Loyola Consumer Law Review

Volume 9 | Issue 4 Article 2

1997

Consumer News

Edward G. Lance IV

Philip Tortorich

CONSUMER NEWS

by Edward G. Lance IV
& Philip Tortorich

Popular Diet Drugs Pulled From Market

Manufacturers recently pulled two of the nation's most popular diet drugs — Redux, also known as dexfenfluramine, and Pondimin, also known as fenfluramine — off the market after the Food and Drug Administration ("FDA") discovered new evidence that these drugs may cause serious medical problems. Wyeth-Ayerst Laboratories, which sells Redux and whose parent company, American Home Products, makes Pondimin, agreed to withdraw the drugs in September 1997. The U.S. move prompted the French company, Servier, which sells fenfluramine and dexfenfluramine abroad, to withdraw the drugs worldwide.

Fenfluramine is one-half of the extremely popular "Fen-Phen" diet combination. The other half, phentermine, appears safe when used alone, the FDA said. Although fenfluramine and phentermine were never approved by the FDA for combined use, in 1992, a researcher found the two drugs to be more effective when taken together. Doctors said phentermine, which was approved in 1959 and is the sole remaining FDA-approved prescription diet drug, has only mixed results when used alone.

The FDA has been struggling to determine the risks of dexfenfluramine and fenfluramine since the FDA and the Mayo Clinic first uncovered cases of heart damage in July 1997. The FDA analyzed heart tests on nearly 300 dieters and found almost one-third of the dieters had damaged aortic or mitral heart valves even though they had not shown symptoms of heart damage. Most of the valves leaked blood, which over time could enlarge the heart and seriously weaken it. In contrast to the diet drug users, less than one percent of the general population has damage to their heart valves.

In addition, the FDA analyzed twenty-five dieters who had their hearts tested before and after taking the diet pills. After taking the drugs, approximately one-third were diagnosed with valve damage. The doctors of ninety-nine other dexfenfluramine and fenfluramine users reported to the FDA their patients' symptoms of heart damage, including shortness of breath, chest pain, and swollen ankles. Three of these patients died, and seventeen underwent heart surgery.

Wyeth-Ayerst's spokesman, Dr. Marc Deitch, called the drug withdrawal "the most prudent course of action." However, he said there is no definitive proof that the drugs are the cause of the dieters' medical problems, and Wyeth-Ayerst will study whether obese people are naturally more prone to valve disease. The FDA said no one knows whether patients' valve leakage will heal once they stop using the drugs. Nonetheless, Florida's Dr. Richard Bowen who conducted tests on diet drug users said three of the patients with severe valve problems recuperated after they stopped using the drugs; therefore, he urged dieters not to rush into heart surgery.

In addition to causing damaged heart valves, a study reported in the September issue of the Journal of the American Medical Association indicated that dexfenfluramine and fenfluramine can reduce the production of a key brain-signaling chemical and adversely affect memory, cognition, and moods. This latest finding, compounded with the previous findings of heart problems, revealed that the drugs "present an unacceptable risk," said FDA Acting Commissioner Dr. Michael Friedman.

Lawyers across the country filed over 100 single party and class-action lawsuits within days after the drug makers pulled the two drugs from the market. The complaints allege that the drug makers failed to warn consumers

about the damages caused by the drugs, including heart valve problems, brain damage, and primary pulmonary hypertension, a rare and fatal lung disease. The targets of these lawsuits have been primarily American Home Products and Interneuron Pharmaceuticals, Inc., a company founded by an M.I.T. neurologist who developed Redux. Also named in many of the lawsuits are SmithKline Beechum, maker of phentermine, and some doctors who prescribed the drugs. The FDA likely will not be named as a defendant because of protections given to government entities against liability.

American Home Products stated that it "acted responsibly in the marketing of these products according to FDA guidelines" and is planning a vigorous defense of the lawsuits. Company spokespersons confirmed reports that they were aware of the heart valve problems for months before the FDA's warnings, stating "we were being very cautious and working with the FDA to determine if these [heart valve problems] were isolated incidents or whether this required a higher level of warning." A New York lawyer who has filed four suits related to the diet drugs says that these cases will represent a "model of relatively easy litigation for lawyers." Lawyers around the country have established a network to share information on diet drug litigation, including a newsletter reporting on the latest developments in their cases. Some analysts estimate total damages could exceed the $2.4 billion paid to breast implant recipients.

Lawyers around the country have established a network to share information on diet drug litigation and have distributed a newsletter reporting on the latest developments in their cases.

Wyeth-Ayerst said two million Americans have taken Redux since its introduction in June 1996, and four million have taken Pondimin since 1973. Worldwide use of the two drugs is estimated at 60 million users. Critics have charged that too many non-obese people risked taking diet drugs just to lose a few pounds. The FDA cautioned that "diet and exercise still are the best treatments," and "these medications have never been, by themselves, ways of simply and permanently having people lose weight."

Severely obese patients now will have few medical options. Some doctors say phentermine, the other half of fen-phen, works very well on its own, but other physicians disagree. According to the FDA, so-called "herbal fen-phen," dietary supplements that contain the chemical ephedrine, are not safe alternatives, and a pending FDA proposal would ban them as well.

Until the FDA releases more information on dexfenfluramine and fenfluramine, dieters can return unused portions of the drugs for a refund and should consult their doctors for more information on the effects of these drugs.

"Project Field of Schemes" Created to Combat Investment Scams

Advances in technology and the recent rapid rise in the stock market have led many people to believe that accruing high profits in little time is a realistic expectation. Scam artists are capitalizing on these beliefs, resulting in more than $40 billion each year in windfall from swindles. In an effort to curb these investment scams, over 21 states, the federal government, and two Canadian provinces have joined forces with the Federal Trade Commission ("FTC") and the North American Securities Administrators Association ("NASAA") to create "Project Field of Schemes."

According to Mark Griffin, president of NASAA, swindlers are becoming more creative and are consequently stealing more of innocent investors' money. Griffin stated that NASAA's network of states and Canadian provinces has filed over 50 complaints in connection with Project Field of Schemes.

Teresa Schwartz, deputy director of the Bureau of Consumer Protection for the FTC, commented that investment frauds such as telemarketing and pyramid schemes are epidemic. Not only are these "traditional" types of investments scams widespread, but new scams involving the internet and technology also are becoming quite popular with swindlers.

According to Schwartz, the FTC has filed nine separate actions in connection with Project Field of Schemes. In total, investors have given the defendants in these cases over $150 million to "invest." Schwartz said, "investment frauds account for more dollar injury to consumers than any other area of telemarketing fraud."

For example, two California companies attempted to raise approximately $2 million to reopen a Colorado gold mine via a telemarketing scheme. The promoters convinced investors to purchase unregistered common stock, claiming that investors would receive a 10:1 return on investment. Promoters enticed investors by claiming that the federal government had surveyed the property and confirmed that the mine had gold that could be worth millions. The government survey, in actuality, made no conclusions concerning the existence of gold on the property. Promoters also indicated that investors needed to seize the investment opportunity quickly because companies such as Exxon and Mitsubishi were interested in buying the property; however, neither Exxon nor Mitsubishi ever expressed interest in the property. These misrepresentations led many investors to hand over $15,000 each to participate in the venture.

Scam artists are capitalizing on these beliefs, resulting in more than $40 billion each year in windfall from swindles.

Another scam concerned a film production company which offered investors the opportu-

nity to take part in films being produced by an "award-winning" producer. Promoters sold the scam to investors by claiming that past movies made by the director and producer generated over 500% profit for the investors. The promoters' claims were overstated, and while it was true that the producer actually was in the business of making films, he never won many of the awards as claimed. Further, the profits generated by his movies were substantially less than what the promoters told investors. Finally, the con-artists oversold the number of partnership positions in the film company which reduced the overall profit potential for the investors.

Investors Should Be Aware of New Scams

Telemarketing and pyramid schemes are the swindlers' traditional weapons of choice and have defrauded innocent investors of more money than any other schemes. Now promoters are creating new investment scams that revolve around high technology and the internet.

In one case, the FTC alleged that the defendants lied to investors by claiming a profit potential of over 600% on an alleged "virtual shopping mall." The main idea was to create an online website which would sell products similar to the television version of the Home Shopping Network. However, the con-artist never actually created the website; rather, he simply spent the majority of the consumers' money that he collected on the promise of high return. This left consumers with worthless stock certificates. The swindler also took all of the remaining money, moved it to a shell corporation, and refused to return the money from the shell corporation or to create an operational Internet shopping mall.

Consumers Can Protect Themselves

Many investment promoters use similar tactics in attempting to sway innocent investors to "invest" substantial sums of money. First, promoters closely follow newspaper headlines to determine what types of ventures are likely to appeal to consumers. Second, promoters purport to offer investments with little risk yet high profit potential. Third, many promoters make entirely false claims concerning past investments. Finally, if a promoter sends information in the mail to an investor, it usually consists of high quality materials that give the "illusion of legitimacy and success."

The FTC warns that consumers should be aware of these tactics. In addition, the FTC offers educational pamphlets to help investors learn about potential investment pitfalls and scams.

Contact the FTC's Consumer Response Center at 202-326-3128 for more information.

Consumer Resources: A Guide to Contact Information

The following information has been compiled to give consumers the ability to make informed decisions about many aspects of their lives. These are just a few of the many resources available.

General Information

Experts have prepared over 10,000 reports to assist Congress in passing legislation. These reports are available to you by calling your Congressperson at (202) 224-3121. This number connects you with the Congressional Switchboard. Simply give the operator your zip code, and the operator will connect you with your Congresspersons in either the House of Representatives or the Senate.

Rural Information

The Rural Information Center ("RIC") provides information and referral services to local government officials, community organizations, health professionals and organizations, rural electric and telephone cooperatives, libraries, businesses, and rural citizens working to maintain the vitality of America's rural areas. RIC combines the technical, subject-matter expertise of the United States Department of Agriculture Cooperative State Research, Education & Extension Services with the information specialists and resources of the world's foremost agricultural library, the National Agricultural Library. Contact RIC at:

Rural Information Center
National Agricultural Library
United States Department of Agriculture
10301 Baltimore Blvd.
Beltsville, MD 20705

1-800-633-7701
http://www.nal.usda.gov/ric

Auto Safety

The Auto Safety Hotline ("Hotline") is a subdivision of the United States Department of Transportation. The main goal of the Hotline is to provide safety information to consumers on specific vehicles. In addition, it provides information on child safety seats, safety belts, anti-locking brakes, and insurance discounts. The Hotline also encourages consumers to report problems with their cars so it can track safety problems and recommend recalls. Contact the Hotline at:

National Highway Traffic Safety Administration
United States Department of Transportation
400 7th St., S.W.
Washington, D.C. 20590

1-888-327-4236
http://www.nhtsa.dot.gov

Shopping

In order to protect consumers from the wiles of unscrupulous merchants, the federal government has authorized the Federal Trade Commission ("FTC") to monitor businesses for deceptive practices and fraud. The FTC provides educational pamphlets which help consumers learn about issues such as investing, credit, and purchasing. For more information, contact:

Public Reference
Federal Trade Commission
Room 130
Washington, DC 20580

1-202-326-2222
http://www.ftc.gov

Food and Drug

The Food and Drug Administration ("FDA") provides a wealth of information concerning drugs monitored by the agency. The FDA is also a source of information on prescription drugs, nutrition, and dietary products. The FDA explains the language on product labels — particularly food labels — enabling consumers to learn what ingredients are contained in food and drug products. In addition, the FDA furnishes information on new developments in medical treatments. Contact the FDA at:

Food and Drug Administration
Office of Consumer Affairs
5600 Fishers Lane
Rockville, MD 20857

1-800-532-4440
http://www.fda.gov

Medical Information

The National Health Information Center ("NHIC") is a health information referral service. Consumers and health professionals with health questions can contact the NHIC to receive referrals to over 1,100 health-related organizations. These organizations can provide answers to health questions on a wide variety of topics including: diseases, health statistics, health education materials, health promotion materials, nutrition, exercise, and general health topics. Contact the NHIC at:

National Health Information Center
U. S. Dept. of Health and Human Services
P.O. Box 1133
Washington, DC 20013-1133

1-800-336-4797
http://www.aoa.dhhs.gov/aoa/dir/205.html

Library of Congress

The Library of Congress is one of the world's largest libraries. It has the most complete collection of American works, making it a valuable source of information. The Library offers many resources over the Internet. You can access the card catalog, view exhibits, or even read new bills proposed by the Senate or the House of Representatives. Contact the Library via the internet at:

http://www.loc.gov

Editor's Note

Website addresses were accurate at time of publication.

Continued Reform of the Managed Health Care Arena

President Clinton Announced New Methods of Managing Medicare Providers

On September 15, 1997, President Clinton announced three new programs that will be implemented by the Department of Health and Human Services ("DHHS"). These initiatives will change the way health care providers operate and will protect consumers by making the health care system easier to understand. First, President Clinton announced a moratorium on certifying new health care providers who apply to enter the Medicare program to give the DHHS time to implement new regulations. Second, the President announced the implementation of a renewal procedure for current Medicare providers to ensure that all Medicare providers follow the same regulations. Finally, the President stated that the DHHS will double the number of health care audits that it performs to eliminate incompetent providers.

The first ever moratorium on new Medicare providers, which started on September 15, 1997, will last approximately six months. During this six-month period, the DHHS will enact three new regulations that will prevent certain health care providers from entering the Medicare system. To ensure financial stability, the first new DHHS regulation requires health care providers to post a surety bond of at least $50,000. This regulation will protect consumers from "low-quality" providers who, because of under-capitalization, are unable to meet the financial burdens of problems arising from lawsuits or financial instability. The second new DHHS regulation will require health care providers to have a minimum number of patients before the DHHS will consider enrolling the provider in the Medicare system. By requiring a minimum number of patients, the DHHS will be able to ascertain the ability of the provider to meet the needs of Medicare patients. The third new regulation will require providers to report information about all of the providers' businesses to the DHHS. This third regulation will reduce fraudulent financial transactions by eliminating various loopholes in the current billing process. The DHHS anticipates that these new regulations will be in place by March 1998. Once the new regulations have been promulgated, the moratorium will be lifted and health care providers will be considered for enrollment in light of the new regulations.

This regulation will protect consumers from "low-quality" providers who, because of under-capitalization, are unable to meet the financial burdens of problems that may arise from lawsuits or financial instability.

After the new regulations are in effect, the second stage of reform will commence: current provider renewal. The provider renewal proposal requires current providers to re-enroll in the Medicare system every three years. Under existing regulations, the government can only remove a provider from the Medicare system if the provider is convicted of fraudulent acts. However, with the proposed renewal process, existing medical providers will be

required to comply with the three new DHHS regulations described above to remain in the Medicare system. Also, the government will audit the renewing providers' records and medical practices. The mandatory renewal process will help ensure that only competent health care providers remain in the Medicare system.

To complete the effort of increased quality assurance, the DHHS will double the number of audits it performs. The DHHS will conduct over 1,800 audits, up from approximately 900 audits performed last year. In conjunction with the increased audits, the DHHS also will increase the number of patient claims it reviews. Presently, the agency reviews 200,000 claims annually and estimates this number will increase to 250,000 claims. Patients lodge complaints when they think they have been mistreated by a Medicare provider. The increased number of audits and complaints reviewed should help to ensure that consumers have competent providers in the Medicare system.

President Clinton Encourages Congress to Pass Consumer Health Care Legislation

In addition to the changes in the DHHS regulation, the President encouraged Congress to pass legislation that will better protect health-care consumers. The President has expressed support for four pieces of legislation which are before Congress. One bill would allow women to stay in the hospital for 48 hours following a mastectomy. Another bill would allow doctors to tell patients all of their treatment options before the patients receive treatment. The third bill would prevent discrimination based on genetic testing. The fourth bill would ensure the privacy of patient medical records.

The first piece of legislation the President encouraged Congress to pass concerned mastectomies. The President championed the proposed legislation after learning that some insurance plans required hospitals to discharge women immediately after the procedure. The new bill would allow women to remain in the hospital for as long as their physicians find necessary and would require insurance companies to pay for these hospital stays. This type of legislation, which deals with specific health problems one at a time, has been called "body part by body part" legislation. Critics of "body part" legislation argue that it does not fix the essential problems with health care, it only deals with tangential problems as they arise. Nevertheless, the bill, if passed, would provide a substantial benefit to women undergoing this surgical procedure.

The second type of legislation the President said he endorses concerns "gag clauses" in certain health plans. Under many insurance health plans, doctors are prevented from discussing the entire scope of available treatments with a patient. Many health care plans require that doctors discuss only the cheapest, but not necessarily the most effective, treatments. The proposed anti-gag legislation would give physicians the freedom to discuss all medical treatments available regardless of cost. The President already has banned gag rules in relation to Medicare and Medicaid patients and now is asking Congress to make this advantage available to private health care patients.

A third type of legislation that the President endorsed involves genetic-based discrimination. While advances in genetics enable earlier detection and treatment of disease, some fear that genetic testing could be used to discriminate against a person who is afflicted with a particular disorder. The President is encouraging Congress to enact legislation that would prohibit insurance plans from dropping an insured or increasing an insured's premiums based on his or her genetic information.

Finally, the President asked Congress to pass legislation that would protect a patient's right to privacy concerning medical records. The President recommended that Congress prohibit the use of personal information contained in medical records and punish those who use it

for non-health related purposes. While technology has advanced, privacy safeguards have not. It is too easy to access a person's medical records if the records are stored on an unsecured computer. The President supports legislation that would require health care personnel to secure patient medical information that is stored on computers and allow patients to review their medical records and change any errors.

The President continues his strong advocacy of health care reform through these new initiatives and endorsements of legislation. He anticipates that these reforms will protect consumers and make the health care industry, particularly Medicare, more effective.

In addition to these federal efforts, states also have considered various health care issues. Consumers should contact their state representatives for information on health care proposals.

FTC Charges Pre-Paid Phone Card Marketer with Deceptive Practices

The Federal Trade Commission ("FTC") and the New York State Attorney General's Office jointly filed a federal lawsuit for deceptive practices against a marketer of pre-paid phone cards. The complaint, filed in the U.S. District Court for the Southern District of New York, alleges that the defendants, Dr. Rajesh Kalra, Trans-Asian Communications, Inc., Raj Telekom, Inc., and TransAmerican Systems, Inc., attracted consumers with promises of low-rate, pre-paid phone cards that allow consumers to purchase telephone time in advance. The complaint further alleges that in some cases the consumer never received the card, received a card that did not work, or received a card that became inoperable before the consumer used the entire amount credited to the card.

Defendants advertised pre-paid phone cards on the Internet, in U.S. newspapers and in certain retail outlets. The FTC said Defendants may have deceived hundreds, maybe even thousands of consumers and distributors. Allegedly, when consumers, many of whom had paid more than $100 for the cards, attempted to inquire about cards which either they had not recieved or which did not work, many could not reach the companies because of busy signals or company stall tactics. Other consumers, who were able to lodge their complaints, were allegedly promised replacement cards but allegedly never received them.

Pre-paid phone cards have become an important part of consumers' lives with students away at college, travelers, and households without a long-distance carrier. According to the FTC, as the industry grows, it provides ample opportunities for "quick buck artists" to sell cards to tens of thousands of consumers and then vanish without following through on their promises.

Pre-paid phone cards were common in foreign countries in the 1970s before being introduced to the U.S. market in 1992. According to the International Telecard Association, the industry's trade organization, sales have grown from 15 million cards sold in 1993 to 200 million sold in 1995. Sales are projected to reach 500 million cards and $4 billion in 2000, up from $1 billion in 1995. The FTC is concerned that fraudulent companies and individuals run the risk of discrediting the otherwise honest pay-per-call industry and depriving millions of consumers of a vital and convenient service.