, which has been commercialized, is not working. The information needs to be accurate, timely and usable for patients.

PPSI strongly recommends that the Food and Drug Administration (FDA) take over the PILs program making the program meaningful to consumers and patients and to help protect the public from preventable drug induced injuries in a fragmented profit driven health system.

Finally, the new FDA regulated PILs program must be incorporated into the new Medicare Prescription Drug Plan so that patients and consumers benefit and public health and safety are overseen by the federal government for accuracy and qualtiy.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H.
President, Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903

Telephone: 415 479-8628; Fax: 415 479-8608
Email: ppsi@aol.com; Website: www.ppsinc.org

Citation and Fine Committee Statistics for May – October 2002

Total cases reviewed by Citation and Fine Committee	Citations Issued with fines	Citations without fines
195	454	162

Subjects referred to:			Subjects closed no further action
AG	Add. Invest.	Add. Insp.	
3	6	1	166

Average number of days for investigation process

Case open to citation issued	Request to Office Conference	Appeal request to hearing date
262 days	20 days	Data not available

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Amended	Dismissed	Withdrawn
34	34	33	20	6	5	2

- The committee has held ten meetings.
- The committee has held six office conferences.

- Total amount of citations issued to date $534,200.00
- Total amount of internet citations issued to date $89,014,500.00

Contested Citation Appeals

Received	Sent to AG	Heard
40	40	0

Citation Breakdown by license type

RPH with fine	RPH no fine	RPH closed	PHY with fine	PHY no fine	PHY closed	PIC with fine	PIC no fine	PIC closed	Other
220	57	113	198	111	92	28	10	19	41

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	22	1716 - Variation from prescription	20	1707.2 – Duty to consult	25
1707.2 – Duty to consult	19	1707.2 – Duty to consult	14	1716 - Variation from prescription	18
1707.3 – Duty to review drug therapy	07	1707.3 – Duty to review drug therapy	06	4115 (d)/1793.7 – Tech activities permitted; Req. supervision/Req. for PHY with techs	11
1714(d) – Operational standards and security	06	1714 (b) – Operational standards & security	05	1714(d) – Operational standards and security	09
4081 – Records of dangerous drugs.	06	1761- Erroneous or uncertain prescriptions	04	4115(e)(1) – Pharmacy technician license req.	06
1761- Erroneous or uncertain prescriptions	05	4342 – Prevent sales of drugs lacking quality	03	1304.11 – General requirements for inventories	03
4115 (d)(e)– Tech activities permitted; Req. supervision	04	4081 – Records of dangerous drugs.	03	1716.2 – Record requirements for compounding	03
1764/56.10/56.36/56.101 – Unauthorized disclosure of Rx	04	1764/56.10/56.36/56.101 – Unauthorized disclosure of Rx	03	1715 – PHY operation in absence of pharmacist	03
4116 – RPH responsible for security of pharmacy	03	4115 (d)/1793.7 – Tech activities permitted; Req. supervision/Req. for PHY with techs	02	4116/1714(d) – Security of DD/Operational standards	03
4040 - container req. for labeling	02	4116 – Security of dangerous drugs	01	4332/4081 –fail to maintain records of DD	03