



Financial Disclosure Requirements Delayed By Obama Administration

This past April, two key senators, Sens. Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.), sent a letter to the Centers for Medicare and Medicaid Services (CMS) calling on the Obama administration to stop its continued foot-dragging in implementing the long-awaited 2010 Physician Payments Sunshine Act (“Sunshine Act”).

The Sunshine Act mandates increased transparency of the financial relationships between pharmaceutical and medical device companies and the physicians who prescribe and use their products. The act requires pharmaceutical and medical device companies to disclose to the federal government all payments made and gifts given to physicians and teaching hospitals. Once the law is fully implemented, CMS would post the data online, where it would be available to the public.

Hidden drugmaker payouts lead to congressional action

Payments from drug manufacturers to physicians have long remained shielded from public view, despite repeated revelations of doctors concealing extravagant payments they received from pharmaceutical companies. Some of these instances have gained national attention.

One such case involved Charles Nemeroff. Nemeroff was chair of the Department of Psychiatry and Behavioral Sciences at Emory University in 2008, when it was revealed that he had failed to disclose \$1.2 million in payments he received from GlaxoSmith-Kline (GSK), one of the largest drug-makers in the world, while he was the

Pervasive industry-physician relationships are concerning in and of themselves, due to the inherent conflict of interest they create.

lead investigator on a federally funded study of one of GSK’s best-selling anti-depressants, Paxil (the generic form is paroxetine).

The revelations led to his removal as department chair and to his subsequent departure from Emory, in addition to the axing of his \$9.3 million National Institutes of Health federal grant for the Paxil study. Nemeroff was not alone; an investigation and hearings initiated by Grassley revealed numerous cases of other physicians who had lied to their respective academic institutions about their ties to the drug industry.

Physician relationships with medical device companies have similarly been concealed, in some cases, even in the peer-reviewed medical literature. A study released last year showed that over half of the scientific articles authored in 2008 by orthopedic surgeons who made at least \$1 million from any of five orthopedic device makers in 2007 did not disclose their relationships in those articles.

These discoveries and long-standing pressure from advocacy groups spurred the passage of the Grassley-Kohl Sunshine Act two years later in 2010. The legislation mandated that the Obama administration publish guide-

lines outlining the specific requirements for pharmaceutical and medical device company disclosures by October 2011. But, as has been the case with many such regulations during President Obama’s term, the administration stalled, missing this and other key deadlines to implement the act.

This past May, the administration announced the latest delay, revealing that pharmaceutical and medical device companies would not be required to collect payment data until at least 2013, three years after the law’s passage, and gave no indication of when that data would then be made public.

Mutual benefit for Big Pharma and doctors profiting from its largesse

The urgency of the act is clear, given the scale of the financial ties between the drug industry and the doctors who are entrusted by the public as the gatekeepers to its products. Pharmaceutical companies’ financial influence within the medical establishment takes several forms. Most commonly, companies will send a marketing representative to

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physicians' offices to promote a specific drug, often with free lunches or samples in hand — and almost always without the patients' knowledge. Companies also routinely invite doctors to all-expense-paid dinners or symposia, during which they are wined and dined while one of their colleagues promotes that company's drug under the pretense of giving an educational seminar.

Drug manufacturers know that physicians are more likely to heed treatment advice from other doctors than from drug representatives and that the doctors are often too busy or negligent to check this advice against more objective evidence. Doctors who are well-known in their fields, such as Nemeroff, are more likely to be heard and have a wider reach among peers. These "thought leaders," as they are referred to in the industry, are therefore targeted most frequently — and paid the highest sums — by companies to promote their drugs.

These physicians-for-hire are predictably under enormous pressure to conform to company talking points when presenting the drug's benefits and risks to other physicians. Although most physicians paid to promote drugs would balk at the suggestion that the medical guidance dispensed at these talks is biased in favor of the drug, it is self-evident that companies would not keep paying physicians if there were not some perceivable return on investment in the form of more favorable prescription patterns.

Doctors as accomplices in fraud

Such pervasive industry-physician relationships are concerning in and of themselves, due to the inherent conflict of interest they create. But, perhaps not surprisingly, given the largely unregulated environment in which these arrangements operate, they have also too often crossed the line into illegal behavior.

Over the past 20 years, the pharmaceutical industry has emerged as the

biggest defrauder of the federal government under the False Claims Act (FCA) and has paid out at least \$23 billion in FCA and other fines and settlement payouts to the federal and state governments. Physicians have been at the center of much of this fraudulent activity, through such practices as off-label promotion, in which a physician-for-hire promotes a company's medications for uses not approved by the Food and Drug Administration (FDA).

In the largest health fraud settlement ever reached between a pharmaceutical company and the federal and state governments, announced last month, it was revealed that, among other violations, GSK had paid doctors to attend lavish resort conferences and promote the antidepressant Paxil for use in children and adolescents. At the time, GSK knew there was evidence that the drug did not benefit, and actually harmed, this population, causing suicidal thoughts.

And in one of the more sensational revelations to come out of the investigation leading to the settlement, Dr. Drew Pinsky ("Dr. Drew"), the prominent sex therapist who regularly doles out medical advice on his radio show, was implicated by the federal government in promoting another of the company's antidepressants, Wellbutrin, for off-label use as a sex enhancer while receiving hundreds of thousands of dollars in payments from GSK. GSK pleaded guilty to several criminal charges and paid \$3 billion in civil and criminal penalties to the federal and state governments.

Doctors have also been implicated in more egregious "kickback" (bribery) cases, in which they receive money from a pharmaceutical company in return for prescribing that company's drugs. This criminal practice has increasingly come to the fore in recent years, with few repercussions for either of these two parties. Although companies are routinely implicated and fined when these practices come to light (albeit paltry amounts relative to the profits

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generated from such activity), the paid-off doctors have, by and large, escaped scot-free.

This illegal activity, brought to light by recent settlements, is likely just the tip of the iceberg. And in the absence of Sunshine Act implementation, the payments that underlie this criminal behavior remain largely hidden from public view.

Transparency as deterrence

What will be the Sunshine Act's impact if and when it is finally implemented? Transparency is the most obvious immediate benefit and an end in itself. The public would be able to look up such payments received by doctors, allowing patients to make an informed decision as to whether that will affect their own doctor-patient relationships.

But transparency is also a means to an end through its potential deterrent effect. If doctors know that these arrangements will be made public, they might be less inclined to accept a gift or promotional speaking opportunity. In the long run, the act's proponents hope it will ultimately counter the conflict of interest inherent in the subtle quid pro quo at the heart of physician-industry financial relationships. However, whether public disclosure results in fewer payments and, more importantly for patients, less biased prescribing habits depends on many factors, such as the integrity of the collected data, how easily the public can access it and industry compliance.

State "sunshine" laws preceding the Sunshine Act provide a window into the potential impact of the federal law. As of 2007, several states (California, Maine, Minnesota, Vermont and West Virginia) and the District of Columbia had already passed sunshine laws mandating government collection of pharmaceutical-company-to-physician payments. However, the laws varied widely in their requirements, and only two states (Vermont and Minnesota) required public disclosure of those payments as of 2007.

Has your doctor received payments from pharmaceutical companies?

The independent, nonprofit news organization ProPublica publishes a database containing recent payments to physicians from several pharmaceutical companies (to access the database, visit <http://projects.propublica.org/docdollars/>). However, the database, as the authors note, is incomplete. It contains data from only the 12 companies that have a combined 40 percent share of the pharmaceutical market, and not all payments from those companies have been disclosed. The database created through implementation of the Sunshine Act would be more comprehensive and provide some measure of accountability on the part of companies that fail to fully report payments.

In addition, the data that has been made public is often incomplete and difficult to access, as was revealed in a 2007 *Journal of the American Medical Association* study co-authored by physicians at Public Citizen assessing the quality of the public posting of payments in Vermont and Minnesota. The study found widespread underreporting by pharmaceutical companies in Minnesota and copious amounts of missing data in Vermont, largely due to companies invoking "trade secret" concerns to conceal the majority of payments. A more recent 2012 study in the *Archives of Internal Medicine* focusing on Maine and West Virginia reported no significant impact of sunshine laws on prescribing patterns for certain expensive medications, when compared to states without such laws.

Experiences in these states demonstrate the limited impact of a sunshine law in the absence of strong disclosure provisions and robust enforcement to ensure compliance by the industries in question. While the federal Sunshine Act is a good first step in requiring most (but not all) payments to be disclosed in a timely manner, companies can be fined up to \$100,000 for each violation, but up to only \$1 million annually. Such trivial fines will not serve as any sort of deterrent against noncompliance for multibillion-dollar pharmaceutical and medical device companies, especially given the profits generated by these financial relationships.

Increased transparency only the first step

Although the Sunshine Act will make these relationships more transparent and possibly deter certain physicians from entering into such arrangements, it will not end them outright.

The Nemeroff scandal prompted more academic medical centers to ban some financial relationships between the pharmaceutical industry and their physicians on staff. Still, these relationships remain the respectable norm, rather than the exception, for the vast majority of medical schools and private hospitals.

At best, the conflict of interest inherent in these financial arrangements erodes the public's trust in the doctor-patient relationship. At worst, it jeopardizes physicians' objectivity in evaluating the best treatment for their patients. To remedy this fundamental problem and move beyond transparency, federal law should place clear restrictions on — and, in many cases, ban outright — pharmaceutical payouts to physicians. ♦

Public Citizen Fights for an End To Double Standard on Drug-Label Warnings

In June 2011, the U.S. Supreme Court ruled in *PLIVA v. Mensing* that manufacturers of generic drugs cannot be sued for failing to update their labels with new information about potential risks, because federal law prevents them from providing such updates. The ruling did more than affect patients suffering adverse events from generic drugs. It also confirmed the existence of a bizarre gap in the drug safety system, whereby companies who make generic drugs have no responsibility to warn patients about known risks. With this ruling, it is much less likely that generic drug manufacturers will notify consumers about safety problems.

The Supreme Court's ruling is significant because generic drugs make up a large part of the U.S. market. In 2010, generics were used to fill 78 of every 100 prescriptions in the country, and the number continues to grow. The sale of generic drugs has been extremely successful at lowering the cost of health care while maintaining quality and safety. Both brand-name and generic drugs must work the same way, and even the labels are identical.

States have worked to encourage the purchase of generics by passing laws allowing pharmacists to substitute generic drugs when filling prescriptions written for brand-name products. In some states, this substitution is mandatory in cases where a generic is available.

Yet under the current law, manufacturers of generic drugs are not allowed to update product labels when they learn of new risks because the Food and Drug Administration (FDA) rules require generic labels to be the same as brand-name labels. Generic manufacturers must (with very limited exceptions) copy the brand-name label exactly. The generic manufacturer cannot update its own labels even if it determines that the brand-name company's label fails to warn of known risks, has inadequate

Brand-name and generic drugs explained

In the grocery store, a brand-name product is easily identified as a particular brand. Think of Kleenex, Ziploc or Pillsbury. People will often pay a premium for brand-name products because they expect them to be of a higher quality or more dependable than generic brands. Generic products do not have the same name recognition.

The terms "brand name" and "generic" mean something a little different when applied to drugs. A version of a drug that is approved by the Food and Drug Administration first is called a brand-name drug. Any versions approved after the first drug are called generics.

Unlike typical grocery store products, both brand-name and generic drugs could be made by well-known companies with strong brand reputations. In fact, sometimes, the company that makes the first approved version of the drug may also sell a generic version at a lower price. These products are sometimes called "branded generics."

instructions for use or is otherwise inadequate. This can pose a big problem if brand-name drug sales are low and the brand-name company falls behind in updating its label. Consumers then miss important information about safety risks.

Given the prevalence of generics in the drug market, Public Citizen is pressing for change and accountability through FDA regulations or legislation.

New safety risks for old drugs

A generic drug becomes available only after the comparable brand-name drug has been on the market for several years. By that time, some safety risks are already known and included in the labels. Yet safety risks are sometimes discovered years after a drug's initial approval.

Safety risks often come to light long after a drug's approval because a risk may affect only a relatively small number of people or appear many years after a patient first begins taking the drug. The tests that are conducted before a drug enters the market usually

involve a few thousand people or fewer, who take the drug for one year or less. The trials also exclude high-risk populations (including older adults, children, pregnant women and people with more than one disease). Often, rare risks will not be seen in pre-market trials and will emerge only after the drug has been marketed for years to a much broader population.

A 2002 study co-authored by Public Citizen found that half of all black box warnings on drugs introduced between 1975 and 2000 were added by the time the drug had been on the market for seven years. Because of this finding, we stress our Seven-Year Rule: Avoid use of any new drug until seven years after it is first approved, unless it is a rare breakthrough drug that offers a documented therapeutic advantage over older, proven drugs.

However, even after seven years, safety risks can still be revealed or clarified.

For example, fenfluramine was first approved in the U.S. market in 1973 and was used for years as an anti-obesity treatment, often in combination with

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phentermine (a mixture popularly known as Fen-Phen). The safety risks of this popular drug did not become clear until 1997, after researchers identified cases of a rare heart valve problem in women who took Fen-Phen. Manufacturers eventually withdrew fenfluramine and the similar drug dexfenfluramine from the market, following an FDA request.

A drug's label might be updated with new information about risks already seen at the time of the drug's approval. In the case of warfarin (Coumadin, Jantoven), a drug used to prevent blood clots since the 1950s and sold in generic form, the original label included information about an increased risk of bleeding. However, this information was not displayed prominently in a boxed warning. In 2006, the FDA modified the drug's label to include a boxed warning featured at the top of the label. The changes were made after non-FDA researchers conducted a large review of many published articles on warfarin to clearly identify the risks.

These cases illustrate how a drug's risks often do not become apparent until after the drug has been on the market for a number of years, when most consumers are purchasing generic versions of the drugs. If generic drug companies could update their labels, they could share this risk information with consumers sooner.

Brand-name drug manufacturers required to comply

Brand-name manufacturers must monitor the safety of their products by analyzing new safety information and delivering warnings to doctors and patients. State tort law reinforces manufacturers' responsibility to update labels by allowing injured patients a means to seek compensation for injuries and deaths that could have been prevented by better warnings. The threat of an expensive lawsuit forces brand-name companies to be vigilant, monitoring safety risks and making sure their warning labels are up to date.

Yet under the current law, manufacturers of generic drugs are not allowed to update product labels when they learn of new risks because FDA rules require generic labels to be the same as brand-name labels.

Manufacturers of brand-name drugs often have superior information about their products, especially as new risks emerge. This information comes from many sources, including reports on side effects submitted to the manufacturers, as well as manufacturers' post-marketing studies.

In addition to requiring manufacturers to keep their warning labels updated with new risks, the FDA allows brand-name companies to strengthen warnings without prior FDA approval. This is important, because learning about new risks often means conducting additional analysis of the raw data available in adverse event reports and post-market studies.

The FDA currently lacks the capacity to adequately monitor and assess information on drugs that have already been approved, largely because it focuses most of its limited resources on pre-market approval of new drugs. Making manufacturers responsible for the information in their labels helps get information to consumers faster.

Generics take market share but not responsibility to update labels

The FDA rules on identical labels give brand-name manufacturers the responsibility for updating labels. Yet as generics enter the market, sales of the brand-name product tend to dry up, leaving the brand-name company with little interest in analyzing information about new risks.

In 2010, 90 percent of the prescriptions for drugs with generic versions were filled with a generic rather than a brand name. After a patent expires, the decline in brand-name drug sales is dramatic. Within six months of the first generic for a particular drug coming onto the market, 80 percent of

the drug's prescriptions are likely to be filled by generics.

Many brand-name companies simply abandon the brand-name product once competitors arrive. Studies have shown that 20 to 30 percent of all approved drugs are only available in generic form.

If 90 percent of all patients take a generic version of a drug, most serious side effects for that drug will therefore occur in patients taking a generic version. Without pressure on generic manufacturers to analyze and report this information to physicians and consumers, it is difficult for the public to learn about new risks.

Generic manufacturers have the resources to monitor emerging risks. They often invest in expensive and sophisticated testing to prove their products are the same as brand-name drugs, and many spend millions annually on research and development. And like brand-name manufacturers, they are required to report adverse events associated with the use of their products.

In fact, in some cases, the generic product may be sold by the same company that makes the brand-name version (see the shaded box on page 4). The current rules allow a company to avoid the responsibility for updating its labels by shifting sales from its brand-name product to its generic version of the same drug.

Public Citizen's efforts

In August 2011, Public Citizen filed a petition (supported by the American Association for Justice) urging the FDA to review its regulations and allow all manufacturers — brand name and generic — to update their labels with new safety information. The change would increase the safety of generic drugs by improving

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the quality of the labels.

The FDA can revise its regulations to fix this safety gap without action by Congress. However, the problem could also be addressed by amending existing statutes that govern drug labels.

We have endorsed two identical pieces of legislation, both titled the Patient Safety and Drug Labeling Improvement Act, that would accomplish the same goal as our petition to the FDA. The Senate version of the bill (S. 2295) was sponsored by Sen. Patrick Leahy (D-Vt.), and the House of Representatives version (H.R. 4384) was sponsored by Rep. Chris Van Hollen (D-Md.).

The bills were introduced in April of this year and have broad support from the American Medical Association, AARP and Alliance for Justice, as well as organizations representing consumers.

The way forward

Through action from Congress or the

Paving the way for new generic drugs

Before the FDA approves a new drug, the drug must undergo a series of expensive tests to show safety and effectiveness. Until 1984, FDA-approved drugs faced little competition even after their patents expired, because companies that might have manufactured the same drug at a lower price were deterred by the expensive process of having to prove safety and effectiveness to the FDA a second time.

Congress created a solution to this problem in 1984 with the Hatch-Waxman Act, which allows copies of a drug to enter the market more easily once the original drug's patent has expired. The manufacturers of the copies do not have to prove safety and effectiveness all over again, but instead need only show that the copy is the same as the original.

FDA, the double standard of drug-label accountability must be addressed. The growing number of generics used in the U.S. and the waning interest of brand-name manufacturers once generics hit the market point to a gap in updated research information on thousands of drugs.

When the FDA, brand-name compa-

nies and generic companies each have a way of avoiding responsibility to update drug labels, it is patients who are kept in the dark. Generic drug companies have the tools necessary to research and update their products' labels with new information on risks. The FDA should take steps to ensure that they do so. ♦

Are your medicines SAFE?



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HRG Works for You!

Our latest work involves: diet drugs, penalties for drugmakers and illegally marketed devices

The work of Public Citizen's Health Research Group (HRG) doesn't end with its *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses current academic research, government data and information from whistle-blowers to advocate for consumers by:

- petitioning the government to remove unsafe drugs or medical devices from the market, and to require warnings of dangerous side effects on other drugs;
- testifying before government committees and arguing against approval of unsafe or ineffective drugs and medical devices;
- writing letters to government agencies about the adverse effects of drugs and medical devices; and
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **Another Harmful Diet Drug** — 6/26/2012 — After a Food and Drug Administration (FDA) advisory committee voted 18-4 on May 10 that the FDA approve the new diet drug lorcaserin (Lorcaserin), HRG director Dr. Sidney Wolfe urged the FDA not to approve the drug, citing evidence of heart valve damage in people using the drug in clinical trials. Like the many other diet drugs HRG has issued warnings about (Qsymia and Alli among them), lorcaserin showed minimal benefit after a year of exposure, while posing the same adverse effect that led the FDA to ban fenfluramine-dexfenfluramine (Fen-Phen) in 1997.
- **GlaxoSmithKline Settlement a Drop in the Bucket** — 7/2/2012 — Wolfe also issued a statement on the recent GlaxoSmithKline settlement payment of \$3 billion as a result of the drugmaker's guilty plea to illegal off-label promotion of the antidepressants Paxil and Wellbutrin and to concealing evidence from the FDA regarding diabetes drug Avandia. Wolfe stated that because the profits made from such activities are so large, penalties levied against drugmakers in these cases do not act as deterrents. He called for more meaningful penalties and the prospect of jail time for the company executives responsible.
- **FDA Knew of Illegally Marketed Medical Device** — 7/18/2012 — Wolfe and HRG deputy director Dr. Michael Carome urged the FDA to expedite its investigation into a California company illegally marketing the widely used LipoTron medical device as a therapeutic massager, when it is actually used for the removal of fat and other purposes. With information from documents obtained from an FDA whistle-blower, the HRG letter stated that the FDA failed to take action after the illegal distribution, sale and promotion of the device was brought to its attention 2 1/2 years ago. Wolfe and Carome strongly recommended that the agency expeditiously complete its investigation, seize all devices that are being held in inventory or have been sold and distributed, and order the manufacturer to cease and desist all activity involving the distribution, sale and promotion of the LipoTron.

Visit www.citizen.org/hrgpuplications to read full reports and testimonies as HRG fights for government accountability in the interest of the public's health.

Product Recalls

June 1, 2012 – July 18, 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

Levothroid (Levothyroxine Sodium) Tablets, USP, 50 mcg, 100-count bottles. Volume of product in commerce: 19,166 bottles. Subpotent (Single-Ingredient Drug): Low assay at the nine-month test interval. Lot #: 1087589. Lloyd Inc.

Levothroid (Levothyroxine Sodium) Tablets, USP, 75 mcg, 100-count bottles. Volume of product in commerce: 19,039 bottles. Subpotent (Single-Ingredient Drug): Low assay at the six-month test interval. Lot #: 1092045. Lloyd Inc.

Mefloquine HCL Tablets, 250 mg, five tablets per blister pack, five blister packs per carton. Volume of product in commerce: 4,188 cartons. Tablet Thickness: Product is being recalled due to the potential of being underweight or overweight. Lot #: 34000741A, expiration date 07/2013. Teva Pharmaceuticals USA Inc.

Methylprednisolone Tablets, USP, 4 mg, 20 tablets per bottle. Volume of product in commerce: 60 bottles. Impurities/Degradation Products: Product is being recalled due to the potential not to meet the Impurity C specification through the product shelf life. Lot #: 5ASX, expiration date 10/31/2011; 5O37; 5QSQ; 5T6J; 5U7Z; 5WIC; 5XDS; 5ZHY; 601J; 63MJ; and 64O0, expiration date 02/28/2012. Physicians Total Care Inc.

Metoprolol Tartrate Tablets, USP, 50 mg, 1,000-count bottle. Volume of product in commerce: 2,268 bottles. Tablet Thickness: Potential for some tablets not to conform to weight specifications (underweight and overweight). Lot #: TE1Y261, expiration date 12/2013. Teva Pharmaceuticals USA Inc.

Morphine Sulfate Extended-Release Tablets, 30 mg, 60-count bottles. Volume of product in commerce: 540 tablets (nine containers of 60 tablets each). Label Mix-Up: Bottles labeled to contain morphine sulfate immediate release may contain morphine sulfate extended release and vice versa. Drug number: 4033; batch number: 65IT; batch date: 10/13/2010; expiration date: 11/30/2011. Physicians Total Care Inc.

Morphine Sulfate Immediate-Release Tablets, 30 mg, 120-count bottles. Volume of product in commerce: 600 tablets (five containers of 120 tablets each). Label Mix-Up: Bottles labeled to contain morphine sulfate immediate release may contain morphine sulfate extended release and vice versa. Drug number: 4973; batch number: 65J2; batch date: 10/13/2010; expiration date: 06/30/2012. Physicians Total Care Inc.

Nisoldipine Extended-Release Tablets, 17 mg, 100-count bottle. Volume of product in commerce: 7,230 bottles. Failed USP Dissolution Test Requirements: Out-of-specification dissolution result at 18-month time point. Lot #: 2021956, expiration date 01/2013. Shionogi Inc.

Thyro-Tab, 0.050 mg, packaged in bulk drums for repackaging. Volume of product in commerce: 1,924,297 bulk tablets. Subpotent (Single-Ingredient Drug): Low assay at the nine-month test interval. Lot #: HB06311. Lloyd Inc.

Thyro-Tab, 0.075 mg, packaged in bulk drums for repackaging. Volume of product in commerce: 1,913,236 tablets. Subpotent (Single-Ingredient Drug): Low assay at the six-month test interval. Lot #: HD17811. Lloyd Inc.

Zeosa (Norethindrone and Ethinyl Estradiol) Tablets, USP, chewable, 0.4 mg/0.035 mg; and ferrous fumarate tablets, USP, chewable, 75 mg. Three blister cards, 28 tablets each; cartons contain three individual blister packs. Volume of product in commerce: 100,761 cartons. Impurities/Degradation: This recall is being carried out due to the potential for some lots not to meet impurity specifications. Lot #: 33800226A, expiration date 07/2012; 33800333A, expiration date 10/2012; 33800870A, expiration date 10/2012; 33802533A, expiration date 04/2013; and 33802720A, expiration date 08/2013. Teva Pharmaceuticals USA Inc.

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

Alprazolam Extended-Release Tablets, USP, 2 mg, 60-count bottle. Volume of product in commerce: 20,921 bottles. Failed USP Dissolution Test Requirements: Routine stability testing for alprazolam extended-release tablets yielded out-of-specification dissolution results. Lot #: 3029082. Mylan Pharmaceuticals Inc.

Arthrotec 75 (Diclofenac Sodium and Misoprostol) Tablets, 75 mg/200 mcg, a) 30-count bottle and b) 60-count bottle. Volume of product in commerce: a) four bottles, b) two bottles. Tablet Separation: The manufacturer had recalled the lots that were used to repack this product because they may contain broken tablets. Lot #s: a) 5NON, expiration date 04/2013, and 5YUN, expiration date 09/2013; b) 5KBJ, expiration date 02/2013 and 5LVX, expiration date 04/2013. Physicians Total Care Inc.

Atenolol Tablets, USP, 25 mg, a) 100-count bottle and b) 1,000-count bottle. Volume of product in commerce: 78,682 bottles. Presence of Foreign Substance(s): This recall is being carried out due to the potential presence of stainless steel particulates in the tablets. Lot #s: a) 90A024 and 90A026, expiration date 09/2013; b) 90A028, expiration date 09/2013. Teva Pharmaceutical Industries Ltd.

Daytrana (Methylphenidate) Transdermal System Patches, 20 mg over nine hours (2.2 mg/hour), 30 patches per box. Volume of product in commerce: 357,510 patches. Miscalibrated and/or Defective Delivery System: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #s: 49203, expiration date 10/2012, and 50265, expiration date 01/2013. Noven Pharmaceuticals Inc.

Daytrana (Methylphenidate) Transdermal System Patches, 20 mg over nine hours (2.2 mg/hour), one patch per pouch, packaged in 3-count patches per box. Volume of product in commerce: 185,160 patches. Miscalibrated/Defective Delivery System: Exceeded the specification for both mechanical peel force and/or the z-statistic value. Lot #: 53995. Noven Pharmaceuticals Inc.

Jolessa (Levonorgestrel/Ethinyl Estradiol) Tablets, USP, 0.15 mg/0.03 mg, 91 tablets per dispenser, 91-day regimen. Volume of product in commerce: 40,750 dispensers. Contraceptive Tablets Out of Sequence: This recall has been initiated due to the potential that some regimen packages may not contain placebo tablets. Lot #s: 33801826A, expiration date 01/2013; 33802144A; 33802323A, expiration date 03/2013; and 33802519A, expiration date 06/2013. Teva Pharmaceuticals USA Inc.

Lipitor (Atorvastatin Calcium) Tablets, 40 mg, 30 tablets. Volume of product in commerce: three bottles. Chemical Contamination: Complaints of an uncharacteristic odor identified as 2,4,6 tribromoanisole. Lot #s: 6284, 60DI and 61AA. Physicians Total Care Inc.

Trizivir (abacavir sulfate, 300 mg; lamivudine, 150 mg; and zidovudine, 300 mg), 60 tablets. Volume of product in commerce: 14,465 bottles. Adulterated Presence of Foreign Tablets: Trizivir 300/150/300-mg tablets. Lot OZP5128, may incorrectly contain Lexiva 700-mg tablets. Lot #: OZP5128, expiration data 08/2013. GlaxoSmithKline Inc.

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

Air Movers/Blowers. The air mover/blower's internal electrical capacitor can fail and overheat, posing a fire hazard. EDIC, at (888) 289-8720 or www.EDIC-USA.com.

Bowflex SelectTech 1090 Dumbbells. The weight selector dial on the units can fail, causing weight plates to fall when the dumbbell is lifted from its cradle. This poses an injury hazard. Nautilus Inc., at (800) 416-7271 or www.bowflex.com.

Boys' and Girls' Pull-On Lounge Pants and Girls' Boxers. The pants and boxers fail to meet the federal flammability standards for children's sleepwear, posing a risk of burn injury to children. Rigo International Inc., at (888) 229-1292 or www.rigointernational.com.

Catbike Musashi Recumbent Bicycle. The bicycle frame can crack, which can cause the rider to lose control and crash. Big Cat Human Powered Vehicles LLC, at (866) 276-2281 or www.catrike.com.

Children's Pajamas. The pajamas fail to meet the federal flammability standards for children's sleepwear, posing a burn risk to children. PajamaGram, at (800) 262-1162 or www.pajamagram.com.

Contours Options Three- and Four-Wheeled Strollers. A child or consumer's finger can become caught in the opening formed when locking and unlocking the hinge mechanism used to adjust the handlebars on the strollers. This presents amputation and laceration hazards to children and to the adults handling the stroller. Kolcraft Enterprises Inc., at (800) 453-7673 or www.kolcraft.com.

Discovery Kids Animated Marine and Safari Lamps. The placement of internal wires near the circuit board can cause electrical short-circuiting and sparking, posing fire and burn hazards to consumers. Innovage LLC, at (888) 232-1535 or www.innovage.net.

Flushmate III Pressure-Assist Flushing System. The system can burst at or near the vessel weld seam, releasing stored pressure. This pressure can lift the tank lid and shatter the tank, posing property damage and impact or laceration hazards to consumers. Flushmate, at (800) 303-5123 or <http://recall.flushmate.com>.

Folding Deck Chair. The chair cannot support the stated weight capacity. This poses a collapse hazard to consumers. West Marine Products Inc., at (800) 262-8464 or www.westmarine.com.

Frigidaire Self-Clean Gas Range. There can be a delayed ignition on the bake/broil features of the oven, posing a fire hazard. Frigidaire, at (888) 360-8556 or www.selfcleangasrangerecall.com.

Gabiano Collection Boys' and Girls' Pajamas, Sets and Gowns. The pajamas fail to meet the federal flammability standards for children's sleepwear, posing a burn risk to children. The garments were advertised and sold as children's sleepwear. Ishtex Textile Products Inc., at (800) 935-0914 or www.ishtex.com.

Harbor Breeze Bath Fans With Heater and Light. The fan's heater blades can fail to rotate properly, causing the fan to overheat and posing a fire hazard. Delta Electronics (Dongguan) Co. Ltd., at (855) 301-6578 or www.heaterfanrecall.com.

Hot Spring Spas and Limelight Hot Tubs. A loose internal electrical connection of the spa heaters can overheat and ignite, posing a fire hazard. Watkins Manufacturing Corp., at (855) 226-1314 or www.thermproducts.com.

Ice/Hot and Ice Gel Packs. If the packs become damaged, they can leak gel that could contain diethylene glycol and ethylene glycol. These substances can cause illness if ingested in large amounts. California Innovations Inc., at (800) 722-2545 or www.californiainnovations.com.

IKEA 365 + SÄNDA track, 28" and 45". The ground connection in the track is defective, posing an electric shock hazard. IKEA North America Services LLC, at (888) 966-4532 or www.ikea-usa.com.

Kawasaki Cordless Drill. The trigger switches can short and generate excessive heat, posing a burn hazard. Wuxi Xinju Electric Tools Co. Ltd., at (800) 727-7420 or www.alltrade2.fox-international.com.

King- and Queen-Size Bordeaux Collection Bed Frames. The hardware holding the headboard and footboard can loosen or detach, posing a fall hazard. Poh Huat Furniture, at (888) 572-9889 or www.sif-co.com.

Notus Air Movers/Blowers. The air mover/blower's internal electrical capacitor can fail and overheat, posing a fire hazard. EDIC, at (800) 543-5362 or AirMoverRecall@Klinedinstlaw.com.

Outdoor Wall Mount Lanterns. An electrical short circuit can occur in the lanterns' internal wiring, posing a risk of fire, burn and electric shock to consumers. Zhongshan De Gao Lighting Co. Ltd. and Zhongshan Huayi Lighting Co. Ltd., at (888) 770-7018 or www.regcen.com/belairlighting.

Portable Space Heater and Portable Oscillating Space Heater. The heaters can overheat and melt, posing a fire or electric shock hazard. Big Lots, at (866) 244-5687 or www.biglots.com.

CONSUMER PRODUCTS (continued)

Recliner Chair. The surface paint on the legs of the recliner contains excessive levels of lead, which is prohibited under federal law. Tone World International Inc., at (763) 513-9596 or jeffg@twmpls.com.

Soy Candles. The candle can burn with a high flame, causing excessive heat and posing a fire hazard. The heat and flame can cause the glass candle holder to shatter, posing a laceration hazard. Bath Petals Inc., at (855) 772-7258 or www.bathpetals.com.

Thomas Lighting Ceiling Flush Mount Light Fixtures. The fixture's socket wire insulation can degrade, leading to charged wires becoming exposed and causing electricity to pass to the metal canopy of the fixture. This poses fire and electric shock hazards to consumers. Thomas Lighting, at (800) 764-0756 or www.thomaslighting.com.

Tricruiser Electric-Powered Adult Tricycles. The rear axle can break, causing a rear wheel to detach and posing a fall hazard to the rider. Acetrikes Industrial Co. Ltd., at (800) 377-4532 or www.currietech.com.



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Outrage of the Month! Profiting from Obamacare

“Buying hospital stocks is the best way to profit on the long side from Obama care.”

This quote is from a Forbes website article that appeared just after the U.S. Supreme Court decision upholding the constitutionality of the Affordable Care Act (ACA). The author is referring to the increased profit-making potential of investing in for-profit hospital chains that will now be faced with fewer poor, uninsured people showing up at their emergency rooms needing treatment but unable to pay.


In the absence of any significant controls on prices of drugs and medical care in the ACA, another parallel reason to buy hospital stocks might be that with more people insured, there will be generally more revenue and the prices might get even higher.

This macabre Forbes quote about the best way to profit from Obamacare reminds me of a comment made 30 years ago by a brilliant, public-spirited health journalist from *The Washington*

Post: Victor Cohn, now deceased. We were both speaking at a health care symposium at a Washington, D.C., hotel when he said that the main problem with our health care system is that there are too many people making too much money from it.

He included the pharmaceutical industry, hospitals, for-profit health insurance companies and those doctors who pick up “extra change” by investing in labs (X-ray facilities to which they too often refer their patients). Even doctors who are not invested in such companies can make extra money by ordering unnecessary tests and engaging in other unethical practices. (Conversely, salaried doctors are less likely to have these financially rewarding temptations.)

A government-financed single-payer insurance entity — an improved Medicare-for-all system — empowered with the ability to control prices, would be a wonderful start toward the demise of Victor Cohn’s main problem with the health care system. ♦

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