

Health Letter

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Criminal Charges Should Be Filed Against Schering-Plough

The following is a letter sent to Tommy Thompson, Secretary, Department of Health and Human Services, on August 9th, by Dr. Sidney Wolfe urging criminal prosecution of Schering-Plough based on their leaving dangerous asthma inhalers on the market knowing they had caused at least one death.

On March 1st of this year [see the April 2001 issue of *Health Letter*], I wrote to you, urging that you “launch an investigation into criminal charges against Schering-Plough based on the possibility that the company knowingly shipped millions of the 59 million units of albuterol-containing asthma drug eventually recalled, between the time the company became aware of the seriously flawed manufacturing processes and the time the March 2000 recall was finally accomplished.” The company had explained that the basis for the recall was “the remote possibility that an aerosol container may not contain active drug.”

The failure to be able to treat and stop an acute asthmatic attack, because there is no asthma drug in the inhaler upon which the patient relies, is obviously a life-threatening situation. We therefore subsequently have analyzed adverse reaction report data obtained from the Food and Drug Administration (FDA) and found that there was a pattern of deaths in users of Schering-

Plough albuterol products which had occurred around the time of the two (9/99 and 3/00) recalls. Thus, this new information, along with other findings discussed below, significantly adds to the compelling case for criminal prosecution of Schering-Plough.

As can be seen on the chart on the following page, there were no deaths reported to the FDA to have occurred in users of Proventil or Warrick’s albuterol (generic version also manufactured by Schering-Plough) during the first three quarters of 1998. However, starting with a death that occurred in the fourth quarter of 1998 and continuing through the second quarter of 2000, there were a total of 17 deaths

for which the Schering-Plough albuterol was listed as the “primary suspect” and in which there is a date of death. During the last two quarters of 2000, the last period for which we have been able to obtain data, there have been no subsequent deaths reported to have occurred in users of these products. For an additional seven deaths in people using these asthma inhalers, there was no exact date of death given and the cases were reported to the company between March 30th and August 9, 2000.

This pattern of deaths, with none occurring before or after the interval during which the defective albuterol inhalers were shipped for use, is known

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Outrage of the Month

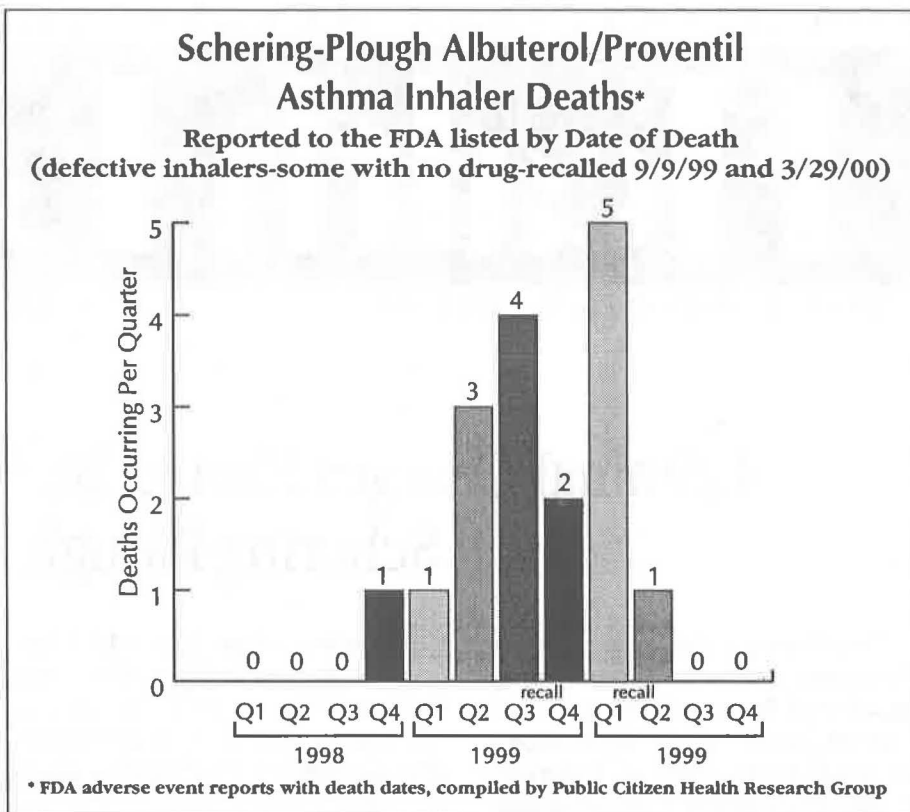
Crouching Government, Hidden Snake Oil

Yet another dietary supplement is making outlandish claims and the FDA can’t do much to stop them. 12

as a point source epidemic and strongly implicates these products as causes of the deaths.

Of the 17 patients with known dates of death, 10 of them were using, or attempting to use, inhalers from the lots which were eventually recalled, including two from the lot recalled in September 1999 and eight from the lots recalled in March 2000 according to the FDA documents. For the other seven patients, lot numbers were not listed in the FDA data we received. In information also included with the FDA adverse reaction reports, for 5 of the 17 patients who died, there were comments indicating that the patients had not gotten relief from their asthmatic attacks from the Schering-Plough inhalers. The remarks included those of a 21-year-old, shortly before his death, who "complained on several occasions that his albuterol inhaler did not seem to treat his asthma attacks as usual." A 10-year-old boy who had an asthmatic attack "reached for his inhaler and obtained no relief" and died shortly thereafter. Both of these people were using inhalers from the recalled lots. Of those who died whose ages were known, six were under the age of 30 including three who were less than 20 (10, 12, and 16).

Although many of these deaths occurred before the first recall and most of the rest before the second recall, most were not reported to the company, according to the company's data, until after the second recall. One likely explanation is that it is counterintuitive for patients, their families, or physicians to believe that an asthma inhaler could be so shoddily manufactured as to fail to contain the asthma drug. Therefore, until the widespread publicity following the second recall, the link between the deaths and the defective inhalers was probably not suspected by many people. It was, in fact, after the second recall, on March 29, 2000, that Schering-Plough advised that "Proventil and Warrick brand albuterol patients using a canister without active drug will not obtain their usual relief from asthma symptoms." The company press release stated that "an inhaler that does not contain active drug is a serious matter that merits immedi-



ate attention."

However, at least one death case was known to the company on January 4, 2000, prior to the second (March 29, 2000) recall and this death may well have helped to precipitate the

inhalers from a lot eventually recalled in March 2000, died in September 1999 and the company was notified on January 4, 2000. Unfortunately, it was almost three months after Schering-Plough learned about her death that the March 29th recall was belatedly undertaken. During these first three months of 2000, while Schering-Plough was aware of her death but did not recall the inhalers, another five deaths occurred in people using inhalers that were recalled on March 29, 2000.

Aside from delaying the second recall almost three months after learning of a death in a woman using the eventually-recalled product, Schering-Plough was reckless in not recalling all of the eventually recalled lots at the time they recalled the one lot, 9-BBS-525, in September 1999. According to the company's press release of September 9, 1999, announcing that first recall of 190,000 asthma inhalers, it was precipitated after "one patient returned an inhaler that did not contain drug substance." It is of great importance that when the massive, 59 million unit recall of March 29, 2000 was finally ordered, lots which, according to their lot number and expiration dates, were

If you were using either an
albuterol, Proventil, or
Warrick inhaler and had a
problem with its
effectiveness, please email us
at hrg1@citizen.org
so we can send you some
questions to answer
concerning the situation.

February to April 2000 outside audit by the AAC Consulting Group, during which the March 29th recall of 59 million units of albuterol aerosol inhalers was finally done.

According to FDA documents, a woman of unknown age who had a previous history of "well-controlled asthma" who was using one of the

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Direct-to-Consumer (DTC) Ads: Illegal, Unethical or Both

The following testimony was given by Dr. Sidney M. Wolfe in front of the Senate Commerce Committee Subcommittee on Consumer Affairs hearing on July 24, 2001.

Because of the strong First Amendment in the U.S. constitution, there is no way that DTC prescription drug advertising could ever be banned in this country. Having said that, however, there is an urgent need for more fine-tuned, better-staffed and much tougher government regulation of its content. There is little doubt that false and misleading advertising to patients and physicians can result in prescriptions being written for drugs that are more dangerous and/or less effective than perceived by either the doctor or the patient. This can then lead to a subsequent toll of deaths and injuries that would not have occurred

had safer, more effective drugs been prescribed.

The more than 500 prescription drug advertisements that have been found by the Food and Drug Administration (FDA) to violate federal laws and regulations from 1997 through the present include approximately 90 DTC ads. These numbers would be significantly larger if FDA's DDMAC (Division of Drug Marketing Advertising and Communication) had more staff to investigate the rapidly expanding area of DTC drug promotion. Such advertising has more than tripled in dollar volume from \$791 million in 1996 to \$2.5 billion in 2000. But the number of FDA staff assigned to reviewing and investigating all of prescription drug advertising, during the same interval, has only increased from 11 in 1996 to 14 at present. I have been informed that there is, or will shortly be, an increase

in DDMAC staff to monitor such advertising and it comes none too soon. Even this may well not be adequate.

As seen in the table on the next page, there has been a sharp and steady decrease during the last three years in the number of FDA warning letters and notices of violation of FDA laws and regulations to drug companies concerning prescription drug advertising. From a peak of 84 such enforcement actions during the first six months of 1998, the number has fallen steadily to 36 FDA actions during the last six months of 2000 and an estimated 38 actions during the first six months of 2001.

For the last year (mid-2000 through mid-2001) the total number of DDMAC advertising enforcement actions—74—was less than one-half (47 percent) of the 158 enforcement actions taken three years ago (mid-1997 through mid-1998). There is no evidence of an advertising/pharmaceutical industry epiphany, resulting in fewer illegal advertisements for prescription drugs. Therefore, the only plausible explanation for this dangerous decrease is that the police force—DDMAC—has not been strong enough in numbers of investigators along with a lack of adequate pro-enforcement leadership from the top officials in the FDA. That this latter explanation, inadequate enforcement, is correct will be seen when the FDA, with the urging and support of your committee, begins to increase the number of actions taken against these violative ads. Until then, Americans—both physicians and patients—will be harmed by prescribing decisions about which drugs to use based on all-too-frequently false and misleading information from advertisements which are much less likely to be stopped because of poorer enforcement by the FDA.

In addition to more staff, there is a dire need for DTC-specific regulations since, other than the late 1990s guidance concerning TV advertising—which

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SCHERING-PLOUGH, from page 2

manufactured both before and after the 9-BBS-525 lot were ultimately recalled. Thus, Schering-Plough made a financially conservative but public health reckless decision in September 1999 that, despite a long history of systemic problems involving the manufacture of albuterol inhalers, only the lot from which the patient was unable to relieve his/her asthma attack would be recalled. At the time of the second (March 2000) recall, the company belatedly admitted that "the [March] recall relates to an aerosol manufacturing problem that had been previously identified in October 1999." Although all lots of the massive March 2000 recall were said to have been manufactured before September 30, 1999, it is likely, if not certain, that the company shipped many of these lots into channels of commerce after that date.

In our initial letter, the request for a criminal investigation was based on the long standing pattern of dangerously sloppy manufacturing, including

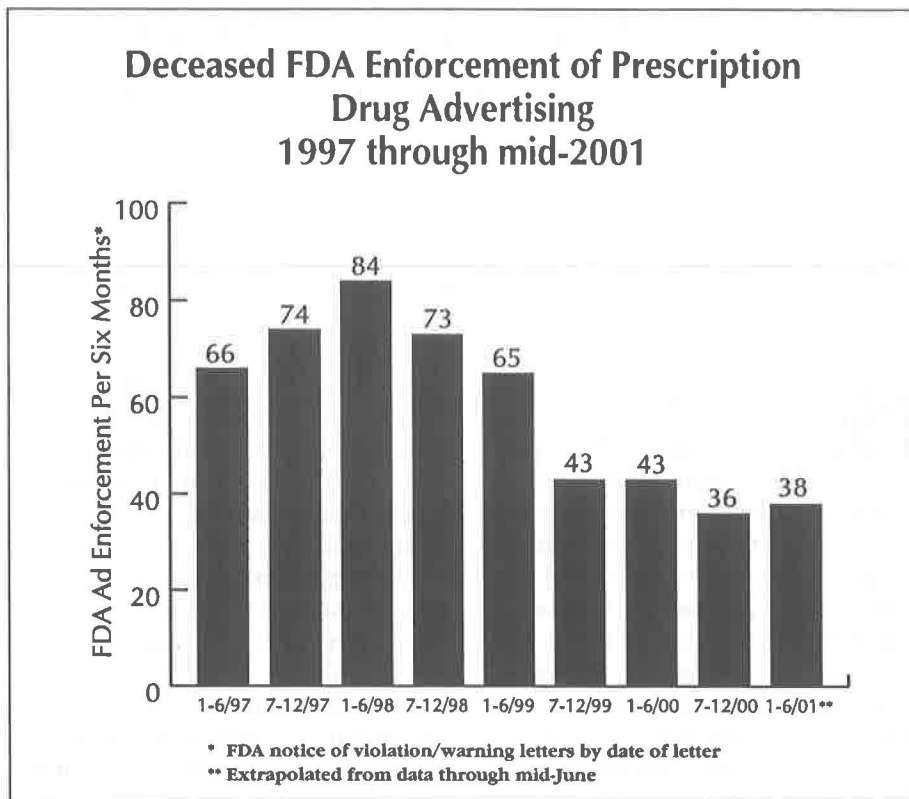
albuterol inhalers, at Schering-Plough's New Jersey plant, repeatedly documented in FDA inspections, FDA warning letters to the company and in the company's private audit by AAC Consulting Group, during which the March 2000 recall finally occurred. Now, there is additional evidence that the company not only failed to recall millions of defective asthma inhalers for three months after learning on January 4, 2000 of a death in a woman using one of these inhalers, but that there were many deaths in people which would have been avoided if there been an earlier, September 1999 recall of the 59 million units.

Based on this new information concerning the deaths, there is even more reason for criminally prosecuting Schering-Plough for introducing these defective products into the marketplace and failing to recall them much earlier. If you have any questions about this serious problem, please call and I will meet with those involved.

is a guidance not a regulation—*there are no regulations specifically written for DTC advertising*. The FDA has been using the regulations promulgated after the 1962 Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act that were clearly intended for prescription drug advertising directed at health professionals such as doctors and pharmacists. We have been urging the agency since the mid-1980s to propose and finalize such consumer specific DTC regulations that would make it easier to evaluate the ads in the context of patient, not health professional, comprehension. Beyond more staff and DTC-specific regulations, there is a need for much more enforcement power. At present, the FDA is limited to a Notice of Violation or Warning Letter to companies found to violate the law or regulations. Theoretically, in the face of multiple warnings to the same company, criminal prosecution is a possible tool. This latter power has only been used a handful of times in the past 35 years. To our knowledge, criminal prosecution has never been used in the context of DTC advertising, despite, for example, a series of 11 illegal ads for Claritin (8 DTC), 14 illegal ads for Flonase/Flovent (8 DTC). (Flonase and Flovent are the same drug in two versions, one used for allergy, the other for asthma). There have also been five illegal ads for Celebrex (1 DTC).

The ability to assess drug companies large civil monetary penalties for advertising violations might actually serve as a deterrent for companies who now just stop the violative ad, when requested by the FDA, then create and massively disseminate a new one shortly thereafter. The FDA currently lacks the authority to impose any civil penalties for drug advertising or, in fact, for any other illegal drug industry activity concerning prescription drugs. It is long overdue that the Congress give the FDA this authority.

A search of the peer-reviewed, published medical studies concerning DTC advertising yields findings that, for the most part, are also quite worrisome:



- In one study, researchers found that consumers rated the safety and appeal of drugs described with an incomplete risk statement significantly more positively than those whose risks were described more completely. (This has significant implications since so many DTC ads understate the safety of drugs.)

- Another study found that consumer beliefs that there was prior scrutiny of DTC ads by the FDA and that they were held to higher standards than other ads were generally wrong. A substantial proportion believed that only the safest and most effective drugs could be advertised DTC and that the FDA required prior review of ads. DTC ads led one-fifth of people to request a prescription.

- A study on the educational content of DTC ads found that while many ads provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, how long you had to use the drug, alternative treatments including behavioral changes which could improve their health, or misconceptions about the disease. The au-

thors concluded that the ads provided only a minimal amount of educational information.

- One study asked patients what they would do if a doctor refused to prescribe a drug that the patient wanted as a result of a DTC ad. One-fourth of patients said they would seek a prescription elsewhere and 15 percent said they would consider terminating their relationship with their physician. The patients with these attitudes were ones who had a more favorable evaluation of DTC advertising and who possessed more faith in the current government regulation of DTC drug ads.

In summary, FDA resources and specific regulatory authority to monitor the accuracy of drug safety and effectiveness portrayed in DTC ads are dangerously inadequate and many patients' perceptions of the ads and their subsequent response to the "information" therein is similarly dangerous. The present situation concerning DTC advertising is unacceptable and it is our hope that your committee will initiate actions to remedy these serious problems.

Below the Beltway

The following column is reprinted from the Washington Post of Sunday, July 29, 2001 with their permission and was written by Gene Weingarten.

If you're like me, you suffer the occasional absent-minded moment: misplacing your keys, losing your train of thought, arriving at work without pants, etc. That is why I snapped to attention the instant I heard the ad on the radio for a food supplement called Focus Factor:

It's one of the top complaints that doctors hear from their patients today. The symptoms include fatigue, poor memory and trouble concentrating. It's called Brain Starvation!

At last, a diagnosis. I wasn't old, I was hungry! Could this be? After I got to work I telephoned my doctor, but when the receptionist answered—true fact—I forgot why I had called. Fortunately, this ad is everywhere, and I soon heard it again on my way home.

Focus Factor's creator, Dr. Kyl Smith, explains in his ad that modern food-processing practices leach nutrients from our foods: This can turn an otherwise healthy brain into mush!

This was more serious than I thought.

To hell with my doctor, a mere GP.

I telephoned Washington's most renowned nutritionist, C. Wayne Calloway, and demanded to know why medical science had not warned us of this national scourge. He listened to the text of the ad, and laughed. "It's ludicrous," he said. The body takes care of the brain first, he said, before any other organ: So, as a medical diagnosis, "brain starvation" can be adequately summarized by its initials.

Dr. Wayne blamed this sort of ad on Congress, which in 1994 passed a law exempting food supplements from

control of the Food and Drug Administration, permitting all sorts of thinly supported claims.

I called the Focus Factor 800 number. The salesman, Tom, kept trying to get me to pay \$149.99 for a special introductory three-month supply, and I kept saying I wanted to talk to Dr. Smith personally. Exasperated, Tom finally said, "If you were gonna buy a Chrysler, would you call up and ask to talk to Lee Iacocca?" and hung up on me.

So then I decided to research Dr. Kyl Smith via Mary Lou. Mary Lou is a *Washington Post* librarian. *Washington Post* librarians—I don't mean to alarm you, personally—can find out everything about you, such as your birth date, your professional affiliations, your address and the price you paid for your home. (Too much, in your case. She checked.)

The most intriguing thing I learned from Mary Lou was that Dr. Smith appears to be "Dr." Smith more or less in the sense that Dr. Seuss was "Dr." Seuss. Kyl Smith lives in Texas, but he is not licensed to practice medicine there. He appears to be a chiropractor.

I tried to phone Dr. Smith to ask him about this, but for two days he didn't answer the messages I left on his machine. I did reach his father-in-law (Mary Lou does good work), who informed me that the best way to reach Kyl was to buy his product, look at the label, and then contact the company and ask for an appointment to speak with Kyl. When I said it would be easier for me to reach, say, the vice president of the United States, Dr. Smith's father-in-law replied huffily that Kyl is a busy man. Reporters, he said, have to learn to go through publicists "the way you do with movie stars."

Even movie stars eventually get interviewed, and Dr. Smith did, eventu-

ally, call me. He talks exactly like he does in the ad—fast, and energetic. No, he is not a medical doctor, he said, but so what? "Are you saying you think you need to be a doctor to be an expert on nutrition?"

Well, um, yeah.

Dr. Smith disagreed. Brain starvation is real, he said: "The brain is the most nutritionally sensitive organ in the body."

It certainly does seem to be susceptible to manipulation.

Later that day I heard the radio ad again—it seems to run every 12 seconds or so on WTOP, Washington's all-news-and-brain-mush station. So I called Matt Mills, WTOP's general sales manager. What did Mills, professionally, think of the ad?

"I am not going to give any opinion," he said, "that might be adversarial or challenging to an advertiser."

This led to the obvious question: If I paid in cash money, would WTOP run an ad for a pill that guaranteed endless sex with strangers? Or offered a car that could go 7,000 mph? Matt said he could not discuss these things because they would involve "internal station procedures."

I was going to write a scathing indictment about WTOP but then had a better idea. Kyl Smith might not be a medical doctor, but he is no dope. He's making money to pay for those ads, and I am guessing it's coming from people who hear his ads and buy Focus Factor. So instead of embarrassing Matt, I am going to become his client.

Coming soon on WTOP:

Do you suffer from extreme gullibility? I have [a] product that can help restore your natural body defenses against hype. For a mere \$149.99, . . .

Product Recalls

July 12–August 18, 2001

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS & DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is www.fda.gov.

Class I Recalls

Name of Drug or Supplement; Class of Recall; Problem

Deltasone Tablets 10 mg. [prednisone tablets] in 500 tablet bottles, Rx; Tablet mix-up, bottles labeled to contain 10 mg tablets may contain 5 mg tablets

Sci-Fit Tri-Cuts Dietary Supplement Capsules sold in 90 and 180 count bottles, contains 1000 mcg of tiratricol (also known as triiodothyroacetic acid or TRIAC), an active thyroid hormone (100 mg of Tricol) and is sold 12 bottles per case; Product's label recommends to not exceed three capsules daily. This dose is in excess of the usual replacement dose of thyroid hormone and therefore would cause hyperthyroidism. Particularly in patients with underlying cardiac disease, this poses a significant health risk because of immediate, life-threatening consequences such as heart attack, stroke, heart failure and arrhythmia

Lot #: Quantity and Distribution; Manufacturer

Lot 29DRB EXP 9/04; 6,792 bottles distributed nationwide; Pharmacia Corporation, Kalamazoo, Michigan. Recall conducted through National Notification Center, Indianapolis, Indiana

All codes of the product on the market; 10,453 bottles distributed nationwide; Synergy Nutritional Industries, Inc., (also known as Trent Pharmaceuticals), Fort Walton Beach, Florida. Recalled by ATF Fitness Products Inc., Oakmont, Pennsylvania

Name of Drug or Supplement; Class of Recall; Problem

AndroGel Testosterone Gel 1%, 5 gram unit doses aluminum foil packets, 30 packets per carton; Class II; Subpotency

Aspirin Tablets (extra strength enteric-coated), 500 mg in 60 tablet bottles, packaged under labels: Equate (Walmart), Bi-Mart (Eugene, OR) and Western Family (Portland, OR); Class III; Dissolution test failed

Lot #: Quantity and Distribution; Manufacturer

Lot 00207, EXP 5/02; 1,512 cartons distributed in Illinois, North Dakota, Florida, Pennsylvania, Indiana, Tennessee, Arizona, New York, Massachusetts, New Jersey, Kentucky; Laboratories Besins Iscovesco, Montrouge, France. Recalled by Unimed Pharmaceuticals, Inc., Deerfield, Illinois

Equate Lot number 0044685 EXP 3/01, Bi-Mart Lot number 8E01222 EXP 3/01, Western Family Lot number: 8E01222 EXP 3/01; 15,192 bottles distributed in Arkansas and Oregon; INK International, Hauppauge, NY. Recalled by Leiner Health Products, Carson, California

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Benadryl Fastmelt Products; Class II; Mislabeled, Phenylalanine amount is 4.6 mg per tablet/capsule but labeled to contain 1.2 mg

Cortisporin TC, topical antibiotic/steroid, 10mL; Class II; Subpotency

Eco Dent Ultimate Natural Daily Rinse, Tangy Orange-Clove; Class II; Bacteria contamination—*Pseudomonas alcaligenes* & *baleurica*

Levothyroxine Sodium Tablets 25 mcg., 50 mcg., 75 mcg. in bottles of 100's and 1000's, some packaged under QT, VPI and URL labels; Class II; Stability, May not maintain potency through the expiration date

Oxycodone HCL/Acetaminophen 5/500 mg, 100 capsule bottles packaged under the Vintage and Qualitest labels; Class II; Dissolution failure (Acetaminophen)

Q Tuss Tablets in bottles of 100's and 500's, packaged under the Zenith Goldline, URL, QT, VPI and URL labels; Class II; Super-Potency (Scopolamine)

Vira-A [Vidarabine Ophthalmic Ointment] 3% sterile ophthalmic ointment, 3.5 gm tubes, Rx; Class II; Stability Failure (9 month assay)

Lot #: Quantity and Distribution; Manufacturer

Children's Benadryl Allergy & Cold FASTMELT Tablets, cherry flavored, Benadryl Allergy Kapseals or Ultratab Tablets packaged in a 48 count box and including a free, 10-count tablet sample of Benadryl Allergy & Sinus FASTMELT, Benadryl Allergy & Sinus FASTMELT, box of 20 tablets; All lots and all configurations; 88,403 cases (24 units/case), 2,382,429 professional samples and 36,780 displays distributed nationwide; Shaklee Technica, Norman, Oklahoma. Recalled by Warner Lambert Consumer Group, Pfizer Inc.

23,316 units distributed nationwide; Warner-Lambert Co, Rochester, Michigan. Recalled by King Pharmaceuticals, Bristol, Tennessee

Lots 9431, 0002, 0376; 14,209 bottles distributed nationwide, and in Canada and Australia; Truett Laboratories, Inc., Azusa, California

Numerous lots; 119,249 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina

Lot 126060A and 126060B; 9,425 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina

Numerous lots; 110,538 bottles distributed nationwide; Vintage Pharmaceuticals, Charlotte, North Carolina

Lot Nos.5550-1 and 53D0-1; 39,338 units distributed nationwide; Warner Lambert Co., Rochester, Michigan. Recalled by King Pharmaceuticals, Inc., Bristol, Tennessee

M E D I C A L D E V I C E S

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is <http://www.fda.gov>.

Name of Device; Class of Recall; Problem

Focus Dailies Spherical Contact Lenses; Class III; Primary label indicates Focus Dailies Spherical, while secondary label indicates Focus Dailies Progressive

H-TRONplusV100 Insulin Infusion Pump; Class II; Labeling claims insulin pump is waterproof but some pumps malfunctioned when exposed to water

Lot #: Quantity and Distribution; Manufacturer

Lot No. 1096004; 10/15 packs shipped to Arizona, Florida, Massachusetts, Missouri, New Mexico, North Carolina, Pennsylvania; Ciba Vision Corp., Duluth, Georgia

30,000 distributed nationwide; Disetronic Medical Systems, St. Paul, Minnesota

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is <http://www.cpsc.gov>.

Name of Product; Problem

Apple AC Adapter; Adapters could overheat, posing a fire hazard

Baby Walkers; Walkers will fit through a standard doorway and are not designed to stop at the edge of a step

Bassinets; Children and adults can be injured when their fingers are pinched or cut between parts of the folding mechanism

Bicycles; Front fork steering tube can break, causing the rider to lose control of the bicycle

Bicycles (Children's); Frame can break during use causing the rider to lose control of the bicycle

Bicycles (Children's); Frames can break during use, causing the rider to lose control of the bicycle

Bicycle Handlebars and "Bar Ends," Handlebars can crack and break, causing the rider to lose control of the bicycle

Bicycle Hydraulic Disc Brakes; Brakes could fail, causing the rider to lose control of the bicycle

Bicycle Suspension Forks; Forks can break, causing the rider to lose control of the bicycle

Cabinet and Drawer Spring Latches; If latch breaks, a small spring could be released. Young children could choke on the small spring or gain access to a cabinet or drawer where dangerous items are stored

Lot #: Quantity and Distribution; Manufacturer

Sold with prior generation PowerBook G3s; 570,000 sold worldwide from May 1998 through March 2000; Apple, Cupertino, California (866) 277-2096 www.apple.com/adapterexchange

Model ST-108ST; 600 sold in California, Arizona and Texas from January 1998 through July 2001; SunTome Trading Corp., Los Angeles, California (888) SUNTOME

Model numbers 79338, 79334 or 79336. Sold under names Sit & Soothe Portable Bassinet, Soothing Sounds Bassinet and Soothing Sounds Portable Bassinet; 569,000 sold nationwide from November 1997 through March 2001; Fisher-Price, East Aurora, New York (800) 285-0324 www.fisher-price.com

Long-wheelbase recumbent models RANS Stratus, Stratus XL, Gliss, Tailwind, Wave, Response and Nimbus; 4,000 sold at specialty bike shops from June 1993 through July 2001; RANS Inc., Hays, Kansas (877) 990-7267 www.rans.com/recall or www.ransbikes.com/recall

2001 Hemi Pro 12-inch boys red and 2001 Hemi Fastgirl 12-inch girls pink; 3,500 sold by specialized dealers nationwide from July 2000 through May 2001; Specialized Bicycles, Inc., Morgan Hill, California (800) 214-1468

Models: Cool Taz, Sweet Tweety, Mudslinger, Secret Treasures, Rugrats, Best Friends, Space Racer, Fairy Magic, MX1200, High Gear, and MX 1800; 38,800 sold nationwide from October 1999 through March 2001; Acetrike Bicycle Co., Taiwan (888) 366-3828

"PAZZAZ" ATB-98 and "PAZZAZ," 125 handlebars (sold from June 2000 through May 2001) and 199 pairs of bar ends (sold from July 2000 through May 2001) at Supergo stores in California and Arizona and nationwide through mail order; Supergo Corp., Santa Monica, California (800) 326-2453 www.supergo.com

2001 Gustav M with silver brake levers, also sold with Cannondale MT 4000 tandem bicycles; 360 sold nationwide from September 2000 through May 2001; Magura USA, Olney, Illinois (800) 448-3876

"Carbon Lefty" on 2001 models Cannondale F4000 SL, Jekyll 4000 SL, Raven 4000 SL; 367 sold at Cannondale dealers from December 2000 through June 2001; Cannondale Corp., Bethel, Connecticut (800) BIKE USA

Made of white plastic with a spring which holds the latch closed. "SAFETY 1st" is written on the top of the latches; 1.7 million packages sold nationwide from January 1993 through December 1999; Safety 1st, Canton, Massachusetts (800) 366-1282 www.safety1st.com

Name of Product; Problem

Coffeemakers; An electrical connection can overheat and ignite the filter basket support, presenting a risk of fire and burn hazard

Contact Adhesive; Adhesive contains toluene, which presents a fire and poisoning hazard and packaging does not have required cautionary labeling

Educational Kits; Red and gold paint contains lead

Electric Wrenches; Power cords can release from handle, posing injury or electrocution hazard

Furnaces; Substantial risk of fire

Hand Trucks; Rims can separate under intense pressure and strike the user or bystanders

High Chairs; When seat is reclined, chairs have space between the armrest and backrest in which a child's head or arm can become entrapped, posing a risk of suffocation or injury

Infant Seat Pads; Pad has two shoulder straps that create a v-shaped opening around the head and neck, presenting a strangulation hazard

Jordan Trunner Cross-Training Shoes; Shoes have a thin metal strip on the outside of the heel that can protrude from the shoe and form a sharp edge that can cut consumers

Kids Meal Toys; Toys can break causing small parts to be released, which poses a choking or aspiration hazard to young children

Lot #: Quantity and Distribution; Manufacturer

Automatic drip Model 398 with black or white exterior, Model 405 with wood-grain; 218,000 sold nationwide from January 1996 through April 2000; Krups North America, Closter, New Jersey (800) 810-8687

Tube is marked, "Super Contact Adhesive," UPC code is 7-31015-04471-9; 90,000 sold at Discount and "Dollar" stores nationwide from January 2000 through January 2001; Kole Imports, Carson, California (866) 251-0982

"Let's Start™ Numbers" and "Optical Illusions Lab," 160,000 sold nationwide from February 1999 through May 2001; Advantage Publishers Group, San Diego, California (866)748-3731 www.advantagebooksonline.com

Model 9070-20 serial numbers 229A401010001 through 229A401250722, model 9071-20 serial numbers 239A401010001 through 239A401250404 and model 9075-20 serial numbers 230A401010001 through 230A401260104; 6,000 sold nationwide from March through July 2001; Milwaukee Electric Tool Corp., Brookfield, Wisconsin (866) 473-2288 www.mil-electric-tool.com

Seven manufacturers with numerous models; 30,000 sold in California from January 1983 through December 1992; For complete details, read the recall notice on the CPSC web site, or call their hotline at (800) 638-2772. You can also call the furnace hotline at (877) 347-6456 or visit the recall web site at www.furnaceinspect.com

P-Handle; 32,000 sold at Sears stores nationwide from February through May 2001; UnionTools, Inc., Columbus, Ohio (888) 808-6657 www.uniontools.com

"Prima Pappa," "Roller," and "Martinelli Pappa and Nanna;" 325,000 sold nationwide from June 1996 through October 1999; Peg Perego USA Inc., Ft. Wayne, Indiana (877) 737-3464 www.perego.com

Baby Sitter brand seat pad designed to restrain a child on a chair in a sitting position; 16,000 sold nationwide from October 1998 through May 2001; Basic Comfort Inc., Denver, Colorado (800) 456-8687 www.basiccomfort.com

Models Trunner, Trunner Mid, Trunner Bubble, and Trunner 2000; 425,000 sold nationwide from July 1999 through July 2001; NIKE USA Inc., Beaverton, Oregon (800) 344-6453 www.nikebiz.com

"Hourglass Space Sprout" and "Look for Me Bumblebee," 2.6 million distributed nationwide from January through July 2001 in Kids Meals at Burger King; Burger King Corporation, Miami, Florida and Alcone Marketing Group, Irvine, California (800) 661-9173 www.burgerking.com

Name of Product; Problem

O-Ring Fire Sprinklers; Performance of sprinklers can degrade over time. Sprinkler heads can corrode or minerals, salts and other contaminants in water can affect the rubber O-ring seals which could cause the sprinkler heads not to activate in a fire

Paint Ball Masks; Plastic facemask could crack around the ear cover when hit by a paint ball

Percolators; If thermostat fails, the plastic housing of the percolator can overheat and melt while in use, posing a fire hazard

Portable Butane Stoves; Unit's safety fuel shut-off system could fail to shut off when overheated, flame from the stove flares up, posing a fire hazard

Stuffed Bears; Pieces can detach, presenting a choking hazard. The eyes also are a sharp point hazard

Toy Feeding Sets; Nipple on the toy baby bottle included in these sets could come off, posing a serious choking hazard to small children

Toy Kittens; Toys contain contaminated water that, if contacted, could cause illness

Velcro Wallets; Zipper pull contains lead, which can present a risk of lead poisoning to young children

Winch Kits (attached to All-Terrain Vehicles and used as a vehicle recovery tool); Electrical component of the winch kit, the solenoid, poses a fire hazard when used in this application, even when the vehicle is parked and the winch is not in use

Lot #: Quantity and Distribution; Manufacturer

Over 35 million manufactured from the mid-1970s though 2000; For more information, call the Notice Packet Request Line at (800) 871-3492 or access the program's web site at www.SprinklerReplacement.com; Central Sprinkler Company, an affiliate of Tyco Fire Products LP, Lansdale, Pennsylvania

Proteus Models 50085090201 and 50105090201; 4,000 sold nationwide from March through May 2001; JT USA Inc. Chula Vista, California (800) 587-2246 www.jtusa.com

Atico's Kitchen Gourmet and Prinetti Electric 10 Cup Percolators; 198,000 sold nationwide from January 1996 through January 2001; Atico International USA Inc., Fort Lauderdale, Florida (800) 645-3867

EXPRESS models B23000 or B23001; 3,500 marketed primarily to the boating industry, sold from March 2000 through April 2001; Kenyon International Inc., Clinton, Connecticut (866) 585-7377 www.kenyonmarine.com

Small, medium and large sized bears with plastic eyes and noses; 2,600 sold at stores in tourist areas throughout Arizona, California, Colorado, Montana, Nebraska, Oklahoma, and Texas from July 1997 through February 2001; Inca Imports, Denver, Colorado (800) 279-4040

Set includes a baby bottle, plastic dish, strainer, spoon, juicer, and, in some sets, a funnel; 100,000 sold nationwide from October 1995 through May 2001; Imperial Toy Corp., Los Angeles, California (800) 543-6551

12 inches long, makes a purring noise when petted, six different styles, item number 16400; 238,000 sold nationwide from September 2000 through May 2001; DSI Toys, Inc., Houston, Texas (800) 628-8882 www.dsitoys.com

3.5 by 5 inches in various colors; 55,000 sold nationwide from August 1998 through April 2001; Raymond Geddes & Co. Inc., Baltimore, Maryland (800) 533-6273 www.raymondgeddes.com

A2000, numerous part numbers; 50,000 sold nationwide from November 2000 through May 2001; Warn Industries Inc., Milwaukie, Oregon (877) 277-0539 www.warn.com. The solenoid was manufactured by White-Rodgers.

OUTRAGE, from page 12
of the world."

Intrigued, we investigated the Biochoice web page where we found a link to an article in *Alternative and Complementary Therapies*, the "official journal of the Society for Integrative Medicine," that explained the secret of Biochoice. Biochoice's producers use "hyperimmune egg" technology, a process in which unsuspecting chickens are inoculated with bacteria, undoubtedly the source for their company's logo: a muscle flexing chicken. The eggs, now enriched with protective antibodies to the aforementioned agents, are then "spray dried and formulated into capsules of pure product or a flavored vitamin-, mineral-, and nutrient-rich powder called Biochoice." Not discussed, however, is the likelihood that human digestive enzymes in the gastrointestinal tract would destroy any active antibody that was spared by the spray dry process. Could it be that somewhere in this country thousands of chickens are being exposed to human pathogens for the sole purpose of producing antibodies that may benefit no one other than DCV? All that chicken power for naught!

Unfortunately, dietary supplement producers are able to make such fantastical claims without adequate supervision by the Food and Drug Administration (FDA). The 1994 Dietary Supplement Health Education Act (DSHEA) explicitly allows producers and distributors of dietary supplements to make "structure and function" claims *without* FDA evaluation. This means that DCV can legally say that

Biochoice "balances and supports the immune system," but cannot claim that Biochoice cures immunologic disease. Perhaps the difference is obvious to the supplement manufacturer's lawyer or federal regulators, but it is a point likely to be glossed over by desperate AIDS patients looking for a cure. These minor distinctions are easily exploited by disingenuous marketing and slick advertising.

Biochoice is relatively benign compared to the hundreds of supplements that actually contain pharmacologically active ingredients. Weight loss supplements containing ephedra and guarana produce effects similar to amphetamines and have been implicated in adverse events ranging from psychosis and stroke to death. The active compounds in St. John's Wort are able to change the way the liver processes other drugs and can cause severe drug interactions with at least 15 medicines, including oral contraceptives, antidepressants, and immunosuppressants used to ward off rejection of transplanted organs. Already several kidney transplant recipients have lost their new kidneys due to the inhibitory effect of St. John's Wort on the anti-rejection drug cyclosporin. Every day that passes without adequate regulation of dietary supplements places more people at risk for lethal drug interactions or direct toxicity from the supplements themselves.

DSHEA has provided the makers of Biochoice and other unscrupulous dietary supplement manufacturers with a shield against false claim liability. The FDA has been made to crouch, ham-

strung by a restrictive law that was strongly supported by the so-called nutraceutical industry. In the meantime, the supplement trade has grown from a \$3.7 billion cottage industry in 1992 to a mighty \$15.3 billion dragon in 1999 that markets an unproven and largely unregulated product. The victims are the vast majority of consumers who mistakenly believe that the law protects them from these modern day snake oil peddlers and prevents the sale of potentially lethal food supplements.

What You Can Do

- Call your congressperson and ask that he or she support the repeal of DSHEA. Congressional Switchboard, (202) 225-3121.
- Call the FDA's Center of Food Safety and Applied Nutrition (CFSAN) and demand that Good Manufacturing Practice regulations for the dietary supplement industry be released. Joseph Levitt, Director of CFSAN, (202) 205-4850.
- Carefully evaluate the contents of any dietary supplements that you might purchase. Many of them contain pharmacologically active compounds that can result in injury and even death.
- Remember that a balanced diet with adequate exercise is a proven and safe way to maintain your health.
- Tell your doctor about any dietary supplements you are taking.
- Report any adverse events due to dietary supplements to the FDA at Food and Drug Administration, Office of Emergency Operations, (301) 443-1240; <http://www.fda.gov/medwatch/index.html>

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Crouching Government, Hidden Snake Oil

Recently, outside the Public Citizen offices in Dupont Circle, a fluorescent yellow flyer appeared heralding the arrival of an "Immunity Breakthrough!! **Biochoice**". This "clinically proven" product was said to be "effective against viruses and bacteria" and "directed against micro-organisms of human concern." The claim that Biochoice would "greatly enhance autoimmune response" was off-putting; which if true, Biochoice would *increase* the severity of diseases like lupus and rheumatoid arthritis, an effect the producer presumably did not wish to claim. Nonetheless, we called the number on the flyer to obtain more information about this product.

A few days later, a few samples of Biochoice Immune Support (french vanilla, strawberry and chocolate flavored) arrived in the mail, along with a mysterious tape entitled "This Tape Is

Banned!" by Mark Yarnell. Yarnell is a "presidential distributor" for Legacy For Life, the marketing arm of Biochoice's producer, DCV Inc.

"I have taken control of my aging so that stroke, cancer, dementia, and dippers are never part of my future; so that I can feel eighteen till the day I die," expounds Yarnell in a tone reminiscent of Jimmy Swaggart (in fact Yarnell was a minister prior to joining the multi-level marketing industry—a polite term for pyramid scheme marketing). Yarnell then relates a heart-wrenching story of how his parents died horrible, tortured deaths and how it "could have been prevented" had Biochoice been on the market. "My mom and dad are gone, are yours? Or could you get them on Biochoice right now?," asks Yarnell. Before we could avail ourselves of this life altering therapy the tape automatically changed

sides and the flip-side of Yarnell's scheme was revealed. Side two of the tape, entitled "What Matters Most," makes it clear that what matters most, to Yarnell at least, is the bottom line.

Apparently Mr. Yarnell has been named "the greatest network marketer in the world" by *Upline Magazine*, a multi-level marketing industry publication. This industry is based on the premise that one can make large sums of money by selling a product from home and recruiting distributors who will become a guaranteed revenue resource for the company. In this scheme, Yarnell benefits from the sale of Biochoice because a portion of all sales through his distributor network is kicked back to him. Graciously, this pyramid scheme profiteer invites us to become distributors of Biochoice so that we may join him "on the beaches

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