PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR APRIL 2013 – Vol. 29, No. 4

Use of Atypical Antipsychotics in Children At All-time High

The use of psychiatric, or psychotropic, mind-affecting drugs in children has increased exponentially over the past two decades. An estimated 8 million U.S. children are now on at least one type of psychiatric medication for a behavioral disorder or mental illness.

Much of the increased use in recent years has involved a class of medicines called atypical antipsychotics. It is a troubling fact, but one that studies have repeatedly shown, that most of these risky antipsychotic drugs are being prescribed to children for unapproved — and unproven — uses. In other words, most of them are not psychotic.

Overview of atypical antipsychotics

The first antipsychotic medications, now known as first-generation or typical antipsychotics, were largely used to treat seriously mentally ill patients, such as those with schizophrenia, institutionalized in inpatient mental-health facilities. In the 1990s, a new class of drugs emerged. Called second-generation or atypical antipsychotics, these drugs had fewer side effects than the first-generation medicines, and their debut coincided with the continued transition of common mental-illness treatment from inpatient institutions to outpatient clinics. (Only one atypical antipsychotic, clozapine [Clozaril], was approved prior to the 1990s.) This timing resulted in the widespread use of atypical antipsychotics in the outpatient setting.

Sales of atypical antipsychotics have risen considerably in recent years, from 2.3 million prescriptions per month in November 2005 to 4 million prescriptions per month by September 2011. Sales of the drugs for children have followed a similar trend, increasing 62 percent between 2002 and 2007 in Medicaid-enrolled children.

> **Most of the new cases [of ADHD and bipolar disorder] likely result from more dangerously liberal diagnostic standards — as well as outright misdiagnosis — within the medical community.**

Unproven, off-label use predominates in children

As of August 2012, atypical antipsychotics were approved by the Food and Drug Administration (FDA) in children only for treatment of bipolar disorder (for ages 10 to 17), schizophrenia (for ages 13 to 17), irritability associated with autism, and "tics and vocal utterances of Tourette syndrome." Yet most atypical antipsychotic prescriptions written for children are not for these conditions. Instead, according to the federal Agency for Healthcare Research and Quality (AHRQ), the majority are for conditions for which the drugs have never been approved by the FDA.

A study of children in the Arkansas Medicaid program found that the most common conditions for which atypical antipsychotics were prescribed were attention deficit hyperactivity disorder (ADHD), followed by depression, conduct disorder, oppositional defiant disorder and adjustment reactions. According to the authors, 41 percent of the children had no diagnosis for which antipsychotic treatment was supported by any published study. Another large study of privately insured children found similar patterns of use, with atypical antipsychotics most commonly prescribed for behavioral or mood disorders (disruptive behavior disorder, followed by mood disorders and anxiety disorder).

There is no solid evidence that the drugs work for these most common off-label uses. Two systematic reviews conducted in 2006 and 2011 by AHRQ found only a handful of published trials that studied any off-label uses of antipsychotics in children. Only one drug, risperidone (Risperdal), demonstrated some benefit for ADHD, but the two trials in which this was shown were exceedingly small (70 children in total) and short-term (four weeks). Another

see CHILDREN, page 2

In This Issue

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CHILDREN, from page 1

drug, aripiprazole (Abilify), was shown to be ineffective in reducing ADHD symptoms in children with bipolar disorder in two other trials.

For all atypical antipsychotics other than risperidone, AHRQ researchers did not find a single trial evaluating the risks and benefits of any off-label uses for children. These two reviews demonstrated that there is no substantial evidence supporting the effectiveness of any atypical antipsychotic for any off-label use in children.

Drug risks without countervailing benefits

The fact that the drugs have not been proven effective for a large proportion of their uses in children puts their risks into sharp relief. The relative safety of atypical antipsychotics compared with their older counterparts is what launched them into widespread use, but the drugs come with serious and insidious side effects, including in otherwise healthy children.

Several atypical antipsychotics cause substantial weight gain, which is often associated with increases in blood glucose and cholesterol levels. In the largest study looking at metabolic side effects in first-time users of atypical antipsychotics, children on the drugs gained between 10 and 19 pounds on average, in some cases with accompanying increases in blood glucose and cholesterol levels, after just 12 weeks. Another, longer-term study found that children gained an average of 36 pounds on olanzapine (Zyprexa), 21 pounds on clozapine and 16 pounds on risperidone after approximately 10 months. These weight and metabolic changes can predispose patients to type 2 diabetes, as suggested in studies of adults taking the drugs. Neurological side effects, including conditions known as neuroleptic malignant syndrome and tardive dyskinesia, can be irreversible and potentially fatal in severe cases.

Questionable psychiatric diagnoses for children

A proliferation of new mental-health diagnoses in children of all ages is partly to blame for the increased antipsychotic drug use in children, with ADHD and bipolar disorder at the center of this trend.

ADHD was the first diagnosis for which psychotropic medications were specifically targeted in children, and it remains one of the most common conditions for which they are prescribed today. Attention deficit disorder (ADD), the precursor diagnosis to ADHD, was first added to the third version of the psychiatric Diagnostic and Statistical Manual (DSM) in 1980 to identify children with perceived attention problems in the home or school. (Hyperactivity was added to ADD more than a decade later, making up the current disease category of ADHD.)

In the past 20 years, rates of diagnosis of ADHD have increased exponentially. A 1995 study documented that the number of people with ADHD in the U.S. more than doubled from 1990 to 1993 alone. By 2011, the Centers for Disease Control and Prevention (CDC) reported that almost 1 in 10, or 9 percent, of all U.S. children under 18 were currently diagnosed with ADHD.

Bipolar disorder, characterized by extreme swings between depressed and manic moods, was first formally classified as a diagnosis in children in the fourth version of the DSM in 1994. Rates of bipolar disorder in children subsequently rose by a factor of 40 between 1994 and 2003 in youth 19 years or younger. By way of comparison, rates in adults increased by 86 percent over the same time period.

Accompanying this explosion of psychiatric diagnoses was a sevenfold increase in doctor visits for antipsychotic medications in children 13 and under between 1993 and 2009.

The sudden increase in the number of ADHD and bipolar disorder cases has made the diagnoses for so many children particularly controversial. Has

see CHILDREN, page 3

CHILDREN, from page 2

there always been a silent epidemic of these diseases that went unrecognized until the mid-1990s? Or is the real epidemic the wave of overdiagnosis (and overtreatment) that predictably followed the diagnoses being formalized within the medical establishment?

There are undoubtedly legitimate cases of these disorders, in which the diagnoses represent increased awareness among physicians and parents of significant mental illness. But most of the new cases likely result from more dangerously liberal diagnostic standards — as well as outright misdiagnosis — within the medical community.

According to the National Institute of Mental Health (NIMH), some studies show that an overexcited and elated mood in normally subdued children can easily be misdiagnosed as bipolar disorder, as can the symptoms of other, less serious conditions, such as ADHD. The NIMH cited as an example a 2001 study in which nearly half of adolescents in inpatient facilities diagnosed with bipolar disorder were later reclassified as having other mental disorders.

Clinical paradigms and pervasive marketing feed overdiagnosis

The propensity to overdiagnose some of these conditions may be particularly strong when dealing with psychiatric conditions with deep-seated social or economic roots that simply cannot be addressed fully in a 15-minute doctor visit. According to a 2011 national survey conducted by the CDC, children living in poverty or in a single-parent or foster home were substantially more likely than other children to be diagnosed with ADHD or a learning disability.

It should come as no surprise that a hungry child living in poverty, or one with an overworked or otherwise absent parent, might find it difficult to concentrate in school or might misbehave as a consequence of his or her situation. Addressing deep social or economic problems takes time that many pediatricians or psychiatrists are simply not given (or may be beyond the scope of their abilities) in a medical system that demands high patient turnover and discrete diagnoses that can be billed to insurers.

The drug industry also has played a decisive role in the overdiagnosis problem. Millions of newly diagnosed children represent a lucrative new market, and manufacturers of atypical antipsychotics have launched aggressive marketing campaigns to pressure physicians to prescribe the drugs. Because there are only a few

see CHILDREN, page 8

Major Settlements With Pharmaceutical Manufacturers Over Allegations Of Illegal, Off-label Marketing of Antipsychotics for Use in Children

Year	Company*	Antipsychotic	Total Penalties (including for other criminal and civil violations)**
2007	Bristol-Myers Squibb	Abilify (aripiprazole)	$515 million
The U.S. Department of Justice (DOJ) alleged that from 2002 through 2005, Bristol-Myers Squibb knowingly promoted the atypical antipsychotic Abilify for sale and use in children (as well as to treat dementia-related psychosis), both of which uses were not FDA-approved.			
2008	Otsuka Pharmaceutical	Abilify (aripiprazole)	$4 million
Otsuka initially developed Abilify and then partnered with Bristol-Myers Squibb to promote the drug, including the unlawful, off-label pediatric sale and use mentioned above. This 2008 penalty settled government charges against an Otsuka subsidiary for its role in the alleged marketing scheme.			
2009	Eli Lilly	Zyprexa (olanzapine)	$1.4 billion
In 2009, drug company Eli Lilly settled civil and criminal allegations that the company persuaded doctors to prescribe the drug Zyprexa to children and geriatric adults. Not only was Zyprexa not approved by the FDA to sedate nursing home patients and treat disruptive children, but such uses were particularly risky in these two vulnerable populations.			
2010	AstraZeneca	Seroquel (quetiapine)	$520 million
A press release issued on April 27, 2010, by the Department of Health and Human Services (HHS) stated that AstraZeneca agreed to pay $520 million to resolve government allegations that the company engaged in off-label promotion between 2001 and 2006. HHS stated that AstraZeneca "targeted its illegal marketing of the anti-psychotic Seroquel towards doctors who do not typically treat schizophrenia or bipolar disorder," including those treating children and adolescents.			
2012	Abbott Laboratories	Depakote (divalproex)	$1.5 billion
The DOJ alleged that between 1998 and 2008, Abbott illegally promoted the drug Depakote for a variety of unapproved uses, including pediatric and adolescent psychiatric conditions.			
2012	Johnson & Johnson	Risperdal (risperidone)	$181 million
A subsidiary of Johnson & Johnson was accused by state and federal authorities of illegally promoting Risperdal for the treatment of bipolar disorder in children and adolescents, among other unapproved indications.			

** Parent companies are listed in all cases, including those involving allegations against subsidiaries of the company.*

*** Penalties include overall settlement totals for all alleged violations, including nonpediatric violations, involving the antipsychotic medication.*

Many Women Undergo Unnecessary Cervical Cancer Screening

Routine screening of women for cervical cancer with Papanicoulaou (Pap) smears, also called Pap tests, has helped saved numerous lives since it was introduced into clinical practice in the U.S. in 1941. However, a recent study conducted by the Centers for Disease Control and Prevention (CDC) revealed that as many as 22 million women who had previously had a hysterectomy may have undergone unnecessary Pap tests over the past decade. The CDC data also suggest that millions of other women older than 65 years who have not had a hysterectomy likewise underwent unnecessary Pap tests during this same time period.

The CDC's data on Pap tests once again highlight a pervasive problem within the U.S. health care system: the frequent use of unnecessary medical tests and treatments. In addition to wasting money, time and clinical resources, unnecessary medical tests and treatments expose patients to risks of complications and adverse events directly caused by the procedure or treatment without offering sufficient benefits to offset the risks.

As noted in past issues of *Health Letter*, unwarranted diagnostic tests can also lead to misdiagnosis or overdiagnosis, both of which can result in patient anxiety as well as more needless medical procedures and treatments that present additional risks of harm and unnecessary costs. Misdiagnosis may occur when a patient undergoes a diagnostic test and has a false-positive result. In this case, the test result is abnormal, but the patient does not have the disease for which he or she is being tested. Overdiagnosis occurs when a test result shows a true abnormality, but one that will never cause symptoms or result in death.

Overview of cervical cancer

The cervix is the lowest part of the uterus (womb) that opens into the top of the vagina. Cancer of the cervix, or cervical cancer, occurs when cells within the outermost lining of the cervix become malignant.

A recent study conducted by the Centers for Disease Control and Prevention (CDC) revealed that [millions of] women ... may have undergone unnecessary Pap tests over the past decade.

Cervical cancer is the third most common type of gynecologic cancer in the U.S. (ranking behind uterine cancer and ovarian cancer). U.S. women have a less than 1 percent chance of being diagnosed with cervical cancer during their lifetimes, with the average age at the time of diagnosis being 48 years. In 2013, approximately 12,000 U.S. women are expected to be diagnosed with invasive (advanced-stage) cervical cancer, and about 4,000 will die from the disease.

Because infection with the human papilloma virus (HPV) is detected in more than 99 percent of cervical cancer cases, it is considered the cause of most such cancers. However, only a very small minority of the 75 to 80 percent of sexually active adult women who contract HPV infection develop cervical cancer.

Well-established risk factors for cervical cancer include:

- Early onset of sexual activity;
- Multiple sexual partners;
- A high-risk sexual partner (e.g., a partner with multiple sexual partners or known HPV infection);
- A history of sexually transmitted infections (e.g., syphilis, chlamydia or genital herpes);
- History of vulvar or vaginal squamous epithelial cancers (other cancers also caused by HPV); and
- Immunosuppression (due to, for example, chemotherapy, organ transplantation, or human immunodeficiency virus infection).

Most of these risk factors are the same as those for developing HPV infection.

The development of cervical cancer is preceded by precancerous changes to cells within the outer lining of the cervix. In many patients, these abnormal changes will regress and not progress to cervical cancer, whereas in others, the precancerous cells will progress to the early, noninvasive stage of cervical cancer over many months to years.

What are Pap tests?

At both the precancerous and the early, noninvasive stages of cervical cancer, patients are asymptomatic. The Pap test is a screening test designed to detect these early stages of the disease when it can be easily treated, thus preventing progression to actual cervical cancer in women with precancerous lesions and curing the disease in those who have early stage cancer.

Pap tests are usually done as part of routine pelvic exams. A small brush, special spatula or both are used to gently remove cells from the lining and opening of the cervix. These cells are transferred to a glass slide and examined under a microscope by a pathologist. Results typically are available after a few weeks. If precancerous or cancerous cells are found, the patient will be asked to undergo additional tests to examine the cervix and, in most cases, take biopsies. If precancerous or cancerous lesions are confirmed upon further testing, appropriate treatment is then offered.

It is important to understand that Pap tests are not perfect. Some patients have false negative results (in which the test results are normal but the patient has

see CERVICAL, page 5

CERVICAL, from page 4

precancerous cervical lesions or cervical cancer), and others have false positive results (in which the results show abnormal cervical cells but the patient does not have precancerous cervical lesions or cervical cancer).

Recommendations for screening for cervical cancer

Over the past two decades, the U.S. Preventive Services Task Force (USPSTF), the American Cancer Society (ACS), and the American College of Obstetricians and Gynecologists (ACOG) have issued and periodically updated separate recommendations regarding when women should undergo screening for cervical cancer and how frequently. Currently, all three groups recommend that women ages 21 to 29 years undergo Pap tests every three years and that women over age 30 undergo these tests either every three years or every five years if combined with simultaneous testing for HPV infection.

Since 2003, all three groups have recommended against screening for cervical cancer in women who have had a total hysterectomy (which includes removal of the cervix) if the following two conditions are met:

- The hysterectomy was for a benign (not cancererous or precancerous) condition (for example, uterine fibroids).
- The patient has no prior history of precancerous cervical changes or cervical cancer.

(Of note, approximately 95 percent of all hysterectomies in the U.S. are total hysterectomies.)

Ten years ago, the USPSTF recommended against routinely screening women older than age 65 for cervical cancer if they had undergone adequate recent screening with normal Pap test results and were not otherwise at high risk for cervical cancer. ACS made a similar recommendation for women older than age 70, whereas ACOG did not have an upper age limit for discontinuing such screening.

In addition to wasting money, time and clinical resources, unnecessary medical tests and treatments expose patients to risks of complications and adverse events directly caused by the procedure or treatment without offering sufficient benefits to offset the risks.

All three groups now recommend against screening women older than age 65 if certain criteria are met regarding the absence of prior cervical cancer or precancerous cervical abnormalities and prior negative Pap test results. (The exact criteria vary somewhat between groups.)

The CDC study

In a study published in the *Morbidity and Mortality Weekly Report* on Jan. 4, 2012, CDC researchers analyzed data from the Behavioral Risk Factor Surveillance System (BRFSS), a state-based system of health surveys established by the CDC in 1984. The BRFSS surveyors call a random sample of civilian adults in all 50 states and the District of Columbia each month to ask questions regarding general health status, health risk behaviors (e.g., smoking, exercise), preventive health practices and access to health care, primarily related to chronic disease and injury. The system surveys more than 350,000 people each year. Every two years, the BRFSS survey includes a section on women's health, asking women, among other things, whether they had ever had a Pap test, how long since their last Pap test and if they had undergone a hysterectomy.

The CDC researchers, interested in trends in screening women for cervical cancer, analyzed data from the women's health section of surveys of women aged 30 years or older from 2000 to 2010. They found that among the women who reported having had a hysterectomy, the proportion who underwent a recent (within three years) Pap test decreased from 73 percent in 2000 to 59 percent in 2010. Among women age 30 to 64 who had had a hysterectomy, the percentage reporting a recent Pap test decreased significantly: from 81 percent in 2000 to 69 percent in 2010. For women 65 or older with a hysterectomy, there was a significant decline, from 62 percent to 45 percent over the same 10-year span. For women 65 or older with no prior hysterectomy, the proportion reporting a recent Pap test declined significantly, from 74 percent in 2000 to 65 percent in 2010.

The CDC noted several important limitations to its study, including:

- Prior studies of self-reported Pap test data have shown that women may overreport being screened with a Pap test and underreport the time since their last test.
- Information on the timing of recent Pap tests relative to the timing of hysterectomy in the women surveyed was not obtained; thus, a small number of hysterectomies may have been performed after the Pap test.
- The BRFSS survey did not ask about the reasons for hysterectomy, whether the cervix was removed, or reasons for which women might need continued screening after a hysterectomy (for example, having a high-grade, precancerous lesion before hysterectomy).
- Survey responses were low, ranging from 40 percent to 56 percent.

Despite these limitations, the study authors were able to make some reasonable general conclusions. In particular, they concluded that although expert recommendations regarding cervical cancer screening have resulted in significantly reduced unnecessary screening in women who have had a total hysterectomy or who are older than 65, many women in these groups are still undergoing unwarranted screening that

see CERVICAL, page 8

Objects Left in the Body After Surgery

It is an event that should never happen to anyone. Ten weeks after Geraldine Nicholson underwent surgery for cancer, doctors discovered that a surgical sponge had been left in her abdomen. The discovery was the beginning of a yearlong hospital stay as Nicholson, a 56-year-old mother of three, struggled with infections and illness that prevented her from receiving follow-up chemotherapy and radiation treatment. Eventually, she succumbed to the cancer that the surgery had been intended to prevent.

Nicholson is one of a small but disturbing number of patients who die each year from infections, complications and other causes related to foreign objects left behind after surgery. Objects, often sponges, that are left behind during surgery can remain in a patient's body for years without detection, adhering to organs and leading to pain, infection and other problems.

The most tragic thing about these deaths and injuries is that they are completely avoidable, so-called "never events" that could be prevented if all hospitals were to enact systematic measures to address them. Some hospitals are now working to take such steps. To help prevent this never event from happening to you, it is important to understand the safety protocols and consider the questions to ask before going in for a nonemergency (elective) procedure.

Scope of the problem

The estimated number of objects left behind after surgery (also called "retained objects") varies each year, ranging anywhere from between 1 in every 1,000 surgeries to 1 in every 18,000 surgeries. However, hospitals vary widely in how many retained objects they report. Some hospitals may claim no retained objects for years, while others report one object left behind every three months.

The reports are even more difficult to interpret because retained objects can easily be missed, meaning that a hospital with poor systems for detecting the objects may not even notice that a mistake has been made until years later, when it causes devastating injury.

Nearly any object that enters the operating room, from small needles to large surgical tools, can be unintentionally left behind after surgery, but the most common retained object is a surgical sponge or similar absorbent pad. These small, soft items are easy to lose because they can be wadded up and become soaked in blood, blending in easily with nearby tissue. Dozens may be used during an extensive procedure, making it more difficult to keep track of each one.

Detecting and removing retained objects

One of the oldest, most widely used techniques to prevent retained objects is a simple count. Sponges and other items should be counted when they arrive at the operating room and then counted again multiple times throughout the procedure to ensure that all objects are all accounted for before any cavity is closed. Unfortunately, it is easy for this system to go wrong. The surgical team may forget to count, count incorrectly, or fail to communicate and work together to find the missing object when a count comes up short.

Routine screenings during or after an operation offer one option. Standard surgical sponges generally contain a small marker embedded in the fabric that will appear on an X-ray, making it possible to scan for these objects. In one study, researchers used routine X-ray scans during and after surgery to identify sponges retained inside patients. Nurses had failed to notice that the sponges were missing during the operation, either because they did not perform a sponge count or because the sponge count appeared to be correct. However, routine X-ray scanning has drawbacks, as it exposes patients to risky radiation,

see SURGERY, page 7

Objects Left Behind After Childbirth

Surgery is not the only procedure in which objects can be left behind. Hospitals are only now beginning to acknowledge that sponges and dressings used to absorb excess blood during a vaginal delivery also can be left behind and cause infections and other problems.

The problem in such cases is often poor communication: The obstetrician who delivers the baby will place a sponge or dressing in the vagina to address bleeding, then give verbal instructions to a nurse to remove the item later. The information is not transmitted to other members of the nursing team, and the patient is eventually discharged from the hospital with the sponge or dressing retained. She may return to the hospital weeks later with a fever or foul discharge, indicating infection.

Unfortunately, many labor and delivery areas have not implemented routine sponge-counting practices similar to those now used in the surgical setting. Hospitals should actively work to change this by introducing such practices and working to improve communication after delivery.

In the meantime, new mothers and their partners or advocates can actively help prevent problems by speaking to their obstetrician after delivery and learning whether a sponge or dressing was used. They can then ask how and when the item should be removed and ensure that this information is appropriately communicated to the nursing staff.

SURGERY, from page 6

and quality images are difficult to obtain during surgery. Newer technologies rely on radio-frequency tags or computer identification chips that can be detected without using X-ray. These technologies, discussed below, may ultimately be safer for patients, although none have been on the market long enough to understand the true best approach.

There may be limited circumstances under which it is undesirable to remove the object. For example, very small needles rarely cause injury, so a small needle found inside the body after surgery may be best left in place.

Even if the risk of injury from an object is small, a surgeon should always inform the patient about the object rather than trying to conceal the mistake. A patient has the right to discuss the options and make an informed decision about removing the object, independent of whether a surgeon thinks the situation is serious.

Solving the problem takes teamwork

Many of the mistakes leading to retained objects are due to inattention, poor communication or lack of organized response on the part of the surgical team. For this reason, the most effective way for a hospital to reduce the number of these events is to change the culture of the operating and delivery rooms through comprehensive training, active learning and sustained follow-up.

The Association of periOperative Registered Nurses (AORN) and American College of Surgeons (ACS) have each developed best-practice guidelines to prevent leaving objects behind after surgery. NoThing Left Behind, a national education project, also has worked with hospitals since 2004 to develop and disseminate evidence-based best practices. Many of the steps recommended are common-sense, such as requiring two people to participate in each sponge count, physically separating sponges as they are counted out loud, and pausing to count objects and visually inspect the patient before closing any body cavity.

Other simple steps are less obvious. For example, NoThing Left Behind recommends placing used sponges in clear plastic receptacles rather than in disposal bins lined with red "biohazard" plastic or white plastic. This is because miscounts can occur when red plastic hides a bloody sponge or white plastic hides a white sponge. Although many hospitals use red "biohazard" bins to ultimately dispose of bloody sponges, a practice required by regulation, doctors may temporarily place sponges in a clear plastic receptacle until a final count is made.

A good program for preventing retained objects takes attention, time and energy to implement. It is thus important for a surgical institution to have some method of measuring the program's success, investigating mistakes and providing feedback to members of the surgical team. Ideally, the hospital will have a system for reporting and investigating cases of retained objects as well as "near misses," or cases in which an object is misplaced during the procedure but located and removed before the procedure is over. A hospital also should conduct routine internal audits, in which each nurse or technician is observed performing surgical counts, with lessons from the auditing shared at staff meetings.

Newer technology

Over the past decade, various device manufacturers have worked to design improved systems to lower the error rates from manual counting. One technique involves barcode technology that allows a nurse or technician to scan each sponge during the counting process, with a running count displayed on a screen. Another system relies on a small radio-frequency tag, roughly the size of a jelly bean, embedded in each sponge. A wand passed over the patient will trigger an audible signal and light upon encountering a tagged sponge. A third system relies on a small identification chip about the size of a dime, also embedded in each sponge. Other new systems are under development.

Although many of these new systems show promise, they are relatively young technologies still being refined based on feedback from experience. No single system has emerged as a clear winner for hospitals and patients.

Some of the new technologies also are expensive and may not provide large improvements over low-tech substitutes, such as installing standardized dry-erase boards in every operating room for recording sponge counts or using designated plastic sponge holders to allow for easier visual inspection after a count is complete. Moreover, no form of technology can substitute for good training, communication and teamwork on the part of the surgical team, and newer devices should not be relied upon as replacements for current best practices.

Questions for your surgeon

If you are considering having an elective surgical procedure, it is always a good idea to explore various options to identify a hospital and surgeon skilled at performing the procedure. When you sit down to talk with a surgeon or hospital staff, one of the things you should discuss is how the institution will ensure that sponges and other objects are not left behind after surgery.

Ask whether the hospital has had any retained objects or close calls in the past few years. Learn what steps are being taken to monitor for and prevent such events and to actively educate hospital staff. Keep in mind that a hospital that reports no objects left behind may simply have inadequate detecting and reporting practices. It generally takes several years of active, concerted effort by a large hospital to reduce the number of retained sponges to zero in a year.

Preventing objects left behind is a team effort, and any member of your surgical team should be ready to provide a detailed description of the practices he or she will use in the operating room to ensure that this never event will not happen to you. ✦

CERVICAL, from page 5

provides no benefit. For women with hysterectomies, the researchers estimated that as many as 22 million may have received unnecessary Pap tests, contrary to the consistent recommendations of the USPTF, ACS and ACOG that have been in place for nearly a decade. The CDC data also suggest that millions of other women older than age 65 also underwent unnecessary cervical cancer screening during this same time period.

Advice for readers

Clearly, many physicians and other health care providers who perform Pap tests are not well-informed about, or fail to follow, the well-accepted guidelines for when such tests are no longer needed. If you have had a total hysterectomy with removal of the cervix and do not have a history of high-grade, precancerous cervical lesions or cervical cancer, or if you are older than 65, have had adequate prior screening and are not at high risk for cervical cancer, you should challenge any health care provider's recommendation that you have a Pap test. In such circumstances, ask your health care provider to explain the basis for the recommendation and the justification for deviating from the current guidelines for such tests. If you are not satisfied with the explanation provided, you should decline to have the test and consider seeking a second opinion. Consider sharing and discussing this article with your doctor. ✦

CHILDREN, from page 3

FDA-approved conditions for the drugs in children, however, many of these promotional campaigns have apparently crossed the line into illegal, off-label marketing. Since 2007, seven different manufacturers of atypical antipsychotics have paid a total of $4.3 billion in settlements with the federal and state governments over allegations including actively marketing the drugs for off-label uses in children.

Thanks to direct-to-consumer marketing campaigns for psychotropic drugs and media stories of an "epidemic" of mental illnesses (such as ADHD) in children, parents may be more prone to pathologize their children's behavior and ask for medications themselves. Children formerly regarded as rambunctious or transiently sad are now often regarded as mentally ill and treated with a medication they may take for years — into adulthood and, in some cases, for life. Beyond the direct impact of ads, the current diagnostic paradigm might inherently appeal to busy and distressed parents looking for an immediate answer to a child's misbehavior while alleviating them of any perceived (and in many cases unfounded) culpability for their child's conduct.

Overprescribing displaces long-term solutions

The result of all these factors is that millions of children are receiving risky antipsychotic medications that have never been shown to provide any benefit to them. A fragmented medical system that encourages overdiagnosis and overmedication, combined with persistent marketing campaigns, fuels this unnecessary use and diverts attention from more effective long-term social interventions and economic policies to alleviate mental-health burdens in children and adolescents. ✦

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- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **Testimony to the Food and Drug Administration's (FDA's) Advisory Committee on Reproductive Health Drugs on Paroxetine and Gabapentin for Menopausal Symptoms — 3/4/2013 —** Public Citizen testified before this advisory committee that the antidepressant paroxetine and the anti-seizure/neuropathic pain drug gabapentin should not be approved to relieve hot flashes and flushing caused by menopause. There is insufficient evidence that the drugs provide clinically meaningful benefits for these very unpleasant but non-life-threatening symptoms, and they can cause serious side effects. The advisory committee subsequently rejected approval of both drugs for these indications.
- **Letter to the FDA Criticizing the Decision to Keep the Wingspan Stent System on the Market — 1/28/2013 —** Public Citizen's letter to the FDA criticized the agency's August 2012 decision to keep a dangerous brain stent, the Wingspan Stent System, on the market after a high-quality clinical trial showed that the device causes death and stroke. The FDA acknowledged in August that the stent was dangerous for most patients, but the agency chose to approve the device for a limited group of patients rather than ban the device outright. Public Citizen condemned the FDA's decision.
- **Testimony to Drug Safety and Risk Management Advisory Committee on Overprescription of Hydrocodone — 1/25/2013 —** Ninety-nine percent of the hydrocodone in the world is manufactured and used in the U.S. This is evidence that hydrocodone products, not used at all in most countries, are being overprescribed and should be severely restricted in the U.S. Although the Drug Enforcement Administration has strongly pushed for tighter restrictions on hydrocodone prescribing, the FDA has unfortunately opposed them. Public Citizen testified before the FDA's Drug Safety and Risk Management Advisory Committee, urging safer controls on the drug, and the advisory committee then voted 19 to 10 to recommend such a change.
- **Testimony on Canagliflozin to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee — 1/10/2013 —** In our testimony before this advisory committee, Public Citizen opposed the FDA's approval of the new diabetes drug canagliflozin because it demonstrates no evidence of any improved clinical outcomes but it creates dangerous side effects, including increased cardiovascular events, risks of kidney damage because of dehydration, and increased genital and urinary infections. Unfortunately, the advisory committee voted 10 to 5 in favor of approving the drug.

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

Product Recalls

February 6, 2013 – March 5, 2013

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

Hydrocodone Bitartrate and Acetaminophen Tablets. Volume of product in commerce: 897,379 bottles. Superpotent (multiple-ingredient) drug: Complaint received of oversized tablets. Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals.

Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg/500 mg; 100 Tablets (5 x 20), 5 cards each containing 20 blistered tablets per carton. Volume of product in commerce: 3,407 cartons. Superpotent (multiple-ingredient) drug: Oversized tablets resulting in superpotent assays of both the hydrocodone and acetaminophen components. Lot #s: 3037841, 3040859 and 3042573, expiration date 12/2013. Mylan Institutional, Inc. dba UDL Laboratories.

SLIM XTREME Herbal Slimming Capsules, 30-count bottles. Volume of product in commerce: 40,400 bottles. Marketed without an approved NDA/ANDA: Product tested positive for sibutramine, an appetite suppressant that was withdrawn from the U.S. market in October 2010 for safety reasons, making this product an unapproved new drug. Lot #s: All lots of SlimXtreme with the following format stamped in black ink on the bottom of the bottle "MFD: XX.XX.20XX EXP: XX.XX.20XX", which were manufactured overseas, are being recalled. Globe All Wellness, LLC.

SLIMDIA Revolution Capsules, 30-count capsules per bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: All lots of the dietary supplement Slimdia Revolution are being recalled because they contain sibutramine, a previously approved FDA drug removed from the U.S. marketplace for safety reasons, making it an unapproved new drug. Lot #s: There are no manufacturing codes associated with the product. Yerba Naturals, P & J Trading Co.

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

Carisoprodol Tablets, USP, 350 mg, packaged in: (a) 500-count tablets per bottle (NDC 0143-1176-05) and (b) 1,000-count tablets per bottle (NDC 0143-1176-10). Volume of product in commerce: 8,585 bottles. Presence of foreign substance: Uncharacteristic black spots on tablets. Lot #s: 69364A, 69365A and 69365B, expiration date 10/2015. West-ward Pharmaceutical Corp.

Carvedilol Tablets, USP, 12.5 mg, 500-count tablets per bottle. Volume of product in commerce: 11,580 bottles. Failed tablet/capsule specifications: Product exceeds specification for tablet weight and tablet thickness. Lot #s: ZCMH12031, ZCMH12032, ZCMH12033 and ZCMH12034, expiration date 02/2014. Mylan Pharmaceuticals Inc.

Lansoprazole Delayed-release Capsules, USP, 30 mg, 500-count capsules per bottle. Volume of product in commerce: 1,894 bottles. Presence of foreign tablets/capsules: Bottles of lansoprazole 30 mg, delayed-release capsules may contain topiramate 100 mg tablets. Lot #: 1110829, expiration date 05/2014. Mylan Pharmaceuticals Inc.

PredniSONE Tablets, USP, 10 mg, packaged in a) 100-count tablets per bottle (NDC 0143-1473-01), b) 1,000-count tablets per bottle (NDC 0143-1473-10). Volume of product in commerce: 128,319 bottles. Presence of foreign substance: Tablets are being recalled due to gray defects identified in the tablets. Multiple lots affected. West-ward Pharmaceutical Corp.

Propranolol Hydrochloride Extended-release Capsules, USP, 80 mg, 100 Capsules. Volume of product in commerce: 60 bottles. Failed dissolution test requirements. Lot #308198, expiration date 03/2014. Upsher Smith Laboratories, Inc.

Taztia XT Capsules (diltiazem HCl extended release capsules, USP, once-a-day dosage, 360 mg, 90 capsules per bottle. Volume of product in commerce: 3,040 bottles. Failed dissolution specification: Out-of-specification result occurred during the 3-month stability testing. Dissolution result at the 4-hour time point was 41% (specification: 20-40%). Lot #: 512146A, expiration date 01/31/2014. Watson Pharmaceuticals.

Temodar (temozolomide) Capsule, 20 mg per capsule, 5 capsules per package, for oral administration. Volume of product in commerce: 17,169 packages. Failed impurities/degradation specifications: The recall is being initiated due to an out-of-specification result in the degradation product testing detected during stability monitoring. Lot #: 0NCW005, expiration date 02/2013. Schering-Plough Products, LLC.

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

4moms® breeze™ Cotton Jersey Playard Sheets. The sheets are too small for the play yards. A sheet that does not properly fit the play yard poses an entrapment hazard that could lead to suffocation. 4moms, at (888) 977-3944 or www.4moms.com.

Beamerzzz™ Stuffed Animals with LED Flashlight. LED flashlight wires can protrude through the stuffed toy, posing a laceration hazard. Purr-Fection by MJC, at (800) 359-0254 or www.purr-fection.com.

BlueStar™ Residential Gas Wall Ovens. Some of the wall ovens have been improperly installed and/or have damaged flexible gas appliance connectors, posing a fire hazard. BlueStar, at (800) 449-8691 or www.bluestarcooking.com.

Canning Jar Lifter. The jar lifter handle can detach over time due to a missing stainless steel core in the hinge. This can cause the tongs to fail to grip and allow a jar being lifted to fall, posing a laceration hazard to the user. Progressive International Corporation Customer Service, at (800) 426-7101 or www.progressiveintl.com.

Dual-Wattage Travel Converter Kits. The converter can overheat if a load in excess of 50 watts is applied to the converter while in the 50-watt setting. This poses a fire and burn hazard to consumers. Samsonite, at (800) 382-7259 or www.samsonite.com.

Easy Go XP Lock Via Ferrata Lanyards. The elastic webbing on the lanyards can deteriorate over time and break while in use, posing a risk of serious injury or death to the climber. Liberty Mountain, at (800) 366-2666 or www.libertymountain.com.

EVO Strollers. The opening between the grab bar and seat bottom of the stroller can allow an infant's body to pass through and become entrapped at the neck, posing a strangulation hazard to young children when a child is not harnessed. Mutsy USA, at (877) 546-9230 or www.mutsy.com.

Expert Gardener Electric Blower Vacuums. Objects that are drawn into the unit during vacuum mode can break through the plastic housing, posing a laceration hazard. OWT Industries Inc., at (800) 597-9624 or www.expertgardenertools.com.

Homelite Electric Blower Vacuums. Objects that are drawn into the unit during vacuum mode can break through the plastic housing, posing a laceration hazard. Homelite Consumer Products, at (800) 597-9624 or www.homelite.com.

Middleton Siege Crossbows. The crossbow can fire unexpectedly when the auto-safety mechanism appears to be on and the trigger is pulled, posing an injury hazard to the user and bystanders. In addition, the crossbow limbs can crack or break under normal use. The Bohning Company, Ltd., at (800) 253-0136 or www.bohning.com.

Motor Scooters with Hello Kitty or Monster High Graphics. The scooters can accelerate suddenly while in use, causing the rider to lose control and fall. Dynacraft, at (800) 551-0032 or www.dynacraftbike.com.

One-cup Coffeemakers. The coffeemaker can overheat, posing fire and burn hazards to consumers. Jerdon Style, at (800) 223-3571 or www.jerdonstyle.com.

Pre-lit Artificial Christmas Trees. The remote control receiver box attached to the Christmas tree can overheat and melt, posing burn and shock hazards to consumers. Balsam Hill, at (877) 694-2752 or www.balsamhill.com.

Ryobi Lithium 18V 4Ah Battery Pack. The battery pack can overheat and burst while on a charger, posing fire and burn hazards to consumers. One World Technologies, at (800) 597-9624 or www.ryobitools.com.

Ski-Doo® Snowmobiles. The fuel pump inlet fitting can come into contact with the oil tank and break, leading to a fuel leak, which poses a fire hazard. BRP, at (888) 638-5397 or www.ski-doo.com.

SlumberWorld Mattresses. The mattresses fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard to consumers. SlumberWorld, at (808) 421-3159 or www.slumberworldhawaii.com.

Task*It 1-UP Folding Step Stool. The folding step stool can crack or break and collapse, posing a fall hazard to the user. Cramer LLC, at (800) 366-6700 or www.cramerinc.com.

Utility Vehicles. The oil filter can leak, posing a fire hazard. Pinholes or cracks have been identified in oil filters installed by the engine supplier that were not manufactured to specification. Deere and Company, at (800) 537-8233 or www.johndeere.com.

PUBLICCITIZEN Health Letter

Outrage of the Month! Republican Politics, Medicaid Expansion and Hypocrisy

Since the 2012 election, an increasing (though still small) number of Republican governors have caved in to their previously announced opposition to expanding Medicaid. But this is not because they are starting to become fans of the government-funded health insurance program. Instead, they are deciding their states should participate so they can get the increased federal dollars that come with such participation.

Never mind that this about-face on Medicaid expansion, which is a part of so-called Obamacare, counters their deficit-reduction mantra, which consists almost entirely of cutting spending as opposed to increasing tax revenue by having wealthy campaign contributors pay a fairer share of taxes.

Florida's governor, Rick Scott, is one of the most recent converts to Medicaid expansion. But in return for offering to add his state to the growing list of Medicaid expanders, Scott extracted a "deal" from the Obama administration: an agreement to be allowed to privatize Medicaid in Florida. This would allow the state to operate its Medicaid program through private insurance companies, the very companies that already greatly inflate the cost of medical care due to massive administrative waste paired with a lack of ability (relative to the government) to control medical costs. Switching from a not-for-profit public insurer to a system of private health insurers is a very good "deal" for the medical industry, with its already bloated bottom lines, but not for taxpayers.

Just as Scott (like other Republican governors) hypocritically bit the Medicaid-expansion bullet to get massive federal money flowing into the state, the checks-and-balances counterweight of Florida's legislative branch lashed out at Scott. True to Republican opposition to using federal spending for valuable, life-saving services for the less fortunate, as Medicaid does, the Republican-dominated legislature does not want to tarnish its own image by opting for more federal spending in the state. Not long after Governor Scott's Medicaid expansion plan was announced, committees in both houses of the legislature showed their strength and defeated the proposal.

You have to be strong — and wrong — to defeat such an expansion, despite the fact that your governor had previously made a deal that would divert much more of the money into the private, for-profit health sector. And so it goes. ✦

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