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FDA issues public health advisory on PPA

Yale hemorrhagic stroke study in medical journal

Just two weeks after the Nonprescription Drug Advisory Committee vote on phenylpropanolamine (PPA), FDA issued a public health advisory and asked companies to stop marketing PPA products. At the same time, the Yale hemorrhagic stroke study was prepublished on the web site of *The New England Journal of Medicine*.

The first action took place on Friday, November 3, when FDA sent a letter to company CEOs and presidents informing them of recent developments including receipt of the Yale report on the link between PPA and stroke, and the NDAC recommendation that PPA not be considered generally recognized as safe. In the letter, **Janet Woodcock, M.D.**, director of FDA's Center for Drug Evaluation and Research (CDER), wrote: "Based on these recent developments, FDA intends to initiate rulemaking to classify PPA as nonmonograph (not generally recognized as safe and effective) for OTC use." The letter also indicated that FDA will take action to remove PPA from prescription drug products. As an interim measure, the letter called upon manufacturers to "voluntarily discontinue marketing any drug products containing phenylpropanolamine."

That request was followed by a public health advisory issued by FDA Monday, November 6. "Although the risk of hemorrhagic stroke is very low, FDA recommends that consumers not use any products that contain phenylpropanolamine," the advisory stated. The advisory said that consumers can identify products containing this ingredient "by looking for 'phenylpropanolamine' in the list of active ingredients on the label." On that same day, *The New England Journal of Medicine* republished the Yale report on its web site.

CHPA responded to FDA's actions by issuing this statement:

"Consumer product safety is paramount to CHPA member companies. Our members have received word from FDA about its public health advisory regarding phenylpropanolamine (PPA),

and the individual companies are reviewing this and making their own individual decisions regarding their products.

Even as CHPA members continue to support their product's safety, they acknowledge FDA's action and its decision to initiate a new regulation to address PPA's safety. We look forward to this continued dialogue with FDA," the CHPA statement concluded.

CHPA contact: Dr. Lorna Totman

Journal prepublishes ephedra report, as well

The New England Journal of Medicine also prepublished a report on ephedra and alleged adverse events November 6 on its web site. The reported analyses were used in the FDA assessment at the U.S. Department of Health and Human Services' August 8-9 public meeting on the safety of ephedra dietary supplements. Report authors **Christine A. Haller**, M.D., and **Neal L. Benowitz**, M.D., concluded: "Our findings indicate the need for a better understanding of the determinants of individual susceptibility to the serious adverse effects of dietary supplements containing ephedra alkaloids so that appropriate dosing guidelines and warnings can be devised."

This journal report follows the October 25 filing of a Citizen Petition by CHPA and three other dietary supplement trade associations that calls for the adoption of a national standard for the formulation, labeling, and marketing of ephedra products (see *XNL* October 27). The full article will be published December 21.

CHPA contact: Dr. Bill Soller

*"suggestive, but not
conclusive"
– FDA on omega-3
health claim*

FDA moves on omega-3 health claim

FDA will use its enforcement discretion to allow a qualified health claim about omega-3 fatty acids (EPA and DHA) in dietary supplements and reduced risk of coronary heart disease. This claim, a result of the *Pearson* court decision, is allowed even though the Agency had determined that it did not meet the "significant scientific agreement" (SSA) standard that had been previously established for such claims.

The suggested qualified health claim states: "The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not

known whether diets or omega-3 fatty acids in fish may have a possible effect on a reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population." Such a claim may be used in labeling for EPA and DHA omega-3 fatty acid-containing dietary supplements, provided that such supplements do not recommend or suggest in the labeling, or under ordinary conditions of use, daily intakes exceeding two grams EPA and DHA omega-3 fatty acids.

FDA's decision is reflected in an October 31 letter.

CHPA contact: Dr. Patrice Wright

R&SDC... one of the best ever

CHPA's Research & Scientific Development Conference (R&SDC) was held November 8-9, and by all counts was one of the best ever. **Herb Cohen**, Ph.D., with the Power Negotiations Institute, provided words of wisdom to help work through conflict. **Jim Morrison**, ombudsman for FDA's Center for Drug Evaluation and Research (CDER), explained the ombudsman's role in helping to resolve communication breakdowns in the CDER review process.

The advisory committee process was the topic of a panel discussion moderated by **Ed Hemwall**, Ph.D., Johnson & Johnson • Merck Consumer Pharmaceuticals Co. During the discussion, **Ralph D'Agostino**, Ph.D., of Boston University and a former chairman of the CDER Nonprescription Drugs Advisory Committee (NDAC), stated a desire for advisory committees to become more involved in the switch process prior to NDAC meetings.

Four workshops provided further education for meeting participants. These workshops focused on techniques for predicting consumer behavior and making industry/FDA meetings more productive, as well as mechanisms for gaining approval to market an OTC drug that fall outside the monograph system. One workshop offered participants an opportunity to resolve OTC product safety issues.

Woodcock states priorities

Janet Woodcock, M.D., CDER director, presented the Agency's OTC priorities for 2001 and its interpretation of the June OTC hearing.

FDA priorities for 2001, explained Woodcock, include a final rule for skin protectants, a proposed rule for UVA sunscreens, the health care antiseptic final rule, a final rule on internal analgesics, a proposed rule

*Panel discussions,
workshops,
Woodcock
presentation provide
valuable education*

to include ibuprofen in the internal analgesic monograph, and a final rule that implements the “material time and extent” criteria. Resolution of the efficacy of analgesic/sleep aid combinations will be deferred out of the internal analgesic monograph.

Woodcock addressed a number of issues regarding the June OTC hearing, as well. The director acknowledged that staffing limitations in the Agency raised the public’s concerns about the speed and process of the monograph system. FDA also acknowledged the concerns raised at the hearing regarding “forced switches” and “barred” indications, and about novel switches, as well. While she conceded that self-diagnostic tests may open up new opportunities, Woodcock stated: “We aren’t there yet to be able to test real-life usage.” The Agency will need to develop its ability in the social sciences as the complexity of future issues cannot be handled only through labeling. The Agency also heard recommendations on the OTC possibilities of emergency contraception, cholesterol-lowering drugs, and antibiotics, and indicated specific indication advisory committee meetings may be on the horizon.

Woodcock also announced that there will be a reorganization of CDER by January, with the intent of making sure that the management load is evenly distributed.

*Program streamlines
process, enhances
FDA/industry
goodwill
– CHPA*

Preannounced inspection program works, CHPA

CHPA sent a letter to FDA October 30 in support of a continuation of the preannounced inspection program for OTC drugs.

CHPA sent the letter following reports that FDA was considering abandoning the program for all product categories except devices. “CHPA members uniformly give the preannounced inspection program high marks,” reads the letter. “The program has helped to streamline routine inspections and has enhanced the goodwill and cooperation between FDA and industry – exactly the goals the program was designed to achieve. CHPA strongly supports the continuation of the program.”

CHPA has offered to include implementation issues on the agenda of the Association’s popular Manufacturing Controls Seminars in 2001 to provide education to companies to address any areas of confusion in the field associated with the program.

CHPA contacts: Eve E. Bachrach and Bill Bradley

Legal & Regulatory Conference adds e-business speaker

CHPA's one-day *not for lawyers only* legal and regulatory conference has added a topic on "eBusiness and the New Direction of Retailer/Supplier Relationships," with **Ashwin Rajah** of Arthur Andersen. E-commerce has spawned much discussion of the retail supply chain. The retail supply chain as we know it in fact no longer exists. Among the new models and means of collaboration that are emerging to reinvent and redefine the supply chain is the digital marketplace. What are some of the concepts involved in it and some of the risks and impacts to be considered? Hear Rajah provide insights and answers.

The conference is set for Thursday, November 30, in Washington, D.C. Visit CHPA's web site – www.chpa-info.org under "CHPA Meetings" – or contact CHPA's Maria Sarabia or Sandra Archer for registration information.

CHPA Legal & Regulatory Conference

*November 30, 2000
Washington, D.C*

FDA will monitor progress of postmarketing studies

FDA announced in the October 30 *Federal Register* that the Agency is changing its requirements for annual postmarketing status reports for approved drugs. The rule implements an FDA Modernization Act provision giving FDA more authority to monitor the progress of postmarketing studies that companies have committed to conduct (including pediatric studies). The Agency plans to make a guidance available, "Reports on the Status of Postmarketing Studies – Implementation of section 130 of the Food and Drug Administration Modernization Act of 1997," to help industry comply with the new final rule. The effective date of the rule is February 27, 2001.

We want your number!

It's no news that the rate at which information travels is speeding up. Your Association, accordingly, is planning changes that will keep pace with technology.

CHPA recently sent a mailing to people in our database who have NOT previously supplied us with their e-mail addresses. If you have not already submitted your e-mail address to us, or if your e-mail address has changed, please contact CHPA's Kathleen McWilliams at kmcwilliams@chpa-info.org or via fax – typed or printed, please – at (202) 223-6835.

Don't miss out on future electronic communications!

**2001 Annual
Executive
Conference**

*March 8-11, 2001
Turnberry Isle Resort
& Club
Aventura, Florida*



AEC sponsors applauded

Thanks to the very generous and continuing support from CHPA member companies, business and social plans for CHPA's 2001 Annual Executive Conference are well underway. Without their added sponsorship, many of the "big name" speakers and added social amenities of the Association's flagship meeting could never come to pass.

With gratitude, a full list of sponsors for the March 2001 meeting is included in this *XL*.

NEWS NOTES

WSMI goes to Australia

Time is almost up to register for the November 21-24 Sydney, Australia, World Self-Medication Industry (WSMI) Asia/Pacific Regional Conference. The host association, the Australian Self-Medication Industry, is bringing together best practice models from around the globe and regulators from the Asia/Pacific region for this meeting. More information is available at www.asmi.com.au; online registration is possible at www.tbs.aust.com.

Crisis management workshop scheduled

The Drug Information Association has announced its 5th Annual Pharmaceutical Industry Crisis Management Workshop December 4-5 in Washington, D.C. The purpose of the workshop is to provide vital information about the types of crises that can develop, how to manage a crisis, and how to gauge the impact of a crisis on a company. In addition, the workshop is designed to provide clues on how to identify potential crises, develop a crisis management plan, and to prevent a crisis. More information is available on www.diahome.org.

Hatch-Waxman conference from FDLI

FDLI will host the Hatch-Waxman: Past, Present & Future conference December 11-12 in Washington, D.C. Designed to provide both brand-name and generic pharmaceutical companies information on FDA regulations, court decisions, and legislative proposals, both Senator **Orrin G. Hatch** (R-Utah) and Representative **Henry A. Waxman** (D-Calif.) are invited keynote speakers. For more information or to register online, visit www.fdl.org.

New dietary supplement resources from FDLI

The Food and Drug Law Institute (FDLI) announced a number of new titles that provide marketing and regulatory information to dietary supplement manufacturers. *Marketing Dietary Supplements*, written by **I. Scott Bass** and **Charles J. Raubicheck**, contains 10 chapters and will be updated as necessary. Other titles focus on the Dietary Supplement Health and Education Act, as well as FDA information. Visit www.fdi.org for a complete list of available publications and an order form.

Tax tips from NAEIR

The National Association for the Exchange of Industrial Resources (NAEIR) is offering a free guide that tells businesses how to earn federal income tax deductions by donating new, nonmoving inventory to charity. The guide lists the types of products that are eligible, and demonstrates how to calculate potential tax savings. Call (800) 289-4551 to receive a free guide.

OTC/Rx manufacturer for sale

A business broker has available for purchase a manufacturer of OTC and prescription cough and flu medicines for diabetics. The company has profitable sales of \$1 million but lacks a good distribution system. Interested parties should send replies marked CONFIDENTIAL to CHPA's Public Affairs department, Box 779, 1150 Connecticut Avenue, NW, Suite 1200, Washington, DC 20036.

CHPA CALENDAR OF EVENTS

CHPA Legal/Regulatory Conference

November 30, 2000
Washington, D.C.

Nutritionals 2001

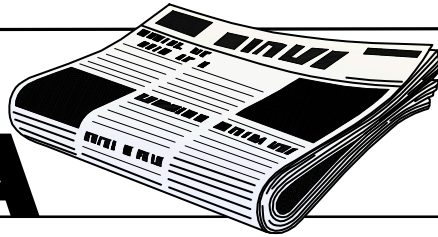
January 29-31, 2001
Anaheim, California

CHPA Annual Executive Conference

March 8-11, 2001
Aventura, Florida



Note: The next issue of the *XNL* will publish December 1.



The following is a partial listing of recent news clips that include CHPA's point of view.

1. "Seeking safer supplements," *Business First*, August 18, 2000.
2. "The 30 Plus Factor," *Supermarket News*, September 4, 2000.
3. "Cold pill control seen as meth lab remedy for Arkansas," *The Commercial Appeal*, September 15, 2000.
4. "Lawmakers mull restrictions on common cold medicines," *The Associated Press*, September 15, 2000.
5. "Just say Yes," *The San Francisco Chronicle*, September 17, 2000.
6. "Fall is a good time for your annual medicine check-up," *Bryan Ohio Times*, September 20, 2000.
7. "Strokes linked to cough syrup, weight-loss aid," *USA Today*, October 17, 2000.
8. "Advisory could pull drugs for colds, appetite suppressants: FDA panel concludes phenylpropranolamine increases risk of stroke," *USA Today*, October 20, 2000.
9. "Medicine Ingredient Linked to Strokes," *The Washington Post*, October 20, 2000.
10. "FDA ban sought on chemical used for cold remedies," *The New York Times*, October 20, 2000.
11. "FDA Panel: Ingredient in some diet, cold medicines unsafe," *Chicago Tribune*, October 20, 2000.
12. "FDA advisers say a common drug ingredient may not be safe," *Philadelphia Inquirer*, October 20, 2000.
13. "PPA under scrutiny for allegedly causing strokes," *NBC Nightly News*, October 20, 2000.
14. "Drug companies defend use of ingredients in cold products," *The New York Times*, October 21, 2000.
15. "Advice to restrict cold drug praised; ingredient also in diet products," *The San Francisco Chronicle*, October 21, 2000.
16. "Cold drug ingredient findings a concern," *Los Angeles Times*, October 21, 2000.
17. "Cold remedies 'increase risk of strokes'," *The Guardian (London)*, October 21, 2000.
18. "Doctors call for caution on drug in diet, cold pills," *The Columbus Dispatch*, October 21, 2000.
19. "The PPA blues," *Time*, October 30, 2000.
20. "An ingredient under fire," *Newsweek*, October 30, 2000.

"Nancy Bukar of the Consumer Healthcare Products Association said although pharmaceutical manufacturers don't want to see their products used in making illegal drugs, it opposed restrictions like the ones being proposed."

The Commercial Appeal
September 15, 2000

"Most health-industry and many patients' rights groups support self-medication. The Consumer Healthcare Products Association, a group representing over-the-counter drugmakers, claims that these medications save the health-care system nearly \$13 billion a year by reducing costly doctor visits and avoiding more expensive prescriptions."

The San Francisco Chronicle
September 17, 2000

Enclosures: Legal/Regulatory Conference Program and Registration Form
CHPA AEC sponsor list

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