

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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The Invisible Plague: The Rise of Mental Illness from 1750 to the Present

It is exciting for us to review a book written by one of our colleagues and staff members who has been working with us since the Health Research Group began, almost 31 years ago. Dr. E. Fuller Torrey, an internationally known psychiatrist and anthropologist is president of the Treatment Advocacy Center in Arlington, Virginia, has extensive experience treating people with serious mental illnesses such as schizophrenia, manic-depressive illness (bipolar disorder), and major depression and has been a leader in research concerning the causes of these diseases. He is also currently professor of psychiatry at the Uniformed Services University of the United States and executive director of the Stanley Medical Research Institute.

(The Invisible Plague: The Rise of Mental Illness from 1750 to the Present, by E. Fuller Torrey and Judy Miller, published in 2001, is available at major bookstores, from Rutgers University Press (1-800-446-9323), and on the Internet at Amazon.com and BarnesandNoble.com.

The Invisible Plague: The Rise of Mental Illness from 1750 to the Present, combines a meticulously researched history of the sharp increases in the prevalence of serious mental illness with the changing societal reactions to this relatively invisible plague. Interwoven through-

out is a brilliant, unprecedented review of dozens of fictional writers such as Coleridge, Wordsworth, Byron, Shelley, Dickens, Lewis Carroll, Yeats, Joyce, Melville and others, their personal or family history of serious mental illness and its evidence in their writings. The reader is reminded of the comparison to the more well understood and highly visible plagues such as the Black Death or bubonic plague at the start of each chapter in the book by a pair of quotes, the first from a

writer describing mental illness and the second from Daniel Defoe's *A Journal of the Plague Year, 1722*, a similarly well-researched book based on the late-17th century London plague outbreak. Chapter 4, for example, begins with Defoe's:

For it was indeed a dismal time, and for about a Month together, not taking any Notice of the Bills of Mortality, I believe there did not
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die less than 1500 or 1700 a Day, one day with another.

Dickens was remarkably knowledgeable about insanity and depicted insane characters in *The Pickwick Papers*, *Barnaby Rudge*, and *David Copperfield*. He had an extensive library of psychiatric books, was close friends with prominent psychiatrists and members of the Lunacy Commission, which inspected insane asylums, and regularly visited asylums himself. During his 1842 visit to America, Dickens visited two asylums. In 1857, in "The Lazy Tour of Two Idle Apprentices," published with Wilkie Collins, Dickens described a fictional visit to an insane asylum, including a poignant description of patients standing idly on the wards of the asylum:

Long groves of blighted men-and-women trees; interminable avenues of hopeless faces; numbers, without the slightest power of really combining for any earthly purpose; a society of human creatures who have nothing in common but that they have all lost the power of being humanly social with one another.

Lewis Carroll was also intrigued by insanity, partly because his uncle and closest friend was a member of the Lunacy Commission. Carroll testified before an 1859 Royal Commission investigating the increase in insanity. It is well known that Carroll used insanity prominently in such works as *Alice in Wonderland* and *Through the Looking Glass*. What has heretofore not been described is the fact that *The Hunting of the Snark* is an allegorical account of the Lunacy Commission and the death of Carroll's uncle, who was killed by a psychiatric patient (see story at <http://www.richmondreview.co.uk/library/torrey01.html>).

A heroine for the authors of *The Invisible Plague* was the 19th century mental illness crusader, Dorothea Dix. Her visits to asylums for the insane and her advocacy on their behalf had a remarkable impact on awakening people to the plight of

the seriously mentally ill. The best aspects of Dix also characterize an important aspect of Dr. Torrey's work and advocacy in that he has made dozens of unannounced visits to mental illness treatment facilities such as hospitals and clinics, documented the problems and frequently presented these outrages to the public with the result that important improvements sometimes followed.

It is widely assumed that the prevalence of severe psychiatric disorders has remained constant over many centuries. Such disorders are now called schizophrenia, manic-depressive illness (bipolar disorder), and major depression, but until a century ago, they were together simply called insanity. Virtually every federal, state, and county mental health planning group assumes that the prevalence of these disorders is constant, and virtually every textbook of psychiatry assures us that this is so.

A careful analysis of available records, however, suggests that this assumption is wrong. Insanity, a traditional shorthand for severe psychiatric disorders, has increased at least fivefold, as a rate per population, over the past 200 years and may be continuing to increase. This increase in prevalence would help explain the continuing increase of individuals with severe psychiatric disorders among the homeless and in jails and prisons. It would also help explain why the planning of services for these individuals, by both government agencies and managed care companies, has so badly underestimated the need for these services. It has been a recurring theme in planning services in recent years that whatever numbers of severely psychiatrically ill individuals are planned for, the numbers actually needing services are invariably much greater.

What evidence is there that the prevalence of insanity is increasing? According to the authors, there is no single smoking gun that proves it but rather an accumulation of data that all point in the same direction. For example, in the early 19th century, when alarms about increasing insani-

ty were first being sounded, surveys were carried out in the United States as well as in several European countries. These reports uniformly reported that the prevalence of insanity was under 1 case per 1,000 population. By the later years of the 19th century, repeat studies revealed that the prevalence had increased. In the United States, for example, the 1880 census included a special initiative to identify every insane person, including those in hospitals, jails, and workhouses as well as those living at home or elsewhere in the community. It was the most complete enumeration of severely psychiatrically ill individuals ever carried out, before or since, in this country. The census reported that the rate had more than doubled since earlier in the century to 1.8 insane persons per 1,000. By 1955, the prevalence of hospitalized individuals with severe psychiatric disorders, not including those in jails, public shelters, or living at home had reached 3.4 per 1,000. More recent surveys carried out through the Epidemiologic Catchment Area (ECA) survey and National Comorbidity Survey (NCS) suggest that by 1990 the prevalence of severe psychiatric disorders was more than 15 per 1,000.

In addition to such prevalence surveys, incidence surveys of first admissions have also shown a progressive increase. For over a century, state psychiatric hospitals were continuously being built and expanded, and almost immediately filled to overflowing.

The apparent increase in insanity over the past two centuries has been widely explained by psychiatric historians as simply the shunting of troublesome persons from the community to state hospitals. According to the authors, an examination of the historical records, however, does not support this interpretation. These records show that the individuals being hospitalized were not merely "troublesome persons" but rather gave clear evidence of having severe psychiatric disorders. The records also indicate that the building of state

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Update on the Illegal Promotion of Gabapentin (Neurontin)

In the May 2002 issue of *Worst Pills, Best Pills News*, we wrote about gabapentin (NEURONTIN), a drug approved by the Food and Drug Administration (FDA) for treating seizures, a somewhat limited potential market, that was illegally transformed into a "blockbuster" drug with sales approaching \$1.5 billion in 2001. The metamorphosis was accomplished by fabricating a number of uses for the drug that are not FDA approved. These included bipolar disorder, attention deficient disorder, and migraine. The use of a drug that is not approved by the FDA is referred to as an "off-label" use.

The May article was based on *New York Times* reporting and documents from the United States District Court for the District of Massachusetts. This court recently released new documents that for the first time gave the public an inside picture of the lengths to which a pharmaceutical company will go to sell a drug even when there is no evidence that it is safe or effective for the uses being promoted.

This article is based on allegations made in recently released court documents.

Gabapentin was originally produced by Parke-Davis, which was acquired by Pfizer, Inc, of New York in 2000. The only FDA approved use for gabapentin at that time was as an add-on treatment for epilepsy. This is a very limited market with little upward potential for sales. The new court documents allege that Parke-Davis knew that pain management, psychiatric disorders, anxiety and depression were immense markets which, if tapped, could yield enormous profits from sales of gabapentin.

The Decision to Promote Gabapentin for Unapproved Uses

Documents revealed that after an extensive economic analysis, senior officials at Parke-Davis determined that it was not sufficiently profitable for Parke-Davis to obtain FDA approval for gabapentin's alternative uses mentioned above by doing the types of studies necessary for

approval. Instead, company officials developed a strategy that would allow Parke-Davis to avoid the costs of proving gabapentin's safety and effectiveness for these other uses, while allowing the company to enter the lucrative off-label markets.

Taking advantage of a loophole in the FDA's off-label marketing rules, Parke-Davis decided to employ a "publication strategy" that would allow it to promote gabapentin by the massive distribution of publications supposedly written by independent researchers who purportedly described the scientific evaluation of gabapentin. Another advantage of this strategy, from the company's perspective, was that it could be done immediately. There was no need to wait for the results of scientifically conducted clinical trials to determine if gabapentin was actually effective in the treatment of these conditions and submit them to the FDA for approval.

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THE INVISIBLE PLAGUE, *from page 2*

hospitals was in response to a perceived need, that there was much taxpayer resistance to building them, and that families were usually reluctant to have their sick family members hospitalized.

The authors believe that the most likely explanation for the apparent increasing prevalence of insanity is simply that it has been truly increasing. Existing data suggest that this increase has corresponded closely with increasing urbanization. The increase does not appear to be related to social stress, since it appears to have been unaffected by the World Wars or the Great Depression. Rather the increase in insanity is most likely related to the biological antecedents of the disease. These may include

such things as changing exposure to infectious agents (e.g., paralytic polio increased as sanitation improved and young children were thus no longer exposed to its innocuous early childhood form), toxins (e.g., PCB's affect mental development in childhood), or dietary changes. At this point in time, the authors admit that we cannot say for certain *what* might be causing increasing insanity. The important thing is to recognize that insanity appears to be increasing and, they argue persuasively, we must proceed with the necessary studies to ascertain why.

The book is an all-too-rare combination of medicine, history, sociology, anthropology and literature which will play an important role in making all the more visible this plague in our society and hopefully

causing society to move much more effectively to do something about it.

Toward the end of the book, the authors quote from the Final Report of the Joint Commission on Mental Illness and Health's 1961 report:

The way society handles its mentally ill has been the subject of scandalized public attack many times. Humane, healing care for the mentally ill...remains the great unfinished business of the mental health movement...A large proportion of mental patients in the present, as in the past, are not treated in accordance with democratic, humanitarian, scientific and therapeutic principles. We have substantially failed them on all counts.

GABAPENTIN, from page 3
Payment to Doctors to Increase Gabapentin Prescriptions

The company's "publication strategy" required doctors to perform the work normally performed by the company's sales force in order to promote gabapentin. This necessitated that Parke-Davis make tens of thousands of payments to the doctors who would act as a surrogate sales force as well as to the practicing physicians who would receive the message. In other words, adoption of the "publication strategy" required the company to pay physicians to either recommend the prescription of gabapentin or to order gabapentin, in violation of the federal anti-kickback regulations, according to the newly released court documents.

A description of the various programs Parke-Davis used to make these payments to physicians follows.

Consultants' Meetings

A common trick used by Parke-Davis to funnel illegal payments to doctors to encourage them to prescribe gabapentin off-label was through "consultants'" meetings. Under this front, Parke-Davis invited doctors to dinners or conferences and paid them to hear presentations about off-label uses of the drug. Under the guise that these doctors were acting as consultants, Parke-Davis sometimes, but not always, had the doctors sign bogus consulting agreements. At these meetings, the company would give these doctors lengthy presentations relating to gabapentin, particularly regarding off-label usage. Presentations would be made by Parke-Davis employees or physician speakers hired by the company for the purpose of promoting gabapentin, and questions relating to the use of gabapentin would be solicited and answered. At some conferences, the sponsoring organization or Parke-Davis intentionally posed questions to the speakers about off-label use to insure that the doctors were exposed to such information.

Parke-Davis would routinely analyze whether the consultants' meetings were successful in getting doctors to change their prescription writing practices. At some meetings, the so-called consultants were asked directly if they would write more gabapentin prescriptions as a result of the meeting. This question would have been irrelevant if the actual purpose of the meeting was to receive the consultants' advice. Parke-Davis also routinely tracked consultants' gabapentin prescription writing practices after these meetings. Parke-Davis actually analyzed whether the doctors they had paid had in fact written more gabapentin prescriptions after the meeting, using market data purchased from third parties.

Medical Education Seminars

The court documents revealed another platform used by the company to pay kickbacks to doctors to hear off-label promotion of gabapentin. These were programs billed as Continuing Medical Education (CME) seminars. These conferences and seminars were set up to appear to qualify for an exception to the FDA's off-label marketing restrictions which permits doctors to learn about off-label uses of drugs at independent seminars. Such seminars, however, must be truly independent of the drug companies. The companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting who attends the seminars. Parke-Davis retained third party companies to present seminars while in fact retaining control of virtually every aspect of these events. The seminar companies obtained Parke-Davis' approval for all content presented at the seminars. Parke-Davis also paid all expenses, including all the seminar companies' fees.

The company designed and approved the seminars, hand-picked the speakers, approved the seminar presentations, previewed (in most cases) the contents of the seminars prior to a presentation, selected the

attendees based on their ability and willingness to prescribe high quantities of gabapentin, evaluated the presentations to make sure Parke-Davis' "message" was appropriately delivered, black-listed presenters whose presentations were not sufficiently pro-gabapentin, and monitored the prescribing patterns of the physicians who attended.

Grants and Studies

Parke-Davis also made outright payments, in the form of grants, to reward demonstrated gabapentin advocates. Company sales managers identified key doctors who actively prescribed gabapentin or programs which were willing to host gabapentin speakers and encouraged such persons or programs to obtain "educational grants" from the company. Parke-Davis' sales people informed leading gabapentin subscribers that significant advocacy for gabapentin would result in the payment of large grants. These studies did not involve significant work for the physicians. Often they required little more than collating and writing up office notes or records. Parke-Davis frequently hired technical writers to write the articles for which the "authors" had been given grants.

Payments to "Authors" of Ghost-Written Articles

Another method of paying off doctors for backing gabapentin was to pay honoraria for the use of their names on scientific articles intended for publication in various neurology and psychiatry journals, but actually ghost-written by technical writers hired by Parke-Davis, which retained control of all such articles. In 1996 Parke-Davis paid for at least 20 such articles, most of which dealt with off-label use of gabapentin, and were placed according to the company's "publication strategy." Naturally, Parke-Davis paid all expenses in connection with these articles.

Once Parke-Davis and the technical writers conceived the articles, the company and its outside firms attempted to find recognized gabapentin prescribers whose names

could be used as the authors of these articles. In some cases, drafts of the articles were completed even before an "author" agreed to place his or her name on the article. This even occurred in connection with case histories that purported to describe the "author's" personal treatment of actual patients. The "authors" were paid an honorarium of \$1,000 to lend their names to these articles, and also were able to claim publication credit on their professional resumes.

Speakers' Bureau

Parke-Davis also formed a Speakers' Bureau, another tactic to make large and numerous payments to doctors who recommended gabapentin at teleconferences, dinner meetings, consultants meetings, educational seminars, and other events. These speakers repeatedly gave short presentations relating to gabapentin for which they were paid anywhere from \$250 to \$3,000. Some speakers received tens of thousands of dollars annually in exchange for recommending to fellow physicians that gabapentin be prescribed, particularly for off-label uses. Speakers who most zealously advocated gabapentin were hired most frequently for speaking events, regardless of the fact that many of these events were billed as independent medical education seminars where objective information was supposed to be delivered.

Circumstantial and some direct evidence over the years suggests that the behavior of Parke-Davis in the off-label promotion of gabapentin is not isolated, but rather an integral part of the pharmaceutical industry's marketing practices. However, in the Health Research Group's experience, the gabapentin episode is the most complete and well documented case of off-label promotion to ever come

into public view. Because of the detail of fabrications, pay-offs, manipulation, and their effect on gabapentin sales some widely held myths have been shattered.

First, and perhaps the most important to the health and safety of patients, is the belief that doctors are not fooled or influenced by drug company promotional ploys such as gifts to attend medical meetings or expensive meals. The evidence presented in the court documents unambiguously shows that such schemes work. Congress recognized 40 years ago that a large proportion of physicians in everyday practice have neither the training nor the background to differentiate between a useful drug and a harmful one. This is why Congress created a process by which the FDA approves drugs based on validated science—to protect patients from worthless or dangerous drugs. But this says nothing about the apparently substantial number of doctors who accepted kickbacks or bribes to prescribe gabapentin for uses that had not been proven. The memorable words of the inspector in the movie *Casablanca*—"I am shocked—shocked!" come to mind.

Second, the sacrosanct position of peer-reviewed medical literature as a vehicle for scientific exchange has been seriously damaged. The manipulation of information about gabapentin that Parke-Davis exercised would astonish George Orwell. In defense of the many physicians who try their best for patients by diligently keeping up with the medical literature, there is no way for a doctor, scientist, or medical journal editor to know if a study is a fabrication.

There are major differences between the way the FDA reviews clinical trials as part of the new drug approval process and the process used by a peer reviewed medical

journal to accept a study for publication. The FDA bases its drug approval decisions on its own review of the actual data submitted by a manufacturer, not on published journal articles. The agency has a staff of highly trained statisticians who do their own analyses of the manufacturer's data, thus ensuring that approval decisions are based on valid data. Also, the agency has authority to inspect clinical sites in order to keep investigators honest.

On the other hand, the editor of a peer reviewed medical journal must accept the veracity of a study submitted for publication. The editor will send the study to several peer reviewers for their recommendations, but these people have other things to do, and may spend only a few hours on their review. Peer reviewers also must accept the veracity of the underlying data presented in the study. The journal editor has neither the authority nor the resources to inspect clinical sites. This is a system that can be "gamed," as documented in the court papers about Parke-Davis' gabapentin publication strategy.

The message for patients is that if you have been prescribed a drug for an off-label use, the evidence supporting such a use may be good or it may be fabricated. The doctor prescribing the drug may have based the decision to use the drug on an expensive dinner, received a kickback or was bribed, or was simply fooled by a fabricated medical journal article.

What You Can Do

If you or a family member receive gabapentin for a use not listed in the FDA approved professional product labeling, discuss with your doctor the continued need for taking gabapentin.

Product Recalls

July 10—August 7, 2002

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 AND 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 Recall

Name of Drug or Supplement; Class of Recall; Problem

Combivir Tablets (lamivudine 150 mg/zidovudine 300 mg) 60 tablet bottles; Counterfeit: bottles labeled to contain Combivir tablets may contain Ziagen tablets

Lot #: Quantity and Distribution; Manufacturer

Lots 1ZP0848, 1ZP2346, 1ZP2347; 1,756 bottles distributed in Illinois, California, Indiana, New York, Tennessee, Pennsylvania, Maryland and New Jersey; Alliance Wholesale Distributor, Richton Park, Illinois

Name of Drug or Supplement; Class of Recall; Problem

Acyclovir Tablets, 400 mg, Rx only, 100-count bottles; Class III; Tablet crumbling

Lot #: Quantity and Distribution; Manufacturer

Lot 106091A EXP 3/04; 11,483 bottles distributed nationwide; Ivax Pharmaceuticals, Inc., Miami, Florida

Colrex Compound Capsules, 100 capsule bottles, Rx only, (Codeine Phosphate 16 mg, Acetaminophen 325 mg, Phenylephrine Hydrochloride 10 mg, Chlorpheniramine Maleate 2 mg); Class III; Low weight capsules

Lot H000449A; 1,853 bottles distributed in New Jersey; Mikart, Inc., Atlanta, Georgia

Desyrel Tablets (trazodone HCL), 100 mg, Rx only, packaged in bottles of 100 and 1,000 tablets; Class III; Lack of content uniformity—subpotent at 18 month stability

Lots MLS08 and MKC09; Undetermined quantity distributed nationwide; Bristol-Myers Squibb Co., Evansville, Indiana

Esgic-Plus Capsules (Butalbital, Acetaminophen and Caffeine Capsules) 50 mg/500 mg/40 mg, 100 and 500 count bottles, Rx only; Class III; Low weight dosage units

Lots D010201A, D010202A, D010203B, J010602A, J010603B and L010742A; 966/500 ct. bottles and 23,081/100 ct. bottles distributed in Missouri; Mikart, Inc., Atlanta, Georgia

Luvox Tablets (Fluvoxamine Maleate) (scored), 25 mg, 50 mg and 100 mg 100 count bottles and unit dose packages of 100, Rx only; Class III; Inaccuracies in data submitted to the New Drug Application by Solvay (stability)

Numerous lots; 1,503,114 units distributed nationwide; Solvay Pharmaceuticals, Inc., Marietta, Georgia

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>.

Class I Recall

Name of Device; Class of Recall; Problem

LTV Series Ventilators; Capacitor malfunction leading to quit with no alarm

Lot #: Quantity and Distribution; Manufacturer

LTV 1000, Catalog No. 10130. LTV 950, Cat. No. 10950. LTV 900, Cat. No. 10638. LTV 800, Cat. No. 11800; 3,348 distributed nationwide and internationally; Pulmonetic Systems, Inc., Colton, California

Name of Device; Class of Recall; Problem

Contact Lens, Choice A.B. (aberation blocking) Daily wear soft (hydrophilic); Class III; Polymer was undercured, lens may appear cloudy

Lot #: Quantity and Distribution; Manufacturer

Lots 0620, 1016, 1009, 0912, 0924, 0925, 0926, 1025, 1004, 0926, 1015, 0829, 0912, 1023, 0912, 0921, 0717, 0916, 10620, 11025, 10823, 10730; 781 units distributed nationwide; Specialty Ultravision, St. Hubert, Quebec, Canada. Recalled by Ciba Vision Corp., Duluth, Georgia

Disposable Syringe Kits; Class II; May exceed endotoxin specification limits

Ct Tri Pak Sterile, catalog number CTP-200-FLS Lots 29764, 29765, and 29766; 41,650 kits distributed nationwide and internationally; Medrad, Inc., Indianola, Pennsylvania

C O N S U M E R P R O D U C T S

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 www.cpsc.gov.

Name of Product; Problem

All-Terrain Vehicles (ATVs); Mounting-bracket weld on rear hub can come loose, resulting in rear brake failure

Lot #: Quantity and Distribution; Manufacturer

Warrior model, years 1997 and 1998; 14,000 sold nationwide from August 1996 through December 1997; Yamaha Motor Corporation, U.S.A., Cypress, California (800) 88-YAMAHA www.yamaha-motor.com

Bicycle Suspension Seat Posts; Cradle, which attaches to the bicycle seat, can break, posing the risk of falls and serious injury

Thudbuster, black and silver with serial numbers ranging between 10894 and 18710; 7,700 sold nationwide from November 2000 through June 2002; Cane Creek Cycling Components, Fletcher, North Carolina (800) 234-2725 www.canecreek.com

Cigarette Lighters; Lighters do not have child-resistant mechanisms, as required by federal law

Shape of Coca-Cola and Budweiser beverage containers; 1,800 sold in Oregon and Washington from October 2001 through February 2002; Young's J.K. Inc., Portland, Oregon (503) 252-3022

Dive Computer Consoles; Pressure gauge can malfunction and display inaccurate pressure readings. Divers could fail to decompress properly during a dive

U-Line, Smart PRO, Pro ULTRA, Sport PLUS; 1,700 sold nationwide from January through May 2002; Johnson Outdoors Inc., Racine, Wisconsin (800) 382-2211 www.scubapro.com

Name of Product; Problem

Electrical Testing Meters; An incompatible grommet, located in battery compartment can cause meter to provide inaccurate voltage and current readings, creating potential for electric shock or electrocution

Extension Cords; Cords have undersized wires, presenting a shock hazard

Gas Grills; Glass casing of thermometer displays attached to grills can break or shatter

Grass Bag Attachments; Rear-mounted grass bag does not seal properly to the rear door of mower, allowing grass and other debris to be thrown out at the top of the bag, creating a potential injury hazard

Juice Extractors or Juicers; Filter and lid can break apart and project metal and plastic into the air

Mosquito Deleto™ Traps; Propane regulator can leak propane or allow an overflow posing a fire hazard

Pull-along Snails; Eyes on pull toy can detach, posing a choking hazard

Riding Lawn Mowers; Excessive heat, vibrations and wear causes the fuel line to droop over time and rub against the transmission fan, causing the fuel line to be cut, posing a fire hazard

Smatter Spray Foam; If the pressurized can is left in a hot automobile, it can forcefully break apart and cause injury to a nearby consumer

Sorter Toys; Plastic windows on the sorting blocks can break, causing beads to be released, presenting a choking hazard

Toddler Puzzles; Dog puzzle included with both products and the rubber handle on the box of the activity set can tear apart into small pieces and pose a choking hazard

Toy Cars; Child can pull the horn from the steering wheel—small part poses a choking hazard

Lot #: Quantity and Distribution; Manufacturer

Models CM-700 and CM-750; 650 sold nationwide during April 2002; Greenlee Textron, Inc., Rockford, Illinois (800) 435-0786 www.greenlee.textron.com

Brown or white, 5-feet 3-inches long; 190,000 sold at discount stores nationwide from October 1998 through March 2002; STK International Inc., Los Angeles, California (800) 536-7855

Series models 2000 and 3000; 1,800 sold in southeastern and south central U.S. and on firm's web site from July 1999 through July 2002; Flat Rock Grill Co., Powhatan, Virginia (888) 308-7399 www.flatrockgrill.com

Attachments for 19-inch electric walk-behind mowers; 5,000 sold nationwide from January through July 2002; MTD Products Inc., Cleveland, Ohio (888) 848-6038

Model ACJ-250; 117,000 sold nationwide from March 1996 through July 2002; Aroma Housewares Co., San Diego, California (800) 276-6286

Sold as part of the Portable and Back Home Systems, 24-inches high with green or gray base; 136,000 sold nationwide from March through July 2002; The Coleman Company Inc., Wichita, Kansas (800) 257-5299 www.coleman.com

Plan Toys, green, yellow and red wood, 10-inches long; 3,000 sold by internet retailers and mail order catalogs from June 2001 through June 2002; BRIO(r) Corp., Germantown, Wisconsin (888) 274-6869

Hustler "FasTrak"; 1,500 sold nationwide from November 2001 through May 2002; Excel Industries Inc., Hesston, Kansas (800) 395-4757 www.excelhustler.com

Date codes 0492PT to 0952PT, sold in 3 varieties; 296,000 cans sold nationwide from February through June 2002; Jakks Pacific Inc., Malibu, California (800) 554-5516 www.jakkspace.com

Sort & See wood box with shaped blocks; 880 sold nationwide from May through June 2002; Small World Toys, Culver City, California (800) 421-4153

Toddler Tote activity sets and Familiar Things puzzles; 121,000 sold nationwide from January 1999 through July 2002; Lauri Inc., Phillips-Avon, Maine (800) 451-0520

Model 8 Roadster, manufactured before January 2002; 59,000 sold nationwide from January 2001 through July 2002; Radio Flyer Inc., Chicago, Illinois (800) 708-9246 www.radioflyer.com

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Pressure On To Ban Ephedra

This story is reprinted from a transcript of an August 13, 2002 broadcast on the CBS Evening News.

Also called "Ma huang," ephedra is banned by the Olympics committee, the NFL and the NCAA. The U.S. military has recorded injuries and deaths in troops that took ephedra.

At age 35 Capt. Michael McDonald was an up-and-coming Army pilot, and as far as anyone knew, the picture of health. But, as CBS News Correspondent Sharyl Attkisson reports, three years ago McDonald's military career came to a sudden halt. During physical training he collapsed. His heart stopped and rescuers shocked him back to life. "I woke up in a hospital," he says. He didn't even recognize his own wife.

"We laughed because he tapped his mother over his shoulder and said, 'Who's that pretty girl over there?' his wife Margaret remembers. Today, he can't recall his own wedding day, and sometimes can't remember from one minute to the next. McDonald's collapse mystified doctors, but they soon honed in on one factor. "The only thing he was really taking was Ripped Fuel," says Margaret.

McDonald is now suing the makers of Ripped Fuel, one of dozens of dietary supplements containing the herb ephedra, a chemical cousin to speed. It's used to boost energy, build muscle or lose weight. Because it's all-natural, McDonald

thought it was safe. But a growing chorus of critics claims ephedra is not safe.

Also called "Ma huang," ephedra is banned by the Olympics committee, the NFL and the NCAA. The U.S. military has recorded injuries and deaths in troops that took ephedra. Yet it remains wildly popular. The industry brags three billion servings are consumed every year.

That frustrates Raymond Woosley, a pharmacologist hired by the FDA in 1995 to analyze a rash of deaths and heart problems in teenagers who'd taken ephedra. "There's no

screened by the FDA before they're put on the market. And the proof required to force them off the market is much higher than what's necessary to ban a dangerous drug.

The ephedra industry says its own scientific studies show the herb is completely safe. "Consumers should understand that if there were any science indicating that the products were doing what some of the critics claim they're doing, that the industry would pull these products off the market in a heartbeat," says Wes Siegner, of the Ephedra Education Council.

In 2000, the FDA again tapped Woosley to review 135 more cases, this time mostly young women and athletes. "We saw the same thing," he says. "People were dying. People were having heart attacks, strokes that (they) shouldn't have."

Despite the second analysis, the FDA failed to act, in part, Woosley says, under pressure from the powerful ephedra industry. Now, the watchdog group Public Citizen is demanding the FDA ban ephedra. The FDA has put off a decision until at least fall 2002.

No matter what the outcome, McDonald blames ephedra for grounding him from the career he's dreamed of since he was a kid. McDonald says he will never fly again in the military. "My military career was cut short," he says. Ironically cut short, he believes, by an herbal supplement he thought would give him an edge.

*Herbal supplements
are officially
classified as a food
and not a drug*

doubt in my mind that these were being caused by the ephedra products," Woosley says. After reporting his findings to the FDA, Woosley thought the agency would move quickly to restrict ephedra. But that didn't happen.

Part of the problem is that herbal supplements are officially classified as a food and not a drug—meaning they don't have to be proven safe or

CONSUMER PRODUCTS *cont.*

Name of Product; Problem

Vacation Station™ Children's Cooler/chairs: Folding mechanism can pose a crushing, cutting or severing hazard to consumers' fingers

Vinyl Post Kits: Cracks can develop near the base of the posts which can allow the railing to collapse, potentially injuring people on the deck

Lot #: Quantity and Distribution; Manufacturer

Purple or green aluminum; 27,000 given to guests at participating Hilton, Doubletree and Hilton Garden Inn hotels from May through June 2002; Hilton Hotels Corporation, Beverly Hills, California (877) 221-2424 www.hilton.com/families

Royal Colonial pre-built rail system; 1,250 sold in mid-Atlantic region from February through April 2002; Royal Outdoor Products, Woodbridge, Ontario, Canada (877) 467-6925 www.royaloutdoor.com

West Nile Virus Activity

United States, August 8–14, 2002, and Mississippi, July 1–August 14, 2002

The following information comes from *Morbidity and Mortality Weekly Report*, a publication of the Federal Centers for Disease Control and Prevention (CDC)

This report summarizes West Nile virus (WNV) surveillance data reported to the CDC by ArboNET and by states and other jurisdictions as of August 14, 2002.

During 2002, a total of 156 human cases with laboratory evidence of recent WNV infection have been reported from Louisiana (n=85), Mississippi (n=48), Texas (n=14), Alabama (n=three), Illinois (n=two), Florida (n=one), Indiana (n=one), Massachusetts (n=one), and District of Columbia (n=one). Nine deaths have been reported from Louisiana (n=seven) and Mississippi (n=two). Among the 154 patients with

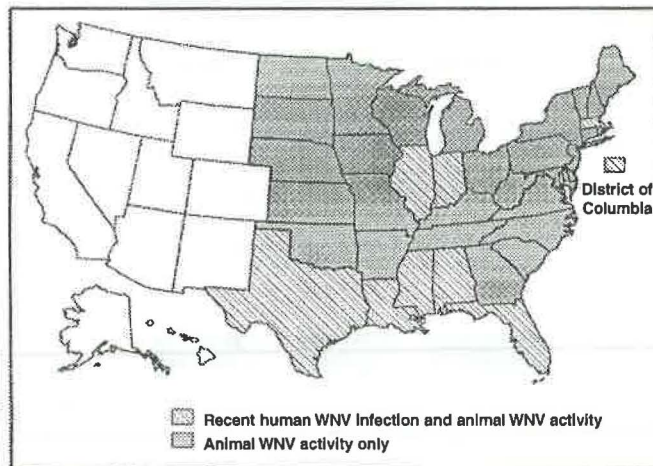
available data, the median age was 54 years (range: 3–94 years), and the dates of illness onset ranged from June 10 to August 13.

In addition, 1,458 dead crows and 1,137 other dead birds with WNV infection were reported from 37 states, New York City, and the District of Columbia (Figure 1); 139 WNV infections in horses have been reported from 15 states (Alabama, Florida, Georgia, Illinois, Kansas, Kentucky, Louisiana, Minnesota, Mississippi, Nebraska, North Dakota, Ohio, South Dakota, Tennessee, and Texas). During 2002, WNV seroconversions have been reported in 62 sentinel chicken flocks from Florida, Nebraska, and Pennsylvania; 787 WNV-positive mosquito pools have been reported from 13 states (Alabama, Georgia, Illinois, Indiana, Massachusetts, Mississippi, Nebraska, New Jersey, Ohio, Pennsylvania, South Dakota, Texas, and Virginia), New York City, and the District of Columbia.

United States

During the reporting period of August 8–14, a total of 44 laboratory-positive human cases of WNV-associated illness were reported from Mississippi (n=20), Louisiana (n=14), Alabama (n=three), Texas (n=two), Florida (n=one), Illinois (n=one), Indiana (n=one), Massachusetts (n=one), and the District of Columbia (n=one). During the same period, WNV infections were reported in 382 dead crows, 310 other dead birds, 52 horses, and 362 mosquito pools.

FIGURE 1. Areas reporting West Nile virus (WNV) activity—United States, 2002*



* As of August 14, 2002

Editor.....Sidney M. Wolfe
Managing Editor.....Phyllis McCarthy
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documented each call received from a consumer.

In order to see if Ellis' allegation was supportable and as an important source of data on the safety of these products, the FDA subsequently asked the Department of Justice "to obtain the consumer adverse reaction reports (AERs) documented by Metabolife." Previous efforts by the DOJ to obtain these reports, filed by Metabolife under a gag order in a California state court ephedra injury case, were thwarted because the judge refused the DOJ request because of the secrecy under which the documents were obtained during discovery from Metabolife in that case. The DOJ subsequently learned from an attorney, according to the July 1 letter to Dan Troy, that in yet another product liability case against Metabolife, the company had "received consumer reports of serious injuries related to the use of Metabolife before Ellis wrote his April 17, 1998 letter to FDA claiming that Metabolife had received no such reports." This is presumably the basis for DOJ's allegation that Ellis may have made false statements to FDA and "thereby, if done willfully, he may have committed a Federal crime."

The DOJ letter goes on to state that "While we were unsuccessful in getting access to the AERS in the California state court, Federal law is much more favorable to granting access to discovery materials when access to those materials will benefit the public health and safety. Gaining access to these AERs will not only give FDA a substantial amount of data with which to study the safety of ephedrine-based dietary supplements, it will also permit FDA and our office to assess the accuracy of Ellis' 4/17/98 letter to FDA and any potential criminal liability Ellis may have for writing that letter. Asking the Alabama court for access to the Metabolife AERS will only require the filing of a motion with the court. My office stands ready to handle making such a request if FDA wishes to seek

access to these AERs." The DOJ underscored the urgency of the July 1 request by referring to the five year statute of limitations that exists between the commission of an alleged crime and the filing of papers concerning criminal prosecution. "The statute of limitations for this crime is five years. Any such charges would have to be brought before 4/17/03 [five years after the letter from Ellis to the FDA]."

Previous Michael Ellis Criminal Record

Metabolife President and co-founder Michael Ellis was convicted in 1990 on a drug-related charge involving the illegal manufacture and sale of methamphetamine which, interestingly, can be produced from ephedra. He pleaded guilty to a felony charge.

Metabolife Political Influence

According to an article in *The Washington Post* (December 25, 2000), Metabolife had, by October 1, 2000, donated \$683,000 to federal campaigns, ranking seventh among all pharmaceutical companies nationwide. In Texas, the site of a battle between ephedra makers and the state health department efforts to more tightly regulate the dietary supplement, Metabolife spent more than \$4 million between 1998 and 2000 to lobby against state regulations. In California, Metabolife ranked fourth in state "soft money" contributions, with \$493,000 in 2000 and a \$100,000 donation to the campaign of Gov. Gray Davis, who subsequently vetoed state legislation imposing restrictions on ephedra use.

More recently, the *Los Angeles Times* (September 6, 2001) reported on the role of the current Bush Administration in suspending enforcement of a Texas regulation to protect athletes and other users of dietary supplements such as ephedra. This occurred, according to the *LA Times*, after telephone calls to Austin, Texas, from one of your senior aides after you were approached by a lawyer representing Metabolife in August

2001.

The lawyer who approached you, Jeff Wentworth, is, according to a May 15, 2000 article in *Time Magazine*, from a San Antonio law firm headed by some of President Bush's closest political associates and was hired by Metabolife when Bush was governor of Texas in order to influence the regulation of ephedra by the Texas State Health Department.

As you are aware, we petitioned HHS to ban the manufacture and sale of all ephedra containing dietary supplements last September. By now, there have been well over 100 deaths reported to the FDA in people using ephedra containing products and, as described in our September 5, 2001, petition to ban these products, there are more reports of death, stroke, arrhythmia, heart attacks, chest pain, seizures and hypertension for ephedra than for all other dietary supplements combined. As long as the FDA delays the inevitable ban of these products, cases will continue to occur.

I urge you to free yourself from the influences that Metabolife and other ephedra makers have had on the Texas Department of Health and their continued massive lobbying in Washington against a ban of these most dangerous "food supplements." Any failure by your department to: a) agree to aggressively pursue a criminal investigation against Metabolife President Michael Ellis for apparently lying to the government; b) to pursue the acquisition of now-sealed court documents concerning serious adverse effects of Metabolife, many likely not to have been reported to the FDA because there is no requirement to do so; and c) to order a ban on the production and distribution of ephedra products will ultimately bring disgrace to you and your department.

The evening this letter was sent, the Department of Justice announced they are starting an investigation into these charges.

Health Research Group Asks for Metabolife President to be Investigated

This letter was sent by Health Letter Editor Dr. Sidney M. Wolfe to Tommy Thompson, Secretary of the Department of Health and Human Services (HHS) on August 15.

This letter strongly urges you to direct FDA Chief Counsel Dan Troy to agree that a criminal investigation of Metabolife be opened, as requested in a July 1, 2002, letter he was sent from Eugene M. Thirolf, Director, Office of Consumer Litigation, U.S. Department of Justice (DOJ). In that letter, the DOJ official states that Michael Ellis, the President of Metabolife, one of the nation's largest producers of ephedrine-based dietary supplements, may have made false statements to the FDA and "thereby, if done willful-

ly, he may have committed a Federal crime, violating 18USC§ 1001 and 1505." The DOJ letter therefore asks if "FDA would like our office to begin investigating this matter." The other request to the FDA in the letter is to agree that the DOJ be given the go-ahead to try to obtain a large number of adverse reaction reports of people using Metabolife, obtained by plaintiffs' attorneys during discovery from the company, which are currently under a gag order in a product liability case pending in Federal court in Alabama.

In a March 18, 1998, Federal Register Notice, the FDA asked for comments concerning the abuse potential, actual abuse, medical usefulness and trafficking of ephedrine. In response, Michael Ellis, President

of Metabolife, wrote a letter to the FDA dated April 17, 1998, in which he contended that ephedrine was being used safely and that there was no widespread pattern of abuse of ephedrine in the U.S. or the world. To support these contentions, Ellis stated in his letter that "Metabolife has never received one notice from a consumer that any serious adverse health event has occurred because of the ingestion of Metabolife 356 [a best selling ephedra-containing diet product]." Ellis also stated that "consequently, since there had been no serious adverse reports [AERs] of any sort, there had been no such reports of overuse or abuse of the product." Ellis described Metabolife's monitoring system, including how Metabolife

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