

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Breast Cancer: New Information About Screening Mammography And Genetics

"Many women remain unaware of the extent to which efforts to achieve breast cancer control through mammography screening may be doing harm as well as good." So begins an October 2003 article in the *Journal of the National Cancer Institute* (JNCI) written by one of the physicians that conducted a pivotal study of screening mammography. [Screening mammography is defined as mammography performed on healthy women without symptoms.] The author pointed to the results of a meta-analysis of randomized trials published in 1997 that showed that screening women aged 40-49 years resulted in an *increase in deaths from breast cancer for the first ten years after beginning screening*. There was a statistically significant two-fold increase in breast cancer deaths after three years of screening. It took a full 16 years of screening to produce a 9% (*non-statistically significant*) decrease in the chance of death from breast cancer. Pondering these results, the author of the article mused: "Are women really given informed consent?"

The U.S. Preventive Services Task Force (USPSTF), a government agency, has also weighed in on the matter, giving only a "fair" rating for the evidence supporting starting screening mammography at age 40. (Their definition of "fair": "evidence

[is] sufficient to determine effects . . . but the strength of the evidence is limited.") Of eight major medical organizations' positions on screening mammography discussed by USPSTF, four recommended starting screening at age 40 and four recommended starting at age 50. The American Cancer Society states that, starting at age 40, "Woman can feel confident about the benefits associated with regular screening mammography." [There are no studies to support this statement, but the ACS seems not to be bothered by facts: they also recommend, on another page of their website, that postmenopausal women take aromatase inhibitors (such as Arimidex, Femara, and Aromasin) to lower their risk of breast cancer, even though no aromatase inhibitors have ever been

approved for this use.]

The controversy about the age at which healthy women should begin to undergo mammography screening was dramatically politicized after a January 1997 consensus conference of experts at the National Institutes of Health (NIH) that concluded that there was not enough information to recommend routine screening for women aged 40 to 49. (A 2002 study found that screening was most effective between 55 and 70 years of age.) As we discussed in our January 2002 *Health Letter* article, the NIH decision unleashed a political storm from radiologists and politicians, with the result that the "scientists" in the United States Senate voted 98-0 to urge the NCI to reject the panel's conclusions, which, in a fit of

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cowardice, they did. This is an example of how politics, and not science, is driving the issue of mammography screening.

The importance of where women get mammograms

A second article, published in the same month (October 2003) in the *Journal of the American Medical Association*, raised further questions about the varying quality of mammography as it is practiced in the U.S. The study compared screening mammography in the U.S. to that in the U.K. looking only at women 50 years of age and older. Recommendations for further evaluation of the mammogram results (i.e., diagnostic imaging, ultrasound, clinical exam, or biopsy) were twice as high in the U.S. for all age groups, as were negative biopsies. Such "false positives" might be tolerable if more cancers were detected. However, the cancer detection rates in the two countries were similar, which means that many U.S. women are being subjected to needless follow-up, including surgery, with its attendant psychological stress for no good reason. Standards, both for the mammography centers and for the radiologists who work in them, are much higher in the U.K., likely explaining the better results obtained in the U.K. The author suggested that U.S. women should go to facilities where "physicians read a large number of mammography examinations, radiologists "devote a large percentage of their practice to

mammography" and where there is "comprehensive auditing . . . of outcomes on a routine basis."

Even though more than 40 percent of clinics were cited for violations between 1997 and 2002 and FDA can levy fines, it had done so only once at the time of an investigative June 27, 2002 *New York Times* article. Perhaps even worse, FDA has minimal authority over doctors, most of whom lack special training and are required to demonstrate only minimal skills in reading mammograms, a type of X-ray said to be the most difficult to analyze.

BRCA1 and BRCA2 mutations as a cause of breast cancer

In about 5% of women, breast cancer is caused by inherited mutations in two genes, known by their abbreviations, BRCA1 and BRCA2.

A paper in the October 24, 2003 issue of *Science* examined the genetics of the BRCA genes in 1008 Ashkenazi Jewish women in New York City who had invasive breast cancer. The authors reached the following conclusions:

- 1) A single mutated copy of either of these genes is all that is required to increase a woman's lifetime risk of breast cancer to 80%;
- 2) Not all women with a mutated gene come from families with a history of breast cancer. This is because the gene can be inherited through males in whom breast cancer is rare (half of the 104 women with BRCA

mutations in this study came from families with no breast or ovarian cancer among mothers, sisters, grandmothers, or aunts);

3) Even with a mutated gene present, environmental (non-genetic) factors can affect the time of onset of cancer. Physical exercise as an adolescent, normal weight at the age of beginning one's period, and lighter weight at age 21, all contributed to a delayed onset of cancer in women with faulty BRCA1 or BRCA2 genes.

The authors concluded that, "exercise and healthy weight in early life are protective against breast cancer after menopause."

The Women's Health Initiative study of over 74,000 women also found that increased physical activity was associated with a reduced risk for breast cancer in women generally, not just those with mutated BRCA genes (the lighter in weight, the greater the effect). Women can take hope from the fact that, while screening mammography may be of only marginal value, especially in women under 50, they have ways to reduce their risk for breast cancer: diet and exercise have great protective value. An alternative to mammography might be a clinical breast exam which a large Canadian study found to be as effective as mammography in reducing breast cancer mortality.

What You Can Do

Current risk assessment tools are
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Product Recalls

November 15—December 15, 2003

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, 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 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.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Actifed Cold & Allergy Tablets (60 mg pseudoephedrine HCl, 2.5 mg triprolidine HCl), 12 count blister/carton; Class III; Misbranding; some of the dosing information and/or ingredient listing information may be missing from the carton.

Comtrex SOFTGELS, Multi-Symptom, Deep Chest Cold, Pain Reliever/Fever Reducer, Expectorant, Cough Suppressant, Nasal Decongestant, 20 and 30 softgel capsule cartons; Class II; Mislabeling: The dosing instructions incorrectly declare a maximum dose of 12 caps.

a) **Don't Be Bald Hair Care Treatment**, Medicated, "The Original Formulas", Net. Wt. 4 oz. Jars; b) BBD 1854 Dandruff Shampoo, For Professional Use Only, Anti-Dandruff Conditioning Shampoo, 8 Fl. Oz. bottles (24 Liters); c) Don't Be Bald, Scalp Stimulate, Organic Formula, 4 Fl. Oz. (118 mL) Jars; Class III; Unapproved New Drug.

Lot #: Quantity and Distribution; Manufacturer

Lot Nos. 24112V Exp. 10/05; 15952V Exp. 6/05; 666,678 distributed nationwide; Pfizer Inc., Morris Plains, NJ

Numerous lots; distributed nationwide and in Trinidad; Bristol-Myers Squibb Co., Hillside, NJ

a) Batch Nos. 55, 64, and 69; b) Batch No. 10269; c) Batch Nos. 020800, 53; 5,580 containers distributed nationwide; Pride and Power, Inc.; Houston, TX

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of little help as they refer to the population of women as a whole and do not take into account individual characteristics. Thus, each woman needs to discuss with her physician her specific risk of breast cancer as well as the benefits and hazards of mammography screening, including the risk of developing and dying from breast cancer, the chance of

successful treatment with or without screening, having a false positive and an invasive breast procedure, and what to do if ductal carcinoma in situ is diagnosed. Those with a family history of breast cancer are candidates for BRCA genetic testing which, if positive, would indicate the need for more frequent mammography and clinical breast exams.

Women can look on the FDA

website for warning letters issued to screening clinics to see if their clinic has been cited for problems in the last two years (http://www.accessdata.fda.gov/scripts/wlcfm/full_text.cfm?full_text=mammography) and check for the Mammography Quality Standards Act certificate that should be displayed prominently in the clinic patient reception area.

Name of Drug or Supplement; Class of Recall; Problem

Kaletra Capsules (Lopinavir/Ritonavir), Each soft gelatin capsule contains: Lopinavir 133.3mg, Ritonavir 33.3mg, 180 capsule bottles, Rx only; Class II; Counterfeit: An unknown number of bottles bearing these lot numbers are counterfeit, in that they have been repackaged, relabeled and/or may contain different strengths or mixed strength tablets differing from their labeled contents and/or bear extended expiration dates, as the source of the repacked and/or relabeled bottles is unknown.

Mexiletine Hydrochloride Capsules, USP, 150 mg, 100 capsule bottles; Class II; Capsule Defects: Split or broken capsules.

Morphine Sulfate (Immediate Release) Concentrated Oral Solution, 20 mg per mL, 30 mL bottle and dropper, Rx Only; Class III; Mislabeling: Correctly labeled Oxydose Oral Concentrate Solution (20mg/1mL) bottles were mispackaged in holding cartons labeled as Morphine Sulfate.

Pert Plus, 2 in 1 Dandruff Control Shampoo plus Conditioner (Pyrrithione zinc 1.0%), 13.5 Fl. Oz. (400 mL), 12 bottles per case; Class III; Subpotent for Pyrrithione Zinc ingredient.

a) **The Skin Culture One Day Peeling Treatment**. 6 Treatments: 6 Cerate 39XXX, 6 Normalizer Applicators, Jars b) Skin Culture 2 Peeling Treatment, Skin Creams, The 6 Day Cosmetic Facial Treatment Kit; c) Skin Culture 3 Peeling Treatment, Skin Creams. The 6 Day Cosmetic Facial Treatment Kit; d) Skin Culture 4 Peeling Treatment, Skin Creams. The 6 Day Cosmetic Facial Treatment Kit; Class III; Misbranding: Product fails to contain declared ingredient Resorcinol and is subpotent for its sulfur ingredient.

a) **Syntes HS (half-strength tablets)**, each tablet contains: esterified estrogens .625mg/Methyltestosterone 1.25mg, Syntho, Rx only, b) Syntest DS (double-strength tablets), each tablet contains: esterified estrogens 1.25 g/methyltestosterone 2.5 mg; 100-tablet bottles; Class II; Subpotency: finished product and/or content uniformity testing.

Tarka Tablets (trandolapril/verapamil HCl ER), 4mg/240mg, 100 count bottles, Rx only; Class III; Extended expiration date-product incorrectly declares expiration date as 12/2004 rather than the correct date of 7/2004.

Vicodin HP Tablets (hydromorphone bitartrate and acetaminophen tablets), 10mg/660mg, 500 count bottles, Rx only; Class III; Mislabeling: Extended expiration date-product incorrectly declares expiration date as 6/06 rather than the correct date of 6/2005.

Zyprexa Tablets (olanzapine), 10 mg and 15 mg 60 tablet bottles, Rx only; Class II; Counterfeit: An unknown number of bottles bearing these lot numbers are counterfeit, in that they have been repackaged, relabeled and/or may contain different strengths or mixed strength tablets differing from their labeled contents and/or bear extended expiration dates, as the source of the repacked and/or relabeled bottles is unknown.

Lot #: Quantity and Distribution; Manufacturer

Lot Nos. 852072E25; 852002E21; unknown number distributed nationwide; Jam Pharmaceutical; Orange, CA

Lot No. 49101M02; Exp. 9/04; 3,352 distributed nationwide; Watson Diagnostic, Inc, Corona, CA

Lot No: 47472; 12,250 bottles Oxydose distributed nationwide; Ethex Corporation, Bridgeton, MO

Lot Nos. 32765395XA and 32885395XA; 1,374 cases distributed nationwide; The Proctor & Gamble Company; Cincinnati, OH

a) Lot Nos. 11132, and 11829; b) Lot No. 27652; c) Lot No. 28132; d) Lot No. 37522; approximately 4,000 jars distributed nationwide; Skin Culture Institute, Inc.; New York, NY

a) Lot Nos. S02D02, S02D03 (Exp. 03/04), S02K02 (Exp. 09/04), S02K03, S02K10 (Exp. 09/04); b) Lot No. S02D01 (Exp. 03/04); 59,693 bottles distributed nationwide; Syntho Pharmaceuticals, Inc., Farmingdale, NY

Lot No. 02TK441016, Exp. 12/04; 7,453 bottles distributed nationwide and in Puerto Rico; Abbott Laboratories HPD/ADD/GPRD; Abbott Park, IL

Lot No. 03VICH5004, Exp. 6/06; 108 bottles distributed nationwide; Abbott Laboratories HPD/ADD/GPRD, Abbott Park, IL

Numerous lots; 547 distributed nationwide; Walsh Southwest, LLC, San Antonio, TX

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 (800) 638-2772. The CPSC web site is www.cpsc.gov.

Name of Product; Problem

Bunk Beds. The bunk beds have openings between the guardrails and in the end structures that are too large. A child's body could slide between the openings and could become trapped by the head, posing a serious strangulation hazard.

Candle Gift Sets. Paint on the exterior surface of the candles could potentially sustain flame posing a potential fire hazard.

Candleholders. Flames from the tealight candle can ignite the candleholder, posing a fire and burn hazard.

Candleholders. Flames from the votive candle can set fire to the rope linking three "sledding" snowmen.

Crazy Bounce Balls. The balls could break apart, posing a choking hazard to young children.

Fleece Pant Sets. Waist drawstring on jacket is longer than 3 inches when the waist is expanded to its fullest width, and there are toggles and knots at the end of the un-tacked drawstring. This can cause the drawstring to catch on protrusions (such as bus doors or handles), potentially causing injury or death if the person is dragged by the vehicle.

Gator Utility Vehicles. Improper crimping of the brake cables could lead to reduced braking capacity, and in some cases, to failure of the foot pedal brake.

Girls' Loungewear. The loungewear failed to meet federal flammability standards for children's sleepwear posing a risk of serious burn injuries to children. The standard requires sleepwear, including loungewear, to be flame resistant and if the garment ignites, the flame must self-extinguish.

Lot #: Quantity and Distribution; Manufacturer

Merit twin-over-twin bunk beds models DLM550, DLM160, and DLM860; 524 distributed nationwide from May 2002 through August 2003; Merit Furniture Distributors, Inc.; Brooklyn, NY; (800) 233-1778; www.meritfurnitureistributors.com

Home Trends Ice Holiday Collection Candle gift sets; 69,804 units of the Snow House Candle gift set; 29,064 units of the Snowman Candle gift set; 62,428 units of the Snowflake Candle gift set sold at Wal-Mart stores nationwide from September 2003 through November 2003; Wal-Mart; Bentonville, AR; (800) 925-6278

Mica Tree Candleholders, copper and mica, in rectangular and square shapes; 800 sold at Coldwater Creek stores nationwide from October 2003 through November 2003; Cape Craftsman; Wilmington, NC and Coldwater Creek, Sandpoint, ID; (800) 262-0040; www.coldwatercreek.com

Snow Play Candleholders; three snowmen sledding down a hill around votive candleholder; 14,338 sold nationwide from July 2003 through October 2003; Home Interiors & Gifts, Inc.; Carrollton, TX; (800) 818-2062

DesignWare(r) Crazy Bounce Balls; 1 1/2-inch multi-colored cluster of green, light green and brick red rubber balls, four balls in each package; 17,000 sold nationwide from November 2002 through August 2003; American Greetings Corp.; Cleveland, OH; (800) 777-4891

Two-piece fleece pant set with long waist drawstring on jacket, pink and royal blue and comes in sizes 4 to 6X; a) 11,187 sold by catalog from August 2003 through October 2003; LTD Commodities; Bannockburn, IL; (866) 736-3654; custserv1@ltdcommodities.com. b) 14,538 sold by catalog from July 14, 2003 through September 30, 2003; abcDistributing; North Miami, FL; (305) 944-6971 c) 3,628 sold by catalog from August 2003 to October 2003; Lakeside Collection; Lincolnshire, IL; (866) 847-4327; customerservice@lakeside.com

Four- to six-wheeled vehicles with cargo boxes; the words "John Deere" and "Gator" appear on the side of the cargo box; 4,600 sold at authorized John Deere dealers nationwide from June 2003 through September 2003; Deere & Company; Moline, IL; (800) 537-8233; www.deere.com

Zutopia Girl's loungewear (15 different styles) in girl's sizes small through extra-large; 5,500 sold in Zutopia stores nationwide from January 2003 through October 2003; The Wet Seal Inc.; Foothill Ranch, CA; (866) 475-2255

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Name of Product; Problem

Hunting Vehicles. The steering connections on the front suspension rack can come loose, posing a risk of the operator losing control of the vehicle.

Jack-In-the-Box Toys. The red bead on the crank of the toy can detach, posing a choking hazard to young children.

Lawn Tractors. The tractor's high/low shift lever could pop out of gear into neutral during operation on steep slopes with attachments, such as a back-hoe or front-end loader installed. This could result in the machine "free-wheeling" until the brake is applied or the transmission is re-engaged, posing a risk of the operator losing control of the tractor.

Mini-flashlights. The mini-flashlight's battery compartment can overheat, presenting a possible burn hazard to consumers.

Mountain Bikes. During heavy braking, the brake tabs on the front forks could break off, possibly causing a loss of control and fall from the bicycle.

Plush Toys. The decorative gem stone on the toy's wings could detach, posing a choking hazard to young children.

Pressure Washers. Overheating, posing a potential for fire and personal injury.

Santa Decorations. The beaded nose on the cloth Santa decoration could detach, posing an aspiration hazard to young children.

Safety and Security Phones. Using the test button can result in the battery being drained without the user's knowledge. Without battery power, the phone is unable to call for assistance in an emergency.

Lot #: Quantity and Distribution; Manufacturer

Lynx Hunting Vehicles, off-road vehicles shaped like golf carts but designed for hunters and sportsman; the name "Club Car" appears on front of vehicle; 158 sold nationwide from May 2003 through September 2003; Club Car Inc.; Augusta, GA; (800) 227-0739

Tin toys have illustrations of bears in various activities on the side, "Schylling" is written on the bottoms; 300 sold nationwide from August 2003 through October 2003; Schylling Associates Inc.; Rowley, MS; (800) 767-8697

Cub Cadet Series 7000 Compact Tractors model numbers 7252, 7254, 7264, and 7304; 2,000 sold nationwide from May 2002 through mid-October 2003; Cub Cadet LLC (Cub Cadet); Cleveland, OH; (888) 848-6038

Provided to consumers as a free gift with the purchase of Aim n' Flame II multi-purpose lighters; the black, plastic flashlight is about 5 1/4-inches long with a thin red ring around the barrel; 448,000 distributed with lighters nationwide from September 2003 through November 2003; SCI Promotion Group LLC; Ontario, CA and Scripto-Tokai Corporation; Rancho Cucamonga, CA; (877) 746-7426

2004 S Works Enduro and 2004 Enduro Expert mountain bikes with 8-inch brake rotors in the front; 250 sold nationwide during September 2003; Specialized Bicycle Components Inc.; Morgan Hill, CA; (800) 432-4144

Flutterby plush toy is a winged horse, pink, blue or purple. 2,300 sold nationwide from July 2002 through November 2002; First & Main Inc.; Lombard, IL; (800) 726-1400; www.firstandmain.com/recall.asp

1500 PSI Mobile Pressure Washers; 38,000 sold nationwide; SK Enterprises, Inc., Newburgh, New York; (800) 367-9444; www.qvc.com

Eight-inch, stuffed, plush Santa decoration with a bean bag-type fill material; 500 sold in Wal-Mart stores nationwide from October 2003 through November 2003; American Greetings Corp., Cleveland, OH; (800) 777-4891

GPS2000 MobilePAL+GPS safety and security phones with serial numbers between 08810948 and 08813447; 1,000 sold nationwide from May 2003 through July 2003; SecureAlert Inc.; Salt Lake City, UT; (800) 584-4176

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Name of Product; Problem

Showerhead Hot Water Heaters. The showerhead hot water heaters are attached to the shower's water supply piping and connected to a household's electrical supply source when central hot water is not available. Undersized wiring prevents this unit from being suitable in wet locations, the rotary switch is not waterproof and the installation instructions fail to recommend an electrical junction box, but instead recommend tape. Another hazard is the plastic enclosure which poses an electrocution and fire hazard.

Sidewalk Chalk. The multi-colored and solid-colored sidewalk chalk contains high levels of lead, posing a risk of poisoning to young children.

Snowmobiles. The red plastic skis used on these 2003 model year snowmobiles could be damaged by UV light exposure. If during off-season storage, the snowmobile was stored with the skis exposed to sunlight, damage may have occurred. If UV damage has occurred, the ski may crack or break during use. If this occurs, it could lead to a loss of control that could result in severe injury or death.

Spas. The motor capacitor, which is a component of the circulating pump, can overheat. This poses a fire hazard.

Television Stands. The television stand can tip over when a television is placed on it, possibly causing injuries to nearby consumers or death to young children.

Weed and Brush Cutters. The operator can come in contact with the rotating blade, even when disengaged, by pulling on the front of the mower deck while the engine is running, posing a serious injury hazard to consumers.

Lot #: Quantity and Distribution; Manufacturer

Model numbers 194310 and 192033; 17,400 sold in Puerto Rico from March 2001 through August 2003; Sintex of Brazil, distributed by Barnett of the Caribbean, of Bayamon, Puerto Rico; (800) 368- 0809; www.e-barnett.com

Chalk is packaged in a clear-plastic, backpack-type carrying case with these words on the label: "Chalk To Go...Totally Me!"; 50,000 packages sold at Toys "R" Us stores nationwide from March 2003 to November 2003; Agglo Corporation, Hong Kong (China), and imported by Toys "R" Us, Inc., Paramus, NJ; (866) 274-6340; www.toysrusinc.com

Snowmobiles' red plastic skis (part number 1703-131) were used on a number of 2003 Arctic Cat Firecat models; 3,700 sold worldwide from June 2002 through December 2003; Arctic Cat Inc.; Thief River Falls, MN; (800) 279-2281; www.arcticcat.com/snowmobiles

Infinity and Lifestyle Spas; 13,000 sold nationwide and in Canada from January 1998 through December 2001; MAAX Spas;Beamsville, Ontario, Canada; (877) 259-0289

Cherry Bentwood television stands, model PTT 22018; 3,500 sold at Circuit City stores nationwide from July 2003 through September 2003; Planet 3; Deerfield, IL; (888) 616-5700

Have an orange or green body and include the W-24 models, sold under the Bachtold Whipper, DR Field & Brush Mower, and B-800 (with a 77-100 deck) brand names; 63,600 sold nationwide from January 1978 through April 2001; Bachtold Brothers Inc., Gibson City, IL; (877) 784-5161

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(through 12/03)

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- A**
- AARP:** V5#6,7;V7#6,8;V8#1,3,4,8;V9#2,5,12;V10#2,9
- Accutane:** V4#5,6;V5#6;V6#7
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OUTRAGE, from page 16

- NIMH rejected funding for a trial to improve the treatment of schizophrenia but funded a study to ascertain how people in Papua New Guinea “think about their own relationships in the real world”;

- NIMH rejected funding for a study of bipolar disorder in children but funded a study of self-esteem in college students.

- NIMH rejected funding for a study to improve the treatment of major depression but funded a study of “sources of friendship” in elementary school students;

- NIMH rejected funding for a study of the causes of postpartum depression but funded a study of the hearing mechanism of crickets;

- NIMH rejected funding for a study of medication noncompliance in individuals with serious mental illnesses but funded a study of social communication among electric fish;

- NIMH rejected funding for research on means of supporting patients being released from psychiatric hospitals but funded a study of preschool children’s understanding of love;

- NIMH rejected funding for research on measuring lithium in the brain but funded a study of how people in Czechoslovakia cope with social change.

In each of the preceding examples, the projects that were rejected would have cost approximately the same amount as those proposed.

Research projects that the Institute chose to fund may be necessary and valid, the report’s authors said, but they should not come at the expense of NIMH’s commitment to studying serious mental illnesses. Many other federal institutions, ranging from the National Science Foundation (NSF) and the National Cancer Institute to

the U.S. Department of Transportation should be funding research currently paid for by NIMH.

“The enormous increase in NIMH’s budget could have been used to advance research and improve the lives of millions of people who have serious mental illnesses or whose family and friends do,” said Sidney Wolfe, M.D., report co-author and director of Public Citizen’s Health Research Group. “NIMH’s failure to ‘stick to its knitting’ is unacceptable.”

Added Mary Zdanowicz, executive director of the Treatment Advocacy Center, “It is nothing less than a national tragedy to misallocate public research dollars that should be used to offer hope of better treatment and possibly a cure for severe mental

illnesses like schizophrenia and bipolar disorder.”

The report’s authors urged Congress to hold hearings and mandate the percentage of the NIMH budget that is devoted to research on serious mental illnesses. They also called for better coordination among the various parts of the National Institutes of Health and the NSF so that research is funded by the appropriate institutes and NIMH strengthens its focus on serious psychiatric disorders.

This report is the third in a series of reports monitoring NIMH’s research. To view the report on the Web, go to www.citizen.org/publications/release.cfm?ID=7293.

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National Institute of Mental Health Fails to Fund Important Mental Health Research

The National Institute of Mental Health (NIMH) continues to underfund scientific research into serious mental illnesses, in spite of the illnesses' enormous economic and societal costs, according to a report released November 19, 2003 by the Treatment Advocacy Center and Public Citizen. NIMH has allocated funds to research irrelevant to its core mission, leaving serious mental illnesses grossly underfunded compared to other diseases.

From 1997 to 2002, the period covered by the report, the NIMH budget doubled from \$661 million to \$1.3 billion. However, the proportion of money spent on research of serious mental illnesses — defined as schizophrenia, bipolar disorder, autism, and severe forms of depres-

sion, panic disorder and obsessive-compulsive disorder — fell by 11 percent, to only 28.5 percent of its budget.

It is estimated that 11.6 million adults in the United States have serious mental illnesses, imposing significant economic and social costs. At any given time, there are approximately 250,000 people homeless or incarcerated who suffer from a serious mental illness. Individuals with a serious mental illness account for 58 percent of total direct costs for all mental illnesses, an amount that includes \$40 billion spent under federal programs such as Medicare. However, only 5.8 percent of the NIMH budget funds "clinically relevant" studies — those that are reasonably likely to improve the treatment

and quality of life for individuals presently affected.

"By not funding research on serious mental illnesses, NIMH isn't simply hurting scientists, it's blocking research that could improve the lives of millions of the most vulnerable Americans," said E. Fuller Torrey, M.D., report lead author and president of the Treatment Advocacy Center's board. "NIMH's refusal to do an adequate amount of research on serious mental illnesses is a federal disgrace and a personal tragedy for individuals affected with these diseases."

NIMH has rejected many valid research proposals and funded others that appear to have no relationship to serious mental illnesses. For example:

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