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SIDNEY M. WOLFE, M.D., EDITOR FEBRUARY 2012 – Vol. 28, No. 2

Florida Sanctions Top Medicaid Prescribers — But Only After a Shove

The following article, by Tracy Weber and Charles Ornstein, was published online by ProPublica on Nov. 17, 2011. It has been reprinted with permission.

At Dr. Huberto Merayo's bustling psychiatry practice in Coral Gables, Fla., hundreds of poor patients on Medicaid walked away each year with prescriptions for powerful antipsychotic drugs.

Merayo's prescriptions for the drugs totaled nearly $2 million in 2009 alone, state records show.

The 59-year-old psychiatrist is also in demand by the makers of these drugs. He's earned more than $111,000 since 2009 delivering promotional talks for AstraZeneca, Eli Lilly & Co. and Pfizer, according to ProPublica's database of drug-company payments to doctors.

This year, Florida regulators finally challenged Merayo's enthusiasm for the pricey drugs, which are used to treat schizophrenia and bipolar disorder. A state review found he hadn't documented why patients were prescribed the pills and had given them to patients with heart ailments or diabetes despite label warnings.

In May, Florida summarily ended his contract with Medicaid. But the action, though decisive, followed years of high prescribing by Merayo, according to Florida's own statistics. And he was booted only after public questioning by U.S. Sen. Charles Grassley, R-Iowa, who had asked states to investigate such cases.

Merayo's situation is one of at least three in which Florida allowed physicians to keep treating and prescribing drugs to the poor amid clear signs of possible misconduct.

> **Medicaid programs across the country have long had evidence that physicians have been prescribing risky drugs in excess and perhaps to the wrong patients.**

The state's responses were marked by head-scratching errors, including the misspelling of Merayo's name on official documents, and lengthy delays.

In another example, Florida allowed Dr. Joseph M. Hernandez of Lake City to continue prescribing narcotic pain pills to Medicaid patients for more than a year after he was arrested and charged in 2010 for trafficking in them.

States pushed to act

Medicaid programs across the country have long had evidence that physicians have been prescribing risky drugs in excess and perhaps to the wrong patients. These prescriptions also racked up huge bills for the programs.

But like Florida, many states did not act on that evidence. Last year, Grassley demanded data from each state about its highest prescribers of pain pills and antipsychotics, and he asked state and federal officials to determine whether the prescriptions written by these doctors were legitimate.

Since then, states including Louisiana, Arizona, Oklahoma and New York have kicked some high-prescribing physicians out of Medicaid. California has temporarily suspended or placed restrictions on 15 to 20 doctors in the past two years for prescribing disproportionately high volumes of painkillers and antipsychotics to Medicaid patients.

Florida has been in sight lines of law enforcement, politicians and government officials because it is widely viewed as a hot spot for health-care fraud. Until recently, the state's lax rules allowed pill mills to proliferate, serving as a hub for painkiller distribution in Florida and beyond.

In April 2008, after much debate over the high number of children being prescribed antipsychotics, Florida began requiring doctors to get preapproval before giving the drugs to kids under age 6 in the Medicaid program. Since then, the number of such prescriptions written for kids has plummeted.

But the same level of scrutiny has not extended to prescriptions written for older Medicaid patients.

Florida health officials declined to discuss specific cases or answer detailed questions about why it has taken so long to investigate and sanction some physicians. State officials also would not

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detail the systems in place to alert them to troubling prescription patterns. The Florida Medicaid program serves about 3.2 million poor children, pregnant women and disabled.

In a statement, the Florida Agency for Health Care Administration said it "employs a variety of detection tools to determine possible overutilization and other departures from peer group or utilization norms."

One prescriber, $4.7 million

When psychiatrist Fernando Mendez-Villamil's role as Florida's top prescriber of antipsychotics became public in 2009, it made the local news. But documents show Florida had known since at least 2004 that Mendez-Villamil, who also heavily prescribed other drugs, was a problem.

It did not bar him from billing Medicaid until last year after Grassley made his prescribing record public.

Mendez-Villamil wrote more than 96,000 Medicaid prescriptions for mental-health drugs from July 2007 to March 2009, more than any other physician in Florida, according to a list compiled by Florida in June 2009 for Grassley.

Mental-health drugs typically include antipsychotics, antidepressants and those to reduce anxiety.

In 2009 alone, Mendez-Villamil prescribed about $4.7 million in antipsychotics to Medicaid patients, according to state records.

Florida had been trying to get Mendez-Villamil to cut back his prescribing for years, according to a March 2010 letter from U.S. Health and Human Services Secretary Kathleen Sebelius to Grassley. The total Medicaid paid for all his prescriptions dropped by more than half from 2004 to 2008, she wrote, "Nonetheless the level of activity remains concerning."

Yet, just months prior to Sebelius' letter, a Florida Medicaid spokeswoman told *The Miami Herald* that Mendez-Villamil's prescriptions didn't "indicate that there is anything improper."

Mendez-Villamil, who was officially terminated "without cause," sued the state last year to have his Medicaid contract reinstated; the case is pending. His lawyer, Robert Pelier, said Mendez-Villamil was "collateral damage" in Grassley's campaign.

"Dr. Mendez-Villamil doesn't benefit by prescribing. He doesn't get paid by the prescription. He doesn't have any interest in generating [prescriptions] other than medication to keep the patient stable," Pelier said.

In a 2010 letter to Grassley, Mendez-Villamil wrote that his prescriptions were justified by his busy practice. He worked at least 60 hours a week and saw patients every 10 to 15 minutes, he said. Most required prescriptions for two or three different drugs, he said, and refills made the numbers add up quickly.

Even though doctors aren't typically paid for prescribing a drug, there are other ways it can be lucrative.

Some doctors require patients to return often for refills, allowing them to bill for office visits. Others dispense drugs in lieu of spending more time with patients, allowing them to squeeze in more appointments. Still others have been arrested or convicted of selling access to their prescription pads.

Top prescriber despite sanctions

Hernandez was Florida's top Medicaid prescriber for the painkiller oxycodone in 2009. In February 2010, he was charged with trafficking in the pills. He kept his license, however, and continued to rank among the state's top Medicaid prescribers.

In July, Hernandez's license was suspended. State officials found that 34 of his Medicaid patients had died — some from drug toxicity — since 2008, according to the state's suspension order.

Moreover, Hernandez previously had been cited for medical lapses. In 2007, the Florida Department of Health barred him from performing surgery,

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saying he was legally blind in his left eye. The agency also fined him $5,000 for leaving a hollow needle or a portion of a catheter in a patient's chest and not telling the patient or the medical staff at the hospital where the patient was transferred. And in 2009, he was fined $1,000 for failing to take a medical recordkeeping course.

Based on Florida's action, the District of Columbia and Illinois revoked his licenses in 2007 and 2008. Florida then fined Hernandez $10,000 for failing to notify the state about the D.C. revocation.

Shelisha Coleman, a Florida Medicaid spokeswoman, said her agency was not told of Hernandez's 2010 arrest until this year — even though state investigators were involved in the case. She could not explain why.

Hernandez's attorney, Gilbert Schaffnit, did not return three calls seeking comment. He told *The Miami Herald* last summer that his client "is very diligent about the way he practices and prescribes, despite what the state would have you believe."

Hernandez could not be reached. His criminal court case is pending.

Dumped from speakers' circuit

In the case of Merayo, ranked second on Grassley's list of Florida's high prescribers of mental-health drugs, the state found a variety of problems with his practice.

Some of Merayo's patients told a reviewer they stopped taking the drugs he prescribed after being granted an exemption from taking the U.S. citizenship test. Immigrants can qualify for citizenship without taking the test if they can prove they are physically or mentally disabled.

A memo from a chief investigator for the Florida Agency for Health Care Administration does not say whether authorities suspect Merayo prescribed the drugs to create evidence of such a disability.

[Dr. Huberto] Merayo's situation is one of at least three in which Florida allowed physicians to keep treating and prescribing drugs to the poor amid clear signs of possible misconduct.

Yet, even when terminating Merayo, Florida had trouble getting it right. The state first informed him that he was being dropped as a Medicaid provider because his license had been suspended — even though it hadn't been. Merayo's license remains clean.

The letter also referred to him as "Humberto" Merayo instead of Huberto.

Medicaid subsequently gave a different reason. Merayo was told his Medicaid contract was being terminated "without cause," something the state can do unilaterally, said his lawyer, Sean Ellsworth.

In a statement provided by Ellsworth, Merayo said he had not been "advised of any allegations involving billing irregularities" by Medicaid. He declined to comment on the allegations in the memo.

Among the companies that paid Merayo as a speaker, Eli Lilly said in an email message that it no longer uses him. AstraZeneca said it doesn't plan to renew his contract for 2012, and Pfizer did not respond to questions.

ProPublica learned about the terminations of Mendez-Villamil and Merayo from Ken Kramer, a Florida Scientologist who runs a website devoted to exposing what he considers abusive practices by psychiatrists. Scientologists believe that the drugs used by psychiatrists "have no basis in science" and create "lifelong drug addicts," according to the Church of Scientology website.

Feds walk a 'fine line'

Officials at the U.S. Centers for Medicare and Medicaid Services, which works with state Medicaid programs and provides part of their funding, said they don't keep track of high prescribers terminated by states. Each state administers its own program.

A partnership between states and the federal government, Medicaid provides health care to millions of low-income patients. Some doctors cater almost exclusively to Medicaid patients.

Angela Brice-Smith, director of the agency's Medicaid integrity program, said her staff is working with some states to ensure the highest prescribers of antipsychotics are using the drugs appropriately, and to educate them if they are not.

"It's sort of a fine line we're treading," she said. "We're not trying to imply that we're practicing medicine, but at the same time trying to share our observations."

High rates of prescriptions do not always mean that physicians are doing something wrong. Some physicians, such as those working in busy urban mental-health centers, may indeed be prescribing properly. Each case needs to be reviewed separately, she said.

Medicaid programs spent more than $27 billion on prescription drugs in 2010, before rebates, according to federal statistics. As state budgets shrink, the pressure on states to "get the bad actors out" is growing, said Matt Salo, executive director of the National Association of Medicaid Directors. "There's only so much you can do with a slap on the wrist."

In an email message, Grassley said states need to use their own records to search for trouble.

"High numbers of prescriptions can indicate a busy medical practice with complicated patient needs, or they can indicate a problem," he said. The government has an obligation to "get to the bottom of anything that looks questionable." ✦

Product Recalls

November 23, 2011 – January 4, 2012

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements (www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Cyclafem 1/35, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Cyclafem 7/7/7, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Emoquette, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Gildess FE 1/20, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Gildess FE 1.5/30, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Orsythia, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Phenobarbital Tablets, USP, 32.4-mg, CIV, 1,000-count bottles. Volume of product in commerce: Unknown. Label mix-up: hydrocodone bitartrate/acetaminophen 10/500 mg may be mislabeled as phenobarbital 32.4 mg. Lot #s: T150G10B, expiration date 08/2013; T120J10E, expiration date 10/2013; and T023M10A, expiration date 12/2013. Vintage Pharmaceuticals LLC dba Qualitest Pharmaceuticals.

Previfem, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Tri-Previfem, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Patheon Inc.

Uprizing 2.0, capsules, 90 count. Volume of product in commerce: 243 bottles. Marketed without an approved NDA/ANDA: FDA analysis found the product to contain a synthetic steroid, making Uprizing 2.0 capsules an unapproved new drug. Lot #s: all lots. Superior Metabolic Technologies.

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Amoxicillin, 250- and 500-mg capsules. Potential for penicillin cross-contamination. Volume of product in commerce: Unknown. Lot #s: Multiple lots affected. Contact your pharmacist. Terry Yon & Associates Inc.

Amoxicillin/Clavulanate K, 875/125-mg tablet. Potential for penicillin cross-contamination. Volume of product in commerce: Unknown. Lot #s: Multiple lots affected. Contact your pharmacist. Terry Yon & Associates Inc.

Amoxicillin Tablets, USP, chewable 250-mg a) 100-count bottle and b) 500-count bottle. Volume of product in commerce: 5,751 bottles. CGMP deviations: Firm's laboratory investigation was not performed in accordance with strict adherence to the "FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #s: a) 35417130A and b) 35417130B. Teva Pharmaceuticals USA Inc.

Cephalexin, 500-mg capsule. Potential for penicillin cross-contamination. Volume of product in commerce: Unknown. Lot #s: Multiple lots affected. Contact your pharmacist. Terry Yon & Associates Inc.

Children's Panadol Chewable Tablets (acetaminophen), 80 mg, 32 count. Volume of product in commerce: Unknown. CGMP deviations: Some of the analytical process validation activities did not contain primary data. Lot #s: Multiple lots affected. Contact your pharmacist. GlaxoSmithKline Inc.

Chlorpap PEH DM, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09G009. TG United Inc.

Chlorpap PSE, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09G002. TG United Inc.

Chlorpap PSE DM, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09G005. TG United Inc.

Etodolac Capsules, USP, 200 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 119087B, expiration date 05/2014. Taro Pharmaceutical Industries Ltd.

Etodolac Capsules, USP, 300 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 119086A, expiration date 02/2014. Taro Pharmaceutical Industries Ltd.

Etodolac Extended-Release Tablets, USP, 400 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #s: 107981A and 107981B, expiration date 10/2013; 106754A, expiration date 11/2013. Taro Pharmaceutical Industries Ltd.

Etodolac Extended-Release Tablets, USP, 500 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 119385A, expiration date 03/2013. Taro Pharmaceutical Industries Ltd.

Etodolac Extended-Release Tablets, USP, 600 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 119395A, expiration date 05/2014. Taro Pharmaceutical Industries Ltd.

Etodolac Tablets, USP, 400 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 119660A, expiration date 05/2014. Taro Pharmaceutical Industries Ltd.

Etodolac Tablets, USP, 500 mg, 100-count bottle. Volume of product in commerce: Unknown. Labeling/incorrect or missing package insert: Certain lots of etodolac immediate-release tablets were packaged with etodolac extended-release inserts. Lot #: 118712B, expiration date 01/2014. Taro Pharmaceutical Industries Ltd.

Fluoxetine Capsules, USP, 10 mg, 1,000-count bottle. Volume of product in commerce: 1,199 bottles. CGMP deviations: Firm's laboratory investigation was not performed in accordance with strict adherence to the "FDA Guidance for Industry Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 35201238A, expiration date 05/2013. Teva Pharmaceuticals USA Inc.

Glyburide Tablets, USP, 5 mg, 1) 30-count bottle, 2) 60-count bottle and 3) 90-count bottle. Volume of product in commerce: 189 packages. Labeling/incorrect or missing package insert: Product is packaged with the incorrect version of the package outset. Lot #s: Multiple lots affected. Contact your pharmacist. Physicians Total Care Inc.

Hydralazine Hydrochloride Tablets, USP, 25 mg, 1,000-count tablets per bottle. Volume of product in commerce: 3,832 bottles. Low tablet weight: There is the potential that some tablets may not conform to weight specifications. Lot #: 315809, expiration date 01/2012. Teva Pharmaceuticals USA Inc.

Leflunomide Tablets, 10-mg, 30-count bottle. Volume of product in commerce: 32,325 bottles. Impurities/degradation products: One lot of this product does not meet impurity specifications. Lot #: 30209292A, expiration date 11/2011. Teva Pharmaceuticals USA Inc.

Levothyroxine Sodium Tablets, USP, 137-mcg (0.137 mg), 1,000-count bottle. Volume of product in commerce: 235 bottles. Subpotent (single ingredient) drug: Out-of-specification results were obtained during routine stability testing at the three-month interval. Lot #: 013911, expiration date 12/2012. Jerome Stevens Pharmaceuticals Inc.

Maxichlor DM, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09M009. TG United Inc.

Maxichlor PEH, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09M011. TG United Inc.

Maxichlor PEH DM, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09M010. TG United Inc.

Maxichlor PSE, immediate-release tablet, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #s: 09F023, 09F024 09F025. TG United Inc.

Maximum Strength Contac Cold + Flu (acetaminophen, 500 mg; chlorpheniramine maleate, 2 mg; and phenylephrine HCl, 5 mg), 30 packets, two caplets per packet. Volume of product in commerce: Unknown. CGMP deviations: Some of the analytical process validation activities did not contain primary data. Lot #s: Multiple lots affected. Contact your pharmacist. GlaxoSmithKline Inc.

Mejoralito, children's chewable tablets (acetaminophen), 80-mg, 32-count bottles. Volume of product in commerce: Unknown. CGMP deviations: Some of the analytical process validation activities did not contain primary data. Lot #s: Multiple lots affected. Contact your pharmacist. GlaxoSmithKline Inc.

Metformin Hydrochloride Tablets, USP, 850 mg, 100-count bottle. Volume of product in commerce: Unknown. Failed USP dissolution: Dissolution trend observed on all stability batches of metformin hydrochloride tablets, USP, 1,000 mg indicates that the batches may not meet specification through shelf life. Lot #s: 1140174, 1140182 and 1140183, expiration date 01/2013. Alkem Laboratories Ltd.

Metformin Hydrochloride Tablets, USP, 1,000 mg, 100-count bottle. Volume of product in commerce: Unknown. Failed USP dissolution: Dissolution trend observed on all stability batches of metformin hydrochloride tablets, USP, 1,000 mg indicates that the batches may not meet specification through shelf life. Lot #s: 1140210, 1140212 and 1140213, expiration date 01/2013; 1140376, 1140377 and 1140378, expiration date 02/2013. Alkem Laboratories Ltd.

Panadol Cold & Flu (acetaminophen, 500 mg; chlorpheniramine maleate, 2 mg; and phenylephrine HCl 5 mg), 16 caplets and two pouch x 50 packets/carton. Volume of product in commerce: Unknown. CGMP deviations: Some of the analytical process validation activities did not contain primary data. Lot #s: Multiple lots affected. Contact your pharmacist. GlaxoSmithKline Inc.

Penicillin VK, 500-mg tablet. Potential for penicillin cross-contamination. Volume of product in commerce: Unknown. Lot #s: Multiple lots affected. Contact your pharmacist. Terry Yon & Associates Inc.

Seroquel (quetiapine gumarate), 300-mg tablet, 60 count. Volume of product in commerce: 16,680 units. Presence of foreign substance(s): Recalled due to the potential presence of inert polyvinyl chloride (PVC) material in the product. Lot #: YB0130, expiration date 01/09/2014. AstraZeneca Pharmaceuticals LP.

Tetracycline Hydrochloride Capsules, USP, 500 mg, 1,000-count bottle. Volume of product in commerce: 1,204 bottles. Presence of particulate matter. Lot #: 34002105B, expiration date 04/2014. Teva Pharmaceuticals USA Inc.

Tetracycline Hydrochloride Capsules, USP, 500 mg, packaged in a) 10-count capsules per blister pack, 10 x 10 blister packs per box; and b) 1,000-count bottles. Volume of product in commerce: 2,572 boxes and bottles. CGMP deviations: Product is being recalled due to out-of-specification particle size. Lot #s: a) 34002104A, expiration date 04/2013 and b) 34002104C, expiration date 04/2014. Teva Pharmaceuticals USA Inc.

Triamterene and Hydrochlorothiazide Capsules, USP, 50/25 mg, 30-, 60- and 100-count bottles. Volume of product in commerce: Unknown. Product recalled due to slow dissolution attributed to CGMP deviations. Lot #s: Multiple lots affected. Contact your pharmacist. Physicians Total Care Inc.

Vitamin D (ergocalciferol capsules), 1.25 mg, 50,000 USP units, 100-count bottle and 50-count bottle. Volume of product in commerce: 131,797 bottles. Presence of foreign substance(s): Paddock Laboratories is recalling Vitamin D Ergocalciferol Capsules because it may contain extraneous foreign matter (glass chip) in product container. Lot #s: Multiple lots affected. Contact your pharmacist. Paddock Laboratories Inc.

Women's Extra-Strength Panadol, Menstrual Relief, Multi-Symptom Caplets (acetaminophen, 500 mg; pamabrom, 25 mg), 24-count bottles. Volume of product in commerce: Unknown. CGMP deviations: Some of the analytical process validation activities did not contain primary data. Lot #s: Multiple lots affected. Contact your pharmacist. GlaxoSmithKline Inc.

The following drugs and supplements were recalled because of the potential for penicillin cross-contamination. Volume of product in commerce: Unknown. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services, LLC.

Ketoconazole, 200-mg tablet.

Ketorolac Tromethamine, 10-mg tablet.

Lacosamide, 50- and 150-mg tablets.

Lactase Enzyme, 3,000-unit caplet and tablet.

Lactobacillin Acidophilus, capsule.

Lactobacillus, capsule and tablet.

Lamivudine, 150-mg tablet.

Lamivudine/Zidovudine, 150/300-mg tablet.

Lamotrigine, 25-, 100-, 150- and 200-mg tablets and 5-mg chewable tablet.

Lamotrigine ER, 100- and 200-mg tablets.

Lanthanum Carbonate, 500- and 1,000-mg chewable tablets.

L-Carnitine, 250-mg capsule.

Leflunomide, 20-mg tablet.

Letrozole, 2.5-mg tablet.

Leucovorin Calcium, 5-mg tablet.

Levetiracetam, 250-, 500- and 750-mg tablets.

Levetiracetam ER, 500-mg tablet.

Levofloxacin, 250- and 500-mg tablets.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Levothyroxine Sodium, 25-, 50-, 75-, 88-, 100-, 112-, 137-, 150-, 175-, 200- and 300-mcg tablets.

Liothyronine Sodium, 5- and 25-mcg tablets.

Lipase/Amylase/Protease, 20/109/68-unit capsule.

Lipase/Amylase/Protease DR, 10,000/55,000/34,000-IU capsule.

Lisinopril, 2.5-, 5-, 10-, 20- and 40-mg tablets.

Lisinopril and Hydrochlorothiazide, 20/25-mg tablet.

Lithium Carbonate, 300-mg capsule.

Lithium Carbonate ER, 300- and 450-mg capsules.

Loperamide HCL, 2-mg capsule.

Lopinavir/Ritonavir, 200/50-mg tablet.

Loratadine, 10-mg tablet.

Lorazepam, 0.5- and 1-mg tablets.

Losartan Potassium, 25-, 50- and 100-mg tablets.

Losartan Potassium-Hydrochlorothiazide, 50/12.5-mg tablet.

Lovastatin, 40-mg tablet.

Loxapine, 5-, 10- and 25-mg capsules.

Lubiprostone, 24-mcg capsule.

Magnesium/Calcium, 71.5/119-mg tablet.

Magnesium Chloride, 64-mg tablet.

Magnesium Chloride DR, 64-mg tablet.

Magnesium/Phosphorus/Calcium, 54/132/175-mg tablet.

Meclizine HCL, 12.5- and 25-mg tablets.

Meclofenamate Sodium, 100-mg capsule.

Medroxyprogesterone Acetate, 2.5-, 5- and 10-mg tablets.

Megestrol Acetate, 20- and 40-mg tablets.

Melatonin, 1- and 3-mg tablets.

Meloxicam, 7.5-mg tablet.

Melphalan, 2-mg tablet.

Memantine HCL, 10-mg tablet.

Mercaptopurine, 50-mg tablet.

Mesalamine CR, 250-mg capsule.

Mesalamine DR, 400-mg tablet.

Metaxalone, 800-mg tablet.

Metformin, 500-mg tablet.

Metformin HCL, 500-, 850- and 1,000-mg tablets.

Metformin HCL ER, 500- and 1,000-mg tablets.

Methazolamide, 50-mg tablet.

Methenamine Hippurate, 1-g tablet.

Methimazole, 5- and 10-mg tablet.

Methocarbamol, 500- and 750-mg tablets.

Methotrexate, 2.5-mg tablet.

Methsuximide, 300-mg capsule.

Methyldopa, 250-mg tablet.

Methylergonovine Maleate, 0.2-mg tablet.

Methylprednisolone, 2- and 4-mg tablet.

Metoclopramide, 10-mg tablet.

Metolazone, 2.5- and 10-mg tablets.

Metoprolol, 50-mg tablet.

Metoprolol Succinate ER, 25-, 50-, 100- and 200-mg tablets.

Metoprolol Tartrate, 25-mg tablet.

Metronidazole, 250-mg tablet.

Mexiletine HCL, 150-, 200- and 250-mg capsules.

Micronized Colestipol HCL, 1-g tablet.

Midodrine HCL, 2.5-, 5- and 10-mg tablets.

Miglitol, 50-mg tablet.

Minocycline Hydrochloride, 50- and 100-mg capsules.

Minoxidil, 2.5- and 10-mg tablets.

Mirtazapine, 15-mg tablet.

Misoprostol, 100- and 200-mcg tablets.

Modafinil, 100- and 200-mg tablets.

Moexipril, 7.5-mg tablet.

Moexipril HCL, 15-mg tablet.

Montelukast Sodium, 10-mg tablet and 4- and 5-mg chewable tablets.

MSM/Glucosamine, 500/500-mg tablet.

Multivitamin/Mineral Aquadeks, tablet.

Multivitamin/Mineral Centrum, tablet.

Multivitamin-Ocular I-Vite, tablet.

Multivitamins/Minerals/Iron/Beta-Carotene (Daily-Vite), tablet.

Multivitamins w/Zinc Adeks, tablet.

Multivitamins w/Zinc Daily-Vite, tablet.

Multivitamin Thera-Plus.

Multivitamin w/Lutein, Centrum Silver, tablet.

Mycophenolate Mofetil, 250- and 500-mg capsules.

Mycophenolate Sodium DR, 360-mg tablet.

Mycophenolic Acid, 180-mg tablet.

Plavix, 75-mg tablet.

Poly Vitamin, chewable tablet.

Poly Vitamin w/Iron, chewable tablet.

Potassium Acid Phosphate, 500-mg tablet.

Potassium Chloride, 8- and 10-mEq capsules.

Potassium Chloride ER, 600- and 750-mg capsules.

Potassium Citrate, 1,080-mg tablet.

Potassium Citrate ER, 5- and 10-mEq tablets.

Potassium Gluconate, 550-mg tablet.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Pramipexole Di-HCL, 0.125-, 0.25-, 0.5-, 1- and 1.5-mg tablets.
Pravastatin Sodium, 10-, 20-, 40- and 80-mg tablets.
Prazosin HCl, 1-, 2- and 5-mg capsules.
Prednisone, 1- and 20-mg tablets.
Pregabalin, 25- and 75-mg capsules.
Prempro, 0.3/1.8-mg tablet.
Prenatabs RX, tablet.
Prenatal 19, tablet.
Prenatal Low Iron Prenate Plus, tablet.
Prenatal Low Iron Vinate M, tablet.
Prenatal Multivitamin/Mineral, tablet.
Prenatal Multivitamin/Mineral/Folic Acid, tablet.
Prenatal Plus, tablet.
Prenatal Vitamins Trinate, tablet.
Prenavite/Prenatal, tablet.
Preservision, softgel.
Primaquine Phosphate, 26.3-mg tablet.
Primidone, 50- and 250-mg tablets.
Probenecid, 500-mg tablet.
Progesterone, 100- and 200-mg capsules.
Prograf, 0.5-mg capsule.
Promethazine HCl, 25-mg tablet.
Propafenone HCl ER, 225- and 325-mg capsules and 225-mg tablet.
Propantheline Bromide, 15-mg tablet.
Propoxyphene HCl, 65-mg capsule.
Propranolol HCl, 10-, 20- and 80-mg tablets.
Propranolol HCl ER, 80-, 120- and 160-mg capsules.
Propylthiouracil, 50-mg tablet.
Protriptyline HCl, 5-mg tablet.
Pseudoephedrine HCl, 30- and 60-mg tablets.
Pyrazinamide, 500-mg tablet.
Pyridostigmine Bromide, 60- and 180-mg tablets.
Pyridoxine, 25- and 100-mg tablets.
Pyridoxine HCl, 25- and 50-mg tablets.
Pyrimethamine, 25-mg tablet.
Quetiapine Fumarate, 25-, 100- and 300-mg tablets.
Quinapril HCL, 5-, 10-, 20- and 40-mg tablets.
Quinidine Sulfate, 200- and 300-mg tablets.
Quinine Sulfate, 324-mg caplet.
Raloxifene HCL, 60-mg tablet.
Raltegravir, 400-mg tablet.
Ramipril, 10-mg caplet.
Ranexa, 500-mg tablet.
Ranitidine, 75- and 150-mg tablets.
Ranolazine ER, 500-mg tablet.
Rasagiline, 0.5- and 1-mg tablets.
Rena-Vite RX, tablet.
Repaglinide, 0.5-, 1- and 2-mg tablets.
Reserpine, 800-mg tablet.
Reyataz, 100-mg caplet.
Ribavirin, 200-mg tablet.
Riboflavin, 100-mg tablet.
Rifabutin, 150-mg caplet.
Rifampin, 150-, 200- and 300-mg caplets.
Rifaximin, 200-mg tablet.
Riluzole, 50-mg tablet.
Rimantadine HCL, 100-mg tablet.
Risedronate Sodium, 5-, 30- and 35-mg tablets.
Risperidone, 1-, 2-, 3- and 4-mg tablets.
Ritonavir, 100-mg caplet and 100-mg tablet.
Rivastigmine Tartrate, 4.5-mg caplet.
Ropinirole HCl, 0.5-mg tablet.
Ropinirole HCL, 0.25-, 1- and 2-mg tablets.
Rosiglitazone Maleate, 2- and 4-mg tablets.
Rosuvastatin Calcium, 5- and 10-mg tablets.
Saccharomyces Boulardii LYO, 250-mg caplet.
Salsalate, 500- and 750-mg tablets.
Saquinavir Mesylate, 200-mg caplet.
Selegiline HCL, 5-mg caplet.
Selenium, 100- and 200-mcg tablets.
Sennosides/Docusate Sodium, 8.6/50-mg tablet.
Sertraline HCL, 100-mg tablet.
Sevelamer Carbonate, 800-mg tablet.
Sevelamer HCL, 400- and 800-mg tablets.
Sildenafil, 20-mg tablet.
Sildenafil Citrate, 25- and 50-mg tablets.
Simvastatin, 10-, 20-, 40- and 80-mg tablets.
Sitagliptin, 25-, 50- and 100-mg tablets.
Sodium Bicarbonate, 325- and 650-mg tablets.
Sodium Chloride, 1-g tablet.
Sodium Fluoride, 0.5-mg chewable tablet and 1-mg tablet.
Solifenacin Succinate, 5-mg tablet.
Sotalol HCL, 80- and 120-mg tablets.
Spironolactone, 25-mg tablet.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Stavudine, 20- and 40-mg caplets.

Sucralfate, 1-g tablet.

Sular, 25.5-mg tablet.

Sulfadiazine, 500-mg tablet.

Sulfamethoxazole/Trimethoprim, 400/80-mg tablet.

Sulfamethoxazole/Trimethoprim DS, 800/160-mg tablet.

Sulfasalazine, 500-mg tablet.

Sulindac, 150- and 200-mg tablets.

Sumatriptan Succinate, 25-mg tablet.

Sunitinib Malate, 12.5- and 25-mg caplets.

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 CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Arctic Cat All-Terrain Vehicle. The ATV's steering tie-rod can bend, causing loss of control and posing a crash hazard. Arctic Cat Inc., at (800) 279-6851 or www.arctic-cat.com.

Arctic Cat Snowmobiles. The headlamp fuse can fail, disorienting the operator during periods of limited visibility and posing a crash hazard. Arctic Cat Inc., at (800) 279-6851 or www.arctic-cat.com.

Ashland Glass Vase. The glass vases can break or fracture when a consumer picks them up, posing a laceration hazard. Michaels Stores Inc., at (800) 642-4235 or www.michaels.com.

Baby Rattles. The recalled rattles can break into small parts, posing a choking hazard to young children and violating the federal safety requirements for rattles. In addition, the size of the handle on some of the rattles is small enough to enter an infant's mouth, lodge in the throat and cause a choking hazard or lead to bruises and lacerations. Winning Key Manufacturing and Topwin Toys, at (323) 266-8088 or mailbox@shoptdi.com.

Bed Canopy. The connections of the posts to the top rails of the canopy can come apart, allowing components of the canopy to fall and posing an impact hazard to consumers. Pottery Barn Kids, at (855) 662-4114 or www.potterybarnkids.com.

Brookfield Entry Way Tree Sets. The battery box that powers lights on the artificial wreath can overheat, posing a fire hazard. General Foam Plastic Corp., at (855) 277-0085 or www.genfoam.com.

Bugaboo Bee Strollers. The front swivel wheels can lock while the stroller is in motion, causing the stroller to tip and posing a fall hazard. Bugaboo Americas, at (800) 460-2922 or www.bugaboo.com/non-swiveling-wheels.

Can-Am ATVs. The Dynamic Power Steering (DPS) main shaft can crack, and pieces can detach. Those pieces inside the DPS can block gears and cause limited steering ability, posing a loss-of-control hazard, with risk of serious injury or death to the operator. BRP Mexico S.A. de C.V., at (888) 638-5397 or www.can-am.brp.com.

Car Seat Adapter. When the adapter is used on a stroller that also has a wheeled board accessory attached for transporting a standing toddler, and the car seat is positioned so the child faces forward, the car seat can disconnect from the adapter and fall. Bugaboo Americas, at (800) 460-2922 or www.bugaboo.com.

Children's Fleece Robes. These children's robes fail to meet the federal flammability standards for children's sleepwear, posing a risk of burns to children. C.F.L Commercial, at (800) 222-0544 or www.HannaAndersson.com.

Children's Henley Pima Cotton Pajamas. The pajamas fail to meet the federal flammability standards for children's sleepwear, posing a risk of burn injury to children. Bliss Collection LLC, at (866) 846-5295 or www.bellabliss.com.

Children's Pajamas. The pajamas fail to meet the federal flammability standards for children's sleepwear, posing a risk of burns to children. Group Lemur Inc., at (877) 748-6698 or www.petitlem.com.

Circo 17" Children's Travel Cases. The surface coating on the travel cases contains excessive levels of lead, violating the federal lead paint standard. Target Corp., at (800) 440-0680 or www.target.com.

Colorful Hearts Teddy Bears. The teddy bears' eyes could loosen and fall out, posing a choking hazard to children. Build-A-Bear Workshop Inc., at (866) 236-5683 or www.buildabear.com.

Dover Dining Table. The wooden base of the table can collapse, causing the glass tabletop to fall and posing an injury hazard. West Elm, a division of Williams-Sonoma Inc., at (855) 369-4335 or www.westelm.com.

Elliptical Exercise Trainer. The foot plates can detach from the machine during use, posing a fall hazard. Nautilus Inc., at (800) 259-9019 or www.schwinn.com.

Golf Cars. The fuel tank seam can separate and allow fuel to leak, posing a fire hazard. Club Car LLC, at (800) 227-0739, ext. 3580, or www.clubcar.com.

CONSUMER PRODUCTS (continued)

Halloween Projection Flashlights. The flashlights can overheat, blister and melt, posing fire and burn hazards to consumers. Nygala Corp., at (800) 445-5936 or www.flomousa.com.

Hamilton Beach Classic Chrome 2-Slice Toasters. When the toasters are first plugged into the outlets, the heating element can be energized even though the toaster lifter is in the up or off position, which can pose a fire hazard if the toaster is near flammable items. Hamilton Beach Brands Inc., at (800) 576-6600 or www.hamiltonbeach.com.

Handheld Massage Pets. The massager's batteries can leak, posing a burn hazard or skin irritation to consumers. Dongguan City Liwang Battery Co. Ltd., at (866) 290-6191 or www.fsgrecall.com/massagepets.html.

Heath/Zenith and Wireless Command Motion-Sensing Wall Switches. When the switches are in the auto mode and the light is off, a small amount of leakage current passes through the electric circuit, including the socket. If consumers fail to disconnect the power at the circuit breaker and make contact with both terminals inside the socket while replacing the bulbs, there is a risk of an electric shock. HeathCo LLC, at (855) 704-5438 or www.heath-zenith.com/hzproductnotice.

Ice Cream Dippers. When the liquid-filled ice cream scoop is exposed to warm water, the cap and seal at the end of the scoop handle can fly off with substantial force, posing an impact-injury hazard to nearby consumers. The Zeroll Company, at (877) 917-2433 or www.pamperedchef.com/recall/cust_info_collection.jsp.

Keds "Know It All" Girls' Shoe. Ornamental stars on the heel of the shoe can loosen, posing a laceration hazard. Collective Brands Inc., at (800) 365-4933 or www.collectivebrands.com.

Kidgets Animal Sock Top Slippers. The animal's eyes can detach from the slippers, posing a choking hazard to young children. BCNY International Inc., at (800) 547-0359 or www.familydollar.com.

Liebherr Freestanding 30-Inch Wide, Bottom Freezer Refrigerators. The refrigerator's door can detach, posing an injury hazard to consumers. Liebherr-Hausgeraete Lienz GmbH, at (877) 337-2653 or www.liebherr.us.

Naturalizer "Dare" Women's Dress Shoes. The heels of the shoes can lean to either side, posing a fall hazard when worn by consumers. Naturalizer, at (888) 443-2019 or www.naturalizer.com.

Navien Instantaneous or Tankless Water Heaters. An unstable connection can cause the water heater's vent collar to separate or detach if pressure is applied. A detached vent collar poses a risk of carbon monoxide poisoning. Kyung Dong Navien Co. Ltd., at (800) 244-8202 or www.navienamerica.com.

CONSUMER PRODUCTS (continued)

Omni-Heat Lithium-Polymer Rechargeable Batteries. The batteries have a cell defect that can cause overheating and pose a fire hazard. Columbia Sportswear Co., at (800) 622-6953 or www.Columbia.com/Recall.

Rayovac NI-CD Cordless Tool Battery Packs. The replacement battery pack can explode unexpectedly, posing a risk of serious injury to consumers. BatteriesPlus LLC, at (877) 856-3232 or www.batteriesplus.com.

Rechargeable External Battery Case. The battery case's integrated circuit switch can overheat, posing a burn hazard to consumers. Mophie LLC, at (877) 308-4581 or www.mophie.com/exchange.

Rocketfish Model RF-KL12 Mobile Battery Cases for iPhone 3G and 3GS. The battery case can overheat while charging, posing a fire hazard. Best Buy Co. Inc., at (800) 917-5737 or www.bestbuy.com.

Swimwear Set With Inflatable Inner Tube. The inner tube accessory can be pulled over a small child's head, posing a strangulation hazard. Build-A-Bear Workshop, at (866) 236-5683 or www.buildabear.com.

TXT Golf Cars, Cushman Shuttle Vehicles and Bad Boy Off-Road Utility Vehicles. The threaded end of the rack-rod ball joint can break and the ball joint can become displaced, causing the driver to lose steering control. This can result in a crash. E-Z-GO, at (800) 774-3946 or www.ezgo.com.

Wolfgang Puck Electric Reversible Tri-Grill/Griddles. A defect in the electrical wiring of the electric grills/griddles can pose overheating, melting and electrical shock hazards to consumers. YouO Electric Appliances Co. Ltd., at (855) 666-0478 or www.brtgg010-recall.com.

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PUBLICCITIZEN Health Letter

Outrage of the Month!
American Red Cross Violations

There is little dispute that the American Red Cross (ARC) provides many valuable services, including disaster response and community services that help the needy. One of its most well-known functions involves the collection, processing and distribution of blood and blood components. Serious deficiencies in this important function have been the subject of decades of investigations by the Food and Drug Administration (FDA), with repeated findings of widespread, long-standing and dangerous ARC practices.

In 2000, Public Citizen asked that the ARC be held in contempt of court for repeated violations of a 1993 court-monitored Consent Decree ARC had signed with the FDA. Recent violations, according to the FDA, had included "a deficient quarantine system that does not prevent release of unsuitable products; improper release by ARC of cytomegalovirus (CMV)-positive blood products; donors being associated with incorrect histories; [and] inadequate ARC oversight of system problems."

In 2003, a strengthening of the previous Consent Decree was agreed upon, in an effort to further ensure the safety of the nation's blood supply, because of continued violations of many of the important steps of the collection, processing and distribution of blood and blood products. Since that 2003 agreement was signed, ARC has been forced to pay a total of $47 million to the government as a result of hundreds of adverse findings during a series of FDA inspections.

The most recent example of these massive violations, which resulted in a $9.6 million fine, was discovered in a fall 2010 inspection of ARC facilities that documented hundreds of further violations of the 2003 agreement.

These violations included failing to notify health departments when a blood donor has been determined to have infectious diseases, such as HIV, hepatitis B or C, West Nile virus or syphilis; failing to review donors whose blood donations needed to be quarantined in the past; failing to promptly add people with known problems, such as infections, to the national list of deferred donors; and delays in logging donations more than five days after their discovery.

The substandard performance of critical ARC blood-handling functions continues. Too many lives are at risk if the ARC continues violating the important 2003 Consent Decree it long ago agreed to abide by.