

PUBLIC CITIZEN'S HEALTH RESEARCH GROUP'S<sup>1</sup> STATEMENT BEFORE THE  
PHARMACY COMPOUNDING ADVISORY COMMITTEE

by

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Public Citizen strongly urges that the Food and Drug Administration's (FDA) Pharmacy Compounding Advisory Committee consider the following important issues:

- The nominated bulk drug substances appearing in the FDA's January 7, 1999 proposed rule,<sup>2</sup> as substances that may be used in pharmacy compounding, should be reviewed by the appropriate Agency divisions in a manner similar to the drugs that will be discussed on May 6 and 7 and then discussed by the Pharmacy Compounding Advisory Committee before this rule is finalized.

A list of these 20 bulk drug substances is attached.

- Five of the above mentioned 20 bulk substances are currently ingredients in commercially available products and should not be included on the list of bulk drug substances that may be used in pharmacy compounding. These are: ferric subsulfate, ferric sulfate hydrate, phenindamine tartrate, phenyltoloxamine dihydrogen citrate, and taurine.
- There should be clarification of the reasons for including currently marketed nutritional supplements on the list of bulk drug substances that may be used in pharmacy compounding. Three of the above mentioned substances are currently sold as nutritional supplements. These are: choline bitartrate, glutamine, and taurine. Taurine is also an ingredient in an FDA approved product as mentioned above.

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<sup>1</sup> Since 1971, Public Citizen's Health Research Group has been promoting research-based, system-wide changes in health care policy, as well as advocating for the appropriate prescribing and use of prescription drugs. We testify before Congress and petition the Food and Drug Administration (FDA) on issues such as banning or relabeling of drugs and the misleading advertising of prescription and nonprescription drugs by their manufacturers. Our publications help consumers make informed decisions about the health care they receive and the drugs they are prescribed.

<sup>2</sup> Department of Health and Human Services, Food and Drug Administration. List of bulk drug substances that may be used in pharmacy compounding. *Federal Register* Vol. 64, No. 4, January 7, 1999, pages 996-1003.

- The abuse of pharmacy compounding.

There is evidence for the abuse of pharmacy compounding. The nomination of dimercapto-1-propanesulfonic acid (DMPS), a chelating agent, and piracetam, a "brain booster" on the list of 20 bulk drug substances that may be used in pharmacy compounding are clear examples of this abuse. The suspect use of DMPS is discussed in Public Citizen's comments submitted to Docket No. 98N-0182 regarding the list of bulk drug substances that may be used in pharmacy compounding. Examples of how piracetam is being promoted and for what use it is being sold are given below.

In considering the bulk drug substance that may be used in pharmacy compounding it was the FDA's expectation that "Fraudulent or 'quack' remedies . . . will be less likely to be included on the list [of bulk drug substances]. . . because the practice of compounding such drugs is not expected to be sufficiently prevalent and longstanding."<sup>3</sup> Unfortunately, the misuse of pharmacy compounding for exploitation of the public may constitute a significant segment of pharmacy compounding.

There is an unprincipled symbiotic relationship between some compounding pharmacists and exploitative practitioners of the complementary/alternative medicine movement — each requiring and using the other for their economic well-being.

The web sites for the International Academy of Compounding Pharmacists<sup>4</sup> (IACP) and the Professional Compounding Centers of America<sup>5</sup> (PCCA) link to the web site of the American College for Advancement in Medicine (ACAM) in Laguna Hills CA, an organizations that claims to be ". . . dedicated to educating physicians on the latest findings and emerging procedures in complementary/alternative medicine, with special emphasis on preventive/nutritional medicine."<sup>6</sup>

ACAM has been involved with the promotion of chelation therapy that involves the intravenous injection of ethylene diamine tetra acetic acid (EDTA), approved by the FDA for the treatment of heavy metal intoxication.<sup>7</sup> We have been informed that an

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<sup>3</sup> Department of Health and Human Services, Food and Drug Administration. January 7, 1999, Op. Cit.

<sup>4</sup> <http://www.compassnet.com/~iacp/linksof.htm>. Link established with the American College for Advancement in Medicine (ACAM) web site April 30, 1999.

<sup>5</sup> <http://www.thecompounders.com/pharmink.htm>. Link established with the American College for Advancement in Medicine (ACAM) web site April 30, 1999.

<sup>6</sup> <http://www.acam.org/> April 28, 1999.

<sup>7</sup> <http://www.quackwatch.com/02ConsumerProtection/ftcchelation.html> April 30, 1999.

action is pending between ACAM and the Federal Trade Commission (FTC) over charges that ACAM made unsubstantiated and false advertising claims that non-surgical, EDTA chelation therapy is effective in treating atherosclerosis, and that this has been proven by scientific studies.<sup>8</sup>

The editor of the Public Citizen's *Health Letter*, a newsletter for consumers, received a complementary copy of the March/April 1999 issue of the *International Journal of Pharmaceutical Compounding*, a publication whose editor-in-chief is Loyd V. Allen, Jr., Ph.D. is a member of the Pharmacy Compounding Advisory Committee. He was also listed as a consultant to PCCA<sup>9</sup> in August 1998, though this announcement no longer appears on the PCCA web site.

The *International Journal of Pharmaceutical Compounding* was delivered to our editor bundled with print and promotional materials from Smart Publications of Petaluma CA, an organization that proudly announces on its website "We're the people who created the classic, international bestseller, **Smart Drugs & Nutrients**, pioneering the concept of cognitive-enhancing substances."<sup>10</sup>

A cover letter draws attention to an enclosed press release titled "Natural Testosterone: Good for Your Heart." This is a chapter in a recently released book, "Maximize Your Vitality and Potency: For Men Over 40," published by Smart Publications — a book that "covers natural testosterone and other supplements to reverse the effects of aging."

The cover letter goes on to say:

Also enclosed is a recent copy of the *International Journal of Pharmaceutical Compounding* in which the "Heart Health" chapter [of "Maximize Your Vitality and Potency: For Men Over 40"] is excerpted. What's the connection? Natural Hormones must be custom prepared by a compounding pharmacist; because they are not available from drug manufacturers.

The cover letter also invites our editor to "Please consider reviewing our new book or writing a story on these topics."

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<sup>8</sup> Personal communication with the Federal Trade Commission May 3, 1999.

<sup>9</sup> <http://www.thecompounders.com/new.htm> What's New - Dr. Loyd V. Allen Jr., and PCCA Enter Consulting Agreement downloaded August 31, 1998

<sup>10</sup> <http://www.smart-publications.com/> April 28, 1999.

The press release announcing the book says in part:

The key chapter on heart health from this book has been excerpted in the current issue of the *International Journal of Pharmaceutical Compounding* (IJPC). What's the connection? Natural hormones, like natural testosterone, are available from *compounding pharmacies* represented by this journal.

At the end of the "Heart Health" chapter excerpted in the *International Journal of Pharmaceutical Compounding* is the following advertisement:

*Maximize Your Vitality and Potency* can be purchased direct from Smart Publications . . . Wholesale pricing is available for pharmacies wishing to resell the book to customers (a good way to educate about the value of natural hormones.)

Also in the materials received by our editor was a newsletter entitled *Smart Publications Update* (Issue 102, January 1999), apparently written for distribution to the general public. This newsletter advertises products such as deprenyl citrate drops, piracetam liquid, and triple natural estrogen cream as anti-aging products. On page 6 of the newsletter an article appears entitled "The Top Smart Drugs & Nutrients." Mentioned in this article is piracetam, a bulk drug substance nominated by compounding pharmacists. The article describes piracetam as:

. . . an intelligence booster, and CNS (central nervous system) stimulant with no known toxicity or addictive properties. Piracetam has been described by many people as a drug that "wakes up your brain."

Piracetam has never been approved for use in this country and there is no legitimate medical use for this drug that we could find .

In some Third World countries, it is promoted for the treatment of memory loss, in others for lack of concentration, and in still others for intellectual deterioration. In India and Thailand, piracetam products are promoted for the treatment of mental retardation or learning problems in children. In Malaysia, Singapore, the Middle East, Mexico, and Colombia, they are recommended for the treatment of alcoholism, or alcohol addiction.<sup>11</sup>

Two boxed advertisements appear on page 4 of the *Smart Publications Update* newsletter, in close proximity to each other, in the same style, and with the same color highlighting. These ads are reproduced below without color:

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<sup>11</sup> Silverman M, Lydecker M, Lee PR. *Bad Medicine*. Stanford, CA: Stanford University Press, 1992, page 33.

**How to Find a  
Compounding Pharmacy**

The easiest way to locate a compounding pharmacy is to contact the Professional Compounding Centers of America, Inc. (PCCA) or the International Academy of Compounding Pharmacists (IACP). They can be contacted as follows (you can also ask these organizations for a referral to a physician near you):

<b>PCCA</b> 9901 S. Wilcrest Houston, TX 77099 TEL: 1 800 331 2498 FAX: 1 800 874 5760 www.thecompounders.net	<b>IACP</b> PO Box 1365 Sugar Land, TX 77487 TEL: 1 800 927 4227 FAX: 1 281 495 0602 www.iacp.org
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**How to Find a Knowledgeable and  
Understanding Physician**

The quickest and most efficient way is to visit a medical doctor or osteopath who is a member of the International College of Advanced Longevity Medicine (ICALM) or the American College for Advancement in Medicine (ACAM). All members of these professional organizations are skilled and knowledgeable in the prescription and use of natural hormones and other alternative compounds. For a referral contact:

<b>InCALM</b> P.O. Box 2609 Payson, AZ 85547 Tel: 520 472 9086 Fax: 520 474 1297	<b>ACAM</b> 23121 Verdugo Dr., Ste. 204 Laguna Hills, CA 92653 1 800 532 3688 www.acam.org
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These two advertisements show the completion of a treacherous triad between compounding pharmacists, complementary/alternative medicine practitioners, and an unwitting public. Public Citizen strongly believes that the FDA and the members of the Pharmacy Compounding Advisory Committee must consider that some bulk drug substances have no legitimate medical use and will be compounded by some pharmacists to exploit the public, while making exploitation appear as a noble cause.

THE LIST OF BULK DRUG SUBSTANCES APPEARING IN THE FDA'S JANUARY 7,  
1999 PROPOSED RULE THAT MAY BE USED IN PHARMACY COMPOUNDING

bismuth citrate  
caffeine citrate  
cantharidin  
choline bitartrate  
diloxanide furoate  
dimercapto-1-propanesulfonic acid  
ferric subsulfate  
ferric sulfate hydrate  
glutamine  
guaiacol  
iodoform  
metronidazole benzoate  
Myrrh gum tincture  
phenindamine tartrate  
phenyltoloxamine dihydrogen citrate  
piracetam  
sodium butyrate  
taurine  
thymol iodide  
tinidazole