

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

April 2008 ♦ VOL. 24, No. 4

Medical Errors and State Reporting of Adverse Events

Better health care often carries a price tag, but some improvements result in both better services and lower costs. The reporting of “adverse events” is one of those. “Adverse events” are defined as serious, preventable incidents that cause patient injury and/or are indicative of a problem in the health care safety systems or are important for its public credibility and accountability.

In 1999 the Institute of Medicine (IOM) reported that up to 98,000 deaths per year could be attributed to medical errors in the U.S. This report led to discussions on how best to address the problem. These errors are avoidable, and greater vigilance can greatly reduce both the lives lost and the expenses incurred. But because these problems cannot be dealt with unless they are defined and measured, the IOM called for a nationwide mandatory reporting system to allow state governments to collect standardized information about these events. The system would have two main goals: holding providers and facilities accountable for preventable adverse events, and improving quality and patient safety across facilities. Shortly after the IOM report, legislation to create a national voluntary adverse event reporting system, introduced by Senator Kennedy, was defeated because of lobbying against the bill by the American Hospital Association and the American Medical Association.

In 2002, the National Quality Forum (NQF), a nonprofit entity committed

to improving the quality of U.S. health care, endorsed a list of 27 events that are serious, largely preventable and of concern to both the public and providers. These events, dubbed “never events” because they should never occur (e.g., surgery performed on the wrong patient, leaving a foreign object in a patient in the course of surgery or other procedure), were later expanded and updated in 2002. The resulting list of 28 events is organized into six categories, five that relate to the provision of care and one that comprises four criminal events. The NQF list has provided the basis for the statewide reporting systems.

It has been eight years since the IOM report came out and six years since the NQF’s codification of events. During this period, some states have made significant progress in documenting and following up on adverse events. Others have focused on documenting errors without instituting measures to address them. But a significant proportion of states have lagged in gathering

and reporting the information and in taking corrective action. A recent report by the National Academy for State Health Policy (NASHP) summarizes the current operations of the state adverse event reporting systems and identifies trends that are likely to become stronger in the coming years.

In its survey report, the NASHP found that 26 states and the District of Columbia had reporting systems in place; of this total of 27, all but one required mandatory reporting. Of these, 13 have adopted or adapted the NQF list of events, thereby promoting the standardization of data collection. All states that have instituted reporting systems in the past five years have used the NQF list, which suggests that that is likely to become the template for other states instituting comparable systems.

Four states (Kansas, New York, Oregon and Pennsylvania) also collect data on some types of “near misses.” These include errors that do

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minimal or no harm but which help detect system weaknesses that can be fixed before more harm is done. These states could therefore have an early warning system, although only some transform the information into intelligence, using it to avert more serious problems. Pennsylvania, for example, has used the data on near misses to educate providers, sending them patient safety alerts and taking other measures to correct situations that are potentially dangerous.

By the end of 2007, nine states had the electronic capability to receive reports via an interactive Web-based system that could also be used for analysis and feedback to those reporting the data. This allows providers to access reports and assess their data over time, and compare their performance with other providers.

Increasingly, those states with reporting systems are using the data in a variety of ways:

Root Cause Analysis and/or Corrective Action Plans

The majority of these states (23) require that root cause analysis and/or corrective action plans be submitted in response to serious adverse events. Root cause analysis seeks to identify the underlying issues that may be having an impact on a problem, and collects critical information on what happened, why it happened and how to prevent it from happening again. In most cases, this requires looking at processes rather than just persons or outcomes. States use the data to hold facilities accountable for correcting problems that led to errors; share information about common errors and best practices; and inform decision-makers and consumers about patient safety issues. Ultimately, the data are intended to modify services so that they are safer and better.

Public Access to Adverse Event Reports

Most states with reporting systems (24 out of 27) are making the

collected data public. At present, 16 states post the data on a Web site; an additional five plan to do so when the data are available. Sixteen states and the District of Columbia release aggregate data that does not identify the facilities involved; seven states release or plan to release facility-specific data. Moreover, 11 of the 27 states with reporting systems require facilities to disclose their adverse events to the patients involved and/or their families. The experience to date suggests that such disclosure does not lead to an increase in lawsuits.

Because there is a delicate balance between the information required to improve patient safety and the protection of personal data, 23 of the 27 reporting systems have instituted legal protections to prevent unwanted disclosure of data. Protecting the confidentiality of the information is seen as necessary to encourage honest, accurate and full disclosure of events to the state.

Summing Up

Each state has its own way of identifying and counting events, so the data are not comparable between or among states. As a result, the number of reports in a given time period can vary from a handful to several thousand between one state and another. Both the IOM and NASHP caution that the number of events do not necessarily reflect differences in the quality of care; indeed, "a high number of events ... may be more indicative of a robust reporting system than delivery system flaws."

The reporting of adverse events is therefore just in its adolescence: while some state systems have achieved some degree of maturity, others are still experimenting, not quite sure what is expected of them or how to behave. There are, however, some good role models. States that have not yet instituted reporting systems should thus look to those that have adopted principles of completeness, transparency and accountability and are using the data to flag recurrent errors and improve the delivery of care.

Eight years have passed since the IOM identified the scope and severity of adverse events and urged states to take the lead in protecting their patients. Yet there are 23 states that have done nothing to address the problem. Sixteen others have instituted systems to gather information but have serious limitations concerning disclosure and do not require hospitals to inform patients and their families when an adverse effect has occurred.

Medical Records Clarification

The March *Health Letter* had an article in question-and-answer format on medical records. One answer elicited some concern and potential confusion, so we're clarifying it for our readers.

Our statement on who is covered by HIPAA indicated that the law applies "only to medical records obtained by health care providers, health plans, and health clearinghouses, **and only if the facility maintains and transmits records in electronic form.**" The emphasis given to the latter inaccurately implied that this was a small segment of the total, and that only those providers who are using electronic programs for all their records are subject to HIPAA. In fact, this covers practically all providers, because it refers to all who transmit health information electronically. Even solo practitioners who keep only paper records usually rely on billing services that send information electronically, such as via fax machine. In the words of the Privacy Rights Clearinghouse, "it is nearly impossible to provide health care today without using electronic means in some way."

Public Citizen Testifies on Drug Safety Before Congress

H *Health Letter* Editor Sidney Wolfe recently testified before the Congressional Agriculture-Food and Drug Administration (FDA) Appropriations Subcommittee — the funding committee for the FDA — on drug safety. *The following are excerpts from that testimony.*

Chairwoman DeLauro and Members of the Subcommittee, thank you for the opportunity to discuss the dangerously deepening crisis at FDA Center for Drug Evaluation and Research (CDER). Between the time I left the National Institutes of Health (NIH) in early 1972 to start the Health Research Group and now, two-thirds of our work has focused on the FDA, especially drugs. The situation at the FDA has never been worse than now and this can be attributed to a confluence of three factors:

- Terrible leadership at the FDA, including the Commissioner and most of the Center Directors
- Increasing reliance on industry to fund FDA activities, with almost two-thirds of the drug approval budget coming out of the over \$400 million Prescription Drug User Fee Act (PDUFA) drug allocation for FY 2008
- Relative to the 1970's and 1980's, a perilously low level of Congressional oversight and oversight hearings by the same Congresses that have, since 1992, increasingly turned over FDA funding to the industry

I will discuss the CDER budget from the perspective of funding of activities up through approval and post-approval.

Pre-approval Budget and Function

I do not think that the size of CDER's budget for these activities is inadequate but the source is entirely

wrong. The FDA's public health mission is too important to be left to funding by the drug industry with all of the concessions and negotiations that industry extracts for paying the majority of the bill for the FDA drug approval process. Instead, adequate funds need to be appropriated by the Congress, as they were for the first 86 years of FDA's existence (1906-1992) with structured, regular, mandatory oversight by appropriations and oversight committees.

An analysis of serious post-PDUFA mistakes made by CDER in approving a number of drugs that had evidence prior to approval of bright red warning signs illustrates the problem of CDER funding by industry. Included on the list of pre-approval mistakes are:

- *Duract (bromfenac)*: The FDA Medical Officer reviewing bromfenac sodium — the 20th nonsteroidal anti-inflammatory drug (NSAID) approved in the U.S. — unsuccessfully advocated a black box warning label as a condition of approval because, "The review of the 'liver' laboratory data from the submission shows that bromfenac sodium causes hepatocellular damage to a greater degree than other NSAIDs." After at least four deaths and eight liver transplants, bromfenac sodium was removed from the market.
- *Posicor (mibefradil)*: Data from congestive heart failure trials presented at an FDA Advisory Committee meeting on whether or not to approve mibefradil suggested that more patients treated with the drug experienced sudden death than those taking placebo. Several committee members voted against approval. The drug, the ninth calcium channel blocker approved in the U.S., has since been removed from the market because of life-threatening arrhythmias from drug interactions.

- *Rezulin (troglitazone)*: The 11th drug for diabetes in the U.S., troglitazone was approved even though 1.9 percent of patients in the pre-marketing trials, 54 percent of whom had taken the drug for at least six months, had liver function test results greater than three times the upper limit of normal, and 0.4 percent and 0.2 percent had 10-fold and 20-fold elevations, respectively. Well before it was removed from the market, troglitazone had already been associated with a minimum of 43 cases of liver failure, including 28 deaths.

- *Trovan (trovafloxacin)*: Trovafloxacin was approved by the FDA in 1997. Like Duract, there was also clear evidence of liver damage caused by Trovan in animals and in humans before the drug was approved in December 1997. In one pre-approval study in which the drug was used to treat prostatitis, 10 percent of the men (14 out of 140) given the drug developed evidence of liver toxicity. With eight other drugs in this fluoroquinolone antibiotic family available in the U.S., as well as dozens of other safer and equally or more effective drugs for infections, the removal of Trovan from the market by the FDA would not have deprived doctors or patients of a drug that could possibly be considered indispensable. Instead of banning Trovan in 1999, as was done everywhere else in the world, the FDA chose to "limit" its use in the U.S. to patients who were either hospitalized or in nursing homes. At the time of our petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three liver transplants. There were, as of December 31, 2004, a total of

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58 cases of liver failure, including 29 deaths and nine people requiring liver transplants. This is especially alarming since for the past several years there were a total of only 350,000 prescriptions filled in the U.S. (from April 2002 through Feb 2005). As sales waned following the 1999 market withdrawal in Europe but more and more cases of liver failure and death occurred, Pfizer quietly discontinued making the drug in 2002. However, during the latest year for which U.S. sales data are available, there were still 18,000 prescriptions filled in the U.S. (March 2004 through February 2005), long after Pfizer stopped manufacturing the drug.

- *Lotronex (alosetron)*: Seven cases of life-threatening ischemic colitis occurred in clinical trials for this drug with marginal benefits in treating the diarrhea variety of irritable bowel syndrome. Within six months of marketing an additional 16 cases had occurred. We petitioned the FDA to remove it from the market but, after its removal, it was approved with very limited distribution.

1998 Public Citizen Survey of FDA Medical Officers

In 1998, after two years (1996-1997) of record numbers of FDA new drug approvals and the increasing numbers of these drugs that were rather promptly being taken off the market after post-approval deaths and serious injuries confirmed pre-approval concerns, Dr. Peter Lurie and I conducted a written survey of FDA Medical Officers to find out their views on the changes that had occurred post-PDUFA. This was to be the first of several studies by others concerning this problem.

Of the 53 Medical Officers who responded there were the following findings:

- Nineteen Medical Officers identified a total of 27 new

drugs in the past three years that they reviewed that they thought should not have been approved but were approved.

- Asked how they would compare the current standards of FDA review for safety and efficacy to those in existence prior to 1995, 17 Medical Officers described the current standards as "lower" or "much lower," 13 described them as "about the same" and six described them as "higher." None described the standards as "much higher."
- One Medical Officer stated: "My feeling after more than 20 years at FDA is that unless drugs can not be shown to 'kill patients' outright then they will be approved with revised labeling and box warning."
- Twelve Medical Officers identified 25 new drugs that they reviewed in the past three years that in their opinion had been approved too fast.
- Thirty-four Medical Officers stated that the pressure on them to approve new drugs was "somewhat greater" or "much greater" compared to the period prior to 1995.
- One Medical Officer stated: "We are in the mindset now to approve everything but to describe drug weaknesses in the label. As one high ranking official said 'Everything is approvable. We can use the labeling creatively to lower the problems.'"
- Eight Medical Officers reported 14 instances in the past three years in which they had been instructed, usually by the Office Director, not to present their own opinion or data to an FDA Advisory Committee when to do so might have reduced the likelihood that a drug would be approved.

- Nine Medical Officers identified 19 new drugs that they had reviewed in the past three years that had been inappropriately shifted to the accelerated approval track.
- Thirteen Medical Officers identified 18 occasions in the past three years when a supervisor, usually their Division Director, had asked the Medical Officer to change his or her opinion to agree with the supervisor's, usually in a direction favoring approval.
- One Medical Officer reported: "In the last two years, I recommended that two drugs not be approved. They were both approved without consulting me. This never happened before. In one case, the drug did not meet the standards set up by the division, so they nullified the standards."

2001 FDA Survey of CDER Personnel

One of the reasons the morale in CDER is as low as at any time in the past 35 years was aptly summed up by a statement of CDER Director Dr. Woodcock that "the intense [user fee mandated] schedules create a sweatshop environment that's causing high staffing turnover."

In a survey by the FDA of CDER personnel in 2001, intended to discover the reasons for the high rate of staff turnover, the problems found included the following:

About one-third of respondents did not feel comfortable expressing their differing scientific opinions...over one-third felt that decisions such as holds, refuse-to-file actions, and non-approvals are stigmatized in the agency. Over one-third felt that their work has more impact on a product's labeling and marketability than it does on public health. A number of reviewers added comments stating that decisions should be based more on science and less on corporate wishes.

One of the 13 recommendations in the report is to “encourage freedom of expression of scientific opinion.”

We believe that unless this occurs, along with healthy debates, the FDA will not be able to attract and keep its best staff. Debate, attention to dissident views and freedom of expression are not only the hallmarks of good science; they are also the essence of democratic governance.

HHS Inspector General Study of FDA: 2003

The IG study confirmed that decisions concerning drug safety and effectiveness were being overturned. Eighteen percent of surveyed FDA physicians and scientists felt pressure to recommend that drugs be approved for sale despite their reservations about the drug’s safety, efficacy or quality. The report concluded: “Overall, these findings present a significant warning signal.”

Post-approval Budget and Function

The two topics I will discuss here are post-approval safety reviews of drugs, often precipitated by a series of well-documented adverse reactions to drugs, and post approval compliance activities including inspections of pharmaceutical companies.

The concept of generating a signal from adverse drug reactions is useful only if the signal is taken seriously and the action taken is prompt and proportional to the strength of the signal. This is especially important when the signal confirms earlier pre-approval evidence of dangers seen in randomized controlled trials, as in four drugs cited above. There has been an historic split and an imbalance of power between FDA drug review divisions and the postmarked surveillance (offices of drug safety) divisions. In too many instances, serious post-marketing safety problems identified by the offices of drug safety have not been acted upon because of resistance from FDA management and from the review division that originally approved the drug and now gets the

majority of its funding from industry.

Increased funding, especially with much of it coming from PDUFA, in the absence of the increased independence that would occur if the offices of drug safety were made independent of CDER is not likely to solve this historic imbalance of power. The funds must be directly appropriated from the government.

Enforcement of Laws and Regulations Concerning Prescription Drug Advertising

Although we have always supported more funds for DDMAC (CDER’s Division of Drug Marketing Advertising and Communications), starting in 1999, there has been an enormous reduction in enforcement actions (warning letters and notice of violation letters) each demanding that an illegal ad be stopped. From a maximum number of such illegal ads that were stopped in 1998 (157 ads), the number has fallen drastically and dangerously to 20 last year in the face of an actual increase in the amount of money spent on prescription drug advertising.

The figure below shows that by the end of the Clinton administration there had already been a decrease to 89 such actions (a 43 percent decrease) and

that has fallen to 20 last year (an 87 percent decrease), having bottomed out for the past six years. This is inexcusable and is not proportionate to any decrease in DDMAC staff nor any evidence of a law-abiding epiphany by the drug industry. This means prescribing decisions are too often based on perceptions that drugs are safer and/or more effective than they actually are because of the misleading ads, misleading doctors as well as patients.

Sharp Decrease in Warning Letters for all of FDA to Regulated Companies

There has been a similar FDA-wide decrease in warning letters to all regulated companies. Unlike DDMAC activities, which are accomplished centrally, much of the other compliance activities in FDA depend on inspectors, most of whom are in the field. The number of warning letters decreased from a maximum of 1154 in 2000 to 538 in FY 2006 (a 53 percent decrease), the last year for which data were available.

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(Data compiled from FDA web site)

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Foreign Drug Company Inspections: Sharp Decrease in Funding

Although more funding could be used for domestic inspections which make up the bulk of the companies receiving warning letters and other enforcement actions, the situation with respect to inspections of foreign drug facilities is desperate and the consequences are increasingly being brought to attention in the form of dangerous products being produced in these inadequately inspected plants.

From FY 2002, when the FDA foreign drug company pre-market inspection budget was \$8.274 million, to FY 2007 when it was \$5.836 million, there was a decrease of 30 percent in funds for foreign inspection. Similarly, the post-approval inspection budget decreased from \$5.256 billion in FY 2002 to \$4.345 in FY 2007, a 17 percent decrease. Overall, the foreign inspection budget had a total decrease, during this recent 5-year interval, of 25 percent. This unfortunately, for the health of American consumers of drugs, comes at a time when the number of foreign plants manufacturing drugs for import into the U.S., especially countries such as India and China, was rapidly increasing.

“Debate, attention to dissident views and freedom of expression are not only the hallmarks of good science; they are also the essence of democratic governance.”

China: More Drug Disasters Waiting to Happen

The recent GAO analysis of FDA data on foreign inspections exposes further causes for alarm about products coming from China.

Several inescapable conclusions from this report demand immediate action to remedy the seemingly unending series of dangerous drugs, often contaminated, coming from this country with an extremely low level of FDA inspections:

1. Of the 10 foreign countries with the most FDA inspections in FY 2002 through FY 2007, China was the one with the largest number of drug-producing establishments, 714 establishments.
2. Although India, with 410 establishments, had the second largest number, the odds of an FDA inspection in FY 2007 in that country were much, much higher than in China.

3. India, whose 410 establishments comprised 12.65 percent of all foreign establishments, was the subject of 65 inspections in FY 2007, or 22 percent of all foreign FDA inspections.

4. China, whose 714 establishments comprised 22 percent of all foreign establishments, was the subject of only 13 FDA inspections in FY 2007, or only 4 percent of FDA inspections in foreign countries.

In summary, the FDA pre-approval budget is increasingly coming from industry, a trend which must be reversed as soon as possible. The post-approval budget for inspections was not only grossly inadequate in FY 2002 but has decreased a further 25 percent by FY 2007.

There is an enormous amount of tough policing of the relatively toothless FDA and its budget needed by your appropriations committee. We will help you in whatever way we can.

Editor.....*Sidney M. Wolfe, MD*
Managing Editor.....*Kate Resnevic*
Contributors.....*Annette Ramirez de
Arellano, DrPH*
Sidney M. Wolfe, MD

Proofreader.....*Shiloh Stark*
Production Mgr.....*James Decker*
Public Citizen President.....*Joan Claybrook*

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Published Monthly by
Public Citizen Health Research Group
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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is www.citizen.org/hrg.

Product Recalls

February 21, 2008 - March 14, 2008

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. 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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – CLASS I

Indicates a problem that may cause serious injury or death.

Name of Drug or Supplement; Problem; Recall Information

Encore Tabs For Maximum Sexual Performance All Natural Male Enhancement Dietary Supplement, 962,627 units (each unit contains 2 capsules); Unapproved New Drug; product found to contain an undeclared analog of an active ingredient used in a FDA approved product to treat erectile dysfunction. Lot # 0C85; North West Marketing Co., Inc.

Zencore Tabs All Natural Male Enhancement Dietary Supplement, For Maximum Sexual Performance, packaged in a 2-count blister in a cardboard package, 962,627 units (each unit contains 2 capsules); Unapproved New Drug; product found to contain an undeclared analog of an active ingredient used in a FDA approved product to treat erectile dysfunction. Lot #s ZT500 (exp. date: 12/09), ZT010207 (exp. date: 12/09), ZTS100 (exp. date: 04/07); North West Marketing Co., 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

Name of Drug or Supplement; Problem; Recall Information

Alprazolam Extended-Release Tablets, 3mg, Rx only, packaged in 60 count plastic (HDPE) bottles, 1,566 bottles (60 count); Failed Dissolution Specification (6 month stability). Lot # MK070099; Sandoz, Inc.

Duragesic® 25 mcg/h (Fentanyl Transdermal System), Each transdermal system contains; 2.5mg fentanyl and 0.1mL alcohol USP, supplied in boxes of 5 systems, Rx only, 3,577,458 cartons; Defective Delivery System; drug reservoir containing API concentrated gel is leaking due to improper cutting of patch delivery system. All lot codes; GPSG - Unit of ALZA Corp.

Fentanyl Transdermal System 25 mcg/h, Each transdermal system contains: 2.5mg fentanyl and 0.1 mL alcohol USP, supplied in boxes of 5, Rx only, 3,577,458 cartons; Defective Delivery System; drug reservoir containing API concentrated gel is leaking due to improper cutting of patch delivery system. All lot codes; GPSG - Unit of ALZA Corp.

INTERMUNE Infergen Interferon alfacon-1, A recombinant consensus alpha interferon derived from E. coli, 9 mcg/0.3 mL, Labeling; incorrect expiration date on vial. The cartons of

some lots of Infergen were previously overstickered with an extended expiration date that added an additional 12 months of shelf-life to the product. The vial labels of the product in these lots, however, were not over-stickered with the extended expiration date; Lot # 0 P057622A (original exp. date: 11/30/2007, extended exp. date: 11/30/2008); Lot # P062263A (original exp. date: 10/31/2007, extended exp. date: 10/31/2008), Lot # P063704A (original exp. date: 02/28/2008, extended exp. date: 02/28/2009); Amgen Inc.

INTERMUNE Infergen Interferon alfacon-1, A recombinant consensus alpha interferon derived from E. coli, 15 mcg/0.5mL; Labeling; incorrect expiration date on vial. The cartons of some lots of Infergen were previously overstickered with an extended expiration date that added an additional 12 months of shelf-life to the product. The vial labels of the product in these lots, however, were not over-stickered with the extended expiration date. Lot # P057613A (original exp. date: 11/30/2007, extended exp. date: 11/30/2008) - 4,088 units distributed; Lot # P057614A (original exp. date: 11/30/2007, extended exp. date: 11/30/2008) - 4,818 units; Lot # P057615A (original exp. date: 11/30/2007, extended exp. date: 11/30/2008) - 5,416 units; Lot # P057619A (original exp. date: 12/30/2007, extended exp. date: 12/30/2008) - 2,431 units; Lot # P057620A (original exp.

date: 11/30/2007, extended exp. date: 11/30/2008) - 5,760 units; Lot # P063699A (original exp. date: 12/30/2007, extended exp. date: 12/30/2008) - 3,160 units; Lot # P065733A (original exp. date: 02/28/2008, extended exp. date: 02/28/2009) - 44 units; Lot # P065734A (original exp. date: 02/29/2008, extended exp. date: 02/29/2009) - 761 units; Lot # P065737A (original exp. date: 03/30/2008, extended exp. date: 03/30/2009) - 1 unit; Lot # P066895A (original exp. date: 03/30/2008, extended exp. date: 03/30/2009) - 1 unit; Lot # P068076A (original exp. date: 03/30/2008, extended exp. date: 03/30/2009) - 8 units; Lot # P071927A (original exp. date: 11/30/2007, extended exp. date: 11/30/2008) - 6,076 units; Lot # P073211A (original exp. date: 12/31/2007, extended exp. date: 12/31/2008) - 1,033 units; Lot # P073966A (original exp. date: 03/30/2008, extended exp. date: 03/30/2009) - 3,777 units; Lot # P077786A (original exp. date: 04/30/2008, extended exp. date: 04/30/2009) - 5 units; Lot # P077787A (original exp. date: 04/30/2008, extended exp. date: 04/30/2009) - 7 units; Amgen Inc.

Major Infants' Gas Relief Drops, (Active ingredient in each 0.6 mL) Simethicone, 40mg, 1 Fl. Oz. (30mL) bottles with Plastic Dropper Enclosed, 1440 bottles; Microbial Contamination of Non Sterile Product; Yeast. Lot # E617 exp. date: 04/2009; Tri-Med Laboratories Inc.

OPTIMUM OYSTER SHELL CALCIUM, 250 mg with Vitamin D Dietary Supplement, 100 count bottles, 154 bottles; Presence of Foreign Tablet; acetaminophen tablet was found. Lot # 334830 exp. date 06/2008; Magno Humphries Inc.

Tri-Med Gas Relief Drops, (Active ingredient in each 0.6 mL) Simethicone 40 mg, 1 fl. oz (30 mL) with Plastic Dropper Enclosed, 10,800 bottles; Microbial Contamination of Non Sterile Product; Yeast. Lot # E617 exp. date: 04/2009; Tri-Med Laboratories 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 Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Drug or Supplement; Problem; Recall Information

ATVs. A retention bolt of Select "Outlaw IRS" ATVs, Model Year 2006-2008, can come loose causing the rear wheels to lock up, which poses a risk of serious injury to the rider. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Baby Sling Carriers. The aluminum rings on the Ellaroo Ring Sling Baby Carriers can bend or break. This can cause the fabric to slip through the rings and infants to fall out of the carrier. Ellaroo LLC, (800) 483-4902 or www.ellaroo.com.

Children's Hooded Sweatshirts. The Micros Boys' Hooded Jackets have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Urgent Gear Inc., (213) 741-9926 ext. 247 or www.urgentgear.com.

Children's Metal Jewelry. The Children's Metal Necklaces contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Pecoware Co. Inc., (800) 456-7326 or www.pecoware.com.

Cribs. The Majestic Curved Top and Flat Top Cribs, Essex Cribs, Brighton/Sussex Cribs and Captiva Cribs fail to meet the federal safety standards for cribs. The four support brackets on the mattress support spring are too long. The brackets prevent the spring from lowering to the full 26 inch minimum height in its lowest position, allowing children inside to crawl over the railing, posing a fall hazard. Munire Furniture Inc., (866) 586-9639 or www.munirefurniture.com.

Deep Fryers. The Cooks Deep Fryers have a faulty heating element which can cause it to overheat, posing a fire and burn hazard to consumers. JCPenney, (888) 333-6063 or www.jcp.com.

Electric Grills. Cooking oils or sprays applied to the Electric Contact Grill's cooking plates before preheating can cause the oil to ignite and/or flare up. Cooking sprays can ignite and/or flare up if used on the grill at any time. QVC Inc., (800) 367-9444 or www.qvc.com.

Gas Connectors. The LDR 1200 Series Gas Connectors can leak propane or natural gas, posing a fire and explosion hazard to consumers. LDR Industries, (800) 545-5230 ext. 2345 or www.ldrind.com.

CONSUMER PRODUCTS

Gas Fired Furnaces. The ignition control module of Indirect Gas-Fired Furnaces can fail preventing the unit from shutting down in high temperature conditions. This poses a risk of fire, as well as hazardous fumes being released from burning/melting insulation. Greenheck Fan Corp., (800) 931-6579 or www.greenheck.com.

Girls' Hooded Sweatshirts. The Girls' Hooded Sweatshirts have a drawstring through the hood which poses a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Rebelette International Trading Corp., (626) 448-9988.

Infant Rattles. The tail-piece on the Infantino Lamb Grabby Rattles™ can detach, posing a choking hazard to young children. Infantino LLC, (888) 808-3111 or service.infantino.com.

Magnetic Construction Sets. Small magnets inside the building pieces of Battat Magnabild Magnetic Building Toys or Sets can fall out. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Battat Inc., (800) 247-6144 or www.battatco.com.

Magnetic Dart Boards. Small magnets at the ends of the darts in FUN 'N SAFE Magnetic Dart Boards can detach. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Family Dollar, (800) 547-0359 or www.familydollar.com.

Memory Testing Cards. Surface paint on the Memory Testing Cards (sold as part of educational testing kits) contains excessive levels of lead, violating the federal lead paint standard. Riverside Publishing Co., (800) 323-9540 or www.riverpub.com.

Off-Road Motorcycles. One or more of the Kawasaki KLX140 Off-Road Motorcycle's frame welds could be missing or made incorrectly allowing the frame to crack or break, posing a risk of serious injury to riders. Kawasaki Motors Corp. U.S.A., (866) 802-9381 or www.kawasaki.com.

Portable Air Compressors. The Strike Force™ Portable Air Compressor's motor can overheat and ignite the protective cover, posing a fire hazard to consumers. Also, the cover might not prevent internal components from being touched, which poses an electrical shock hazard. All-Power America, (888) 896-6881 or www.advanceautoparts.com.

Tealight Candle Holders. The spacing of the holes in a concentrated pattern in Silver Square Tealight Candle Holders allows the holder to heat-up. This can cause the tealights to burn unexpectedly fast and with a higher flame height than normal, posing a fire hazard. Pier 1 Imports, (800) 245-4595 or www.pier1.com.

Toasters. The Hamilton Beach® and Proctor-Silex® Toasters can remain "on" (energized) after popping up, and can ignite flammable items covering or in contact with the toaster, posing a fire hazard. Hamilton Beach Brands Inc., (800) 574-6800 or www.hamiltonbeach.com (for Hamilton Beach® toasters) or www.proctorsilex.com (for Proctor-Silex® toasters).

Toggle and Rotary Switches. When switched OFF, one electrical pole of the Toggle Switches and Rotary Switches may remain energized, posing a risk of electrical shock hazard to consumers. Disconnects of Florida Corp., (866) 800-0690 or www.ensto.com.

Toy Airplanes, Cars and Motorcycles. The X Force Commander Toy Airplanes and Super Famous Toy Cars and Motorcycles contain excessive levels of lead, violating the federal lead paint standard. S.U. Wholesale Inc., (877) 580-8883.

Toy Sundae Sets. The wooden cherries on top of the Play Wonder Toy Sundae Sets pose a choking hazard to young children. Battat Inc., (800) 247-6144 or www.battatco.com.

Wall Furnaces. A gasket in the Direct-Vent Wall Furnaces, Models RHFE 431 and RHFE 556 can fail, posing a risk of poisonous carbon monoxide gas leaking into the home. Rinnai America Corp., (866) 746-8344 or www.wallfurnacerecall.com.

CT scan for an adult.

Brenner and Hall state that although the increased cancer risks to an individual are small, "the concern about the risks from CT is related to the rapid increase in its use — small individual risks applied to an increasingly large population may create a public health issue some years in the future. On the basis of such risk estimates and data on CT use from 1991 through 1996, it has been estimated that about 0.4% of all

cancers in the United States may be attributable to the radiation from CT studies. By adjusting this estimate for current CT use this estimate might now be in the range of 1.5 to 2.0%."

Again emphasizing the benefits of CT scans, the authors state that "despite the fact that most diagnostic CT scans are associated with very favorable ratios of benefit to risk, there is a strong case to be made that too many CT studies are being performed in the United States. There is a considerable literature questioning the use of CT, or the use of multiple CT scans, in a variety of contexts, including management of blunt trauma, seizures, and chronic headaches, and particularly [as mentioned above] questioning its use as a primary diagnostic tool for acute appendicitis in children."

Brenner and Hall discuss other options for reducing the overall radiation dose from CT in the population such as reducing the dose in individual patients by means of automatic exposure-control options on the latest generation of scanners. But they conclude that "the most effective way to reduce the population dose from CT is simply to decrease the number of CT studies that are prescribed. From an individual standpoint, when a CT

scan is justified by medical need, the associated risk is small relative to the diagnostic information obtained. However, if it is true that about one third of all CT scans are not justified

by medical need, and it appears to be likely, perhaps 20 million adults and, crucially, more than 1 million children per year in the United States are being irradiated unnecessarily."

A well-researched pamphlet sponsored jointly by the National Cancer Institute and the Society for Pediatric Radiology titled *Radiation Risks and Pediatric*

Computed Tomography (CT) (available at <http://www.nci.nih.gov/cancertopics/causes/radiation-risks-pediatric-CT>) contains useful information about the enhanced risks of excessive radiation for children:

Unique Considerations for Radiation Exposure in Children

Radiation exposure is a concern in both adults and children. However, there are two unique considerations in children.

- Children are considerably more sensitive to radiation than adults, as demonstrated in epidemiologic studies of exposed populations.
- Children also have a longer life expectancy, resulting in a larger window of opportunity for expressing radiation damage.

As an example, compared with a 40-year-old, the same radiation dose given to a newborn is several times more likely to produce a cancer over the child's lifetime.

Moreover, the same exposure parameters used for a child and an adult will result in larger doses to the child. There is no need for these larger doses to children, and CT settings can be reduced significantly

while maintaining diagnostic image quality.

Therefore, children should not be scanned using adult CT exposure parameters. Currently, adjustments are not frequently made in the exposure parameters that determine the amount of radiation children receive from CT, resulting in a greater radiation dose than necessary.

Radiation Risks from CT in Children: A Public Health Issue

Major national and international organizations responsible for evaluating radiation risks agree there probably is no low-dose radiation "threshold" for inducing cancers, i.e., no amount of radiation should be considered absolutely safe. Recent data from the atomic bomb survivors and medically irradiated populations demonstrate small, but significant, increases in cancer risk even at the low levels of radiation that are relevant to pediatric CT scans. Doses from a single pediatric CT scan can range from about 5 mSv (a measure of radiation dose) to 60 mSv. Among children who have undergone CT scans, approximately one-third have had at least three scans. Multiple scans present a particular concern. For example, three scans would be expected to triple the cancer risk of a single scan. Although the benefits of properly performed CT examinations almost always outweigh the risks for an individual child, unnecessary exposure is associated with unnecessary risk. Minimizing radiation exposure from pediatric CT, whenever possible, will reduce the projected number of CT-related cancer deaths.

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Unnecessary Medical Radiation — Children the Most Vulnerable

Thirty years ago, Public Citizen's Health Research Group was involved in the publication of a book, researched and written by Physics Professor Dr. Priscilla Laws, titled *The X-Ray Information Book: A Consumer's Guide to Avoiding Unnecessary Medical and Dental X-Rays*. Based on estimates by the Food and Drug Administration (FDA), 30 percent of diagnostic X-ray procedures were then estimated to be unnecessary. As much as we were concerned about this unnecessary radiation and its attendant increased risk of cancer, one of the current major sources of x-radiation, CT (computerized tomography) scans, was in its infancy relative to current use. Whereas there were an estimated 3 million CT scans a year in 1980, it is estimated that there are more than 62 million CT scans per year currently

obtained in the U.S., including at least 4 million for children.

The benefits of appropriate CT scanning can not be overemphasized. As Columbia University radiation experts Drs. David Brenner and Eric Hall recently wrote in an article in the *New England Journal of Medicine*, "the widespread use of CT represents probably the single most important advance in diagnostic radiology. However, as compared with plain-film radiography, CT involves much higher doses of radiation, resulting in a marked increase in radiation exposure in the population."

How much higher CT radiation doses are than plain-film x-rays can be seen by comparing the received dose of an abdominal CT scan with that of a regular chest x-ray. An adult abdominal CT scan has a radiation exposure 1000 times higher than

that of a chest x-ray and a neonatal abdominal CT scan has 2000 times more radiation.

According to Brenner and Hall, "the major growth area in CT use for children has been presurgical diagnosis of appendicitis, for which CT appears to be both accurate and cost-effective — though arguably no more so than ultrasonography [ultrasound] in most cases."

Most of the numerical estimates of radiation-induced cancer risk are derived from analyses of those atomic-bomb survivors with amounts of radiation in the same range as CT scanning. But other studies supporting this relationship include a recent large-scale study of nuclear industry radiation workers who were exposed to an average dose similar to the typical organ dose from a single

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