



Youth Stimulant Abuse at Record High

The prescription of stimulant medications, usually used to treat attention deficit hyperactivity disorder (ADHD), has hit an all-time high in the U.S., increasing more than nine-fold between 1991 to 2009. Young adults represent the fastest-growing population of users of these drugs. According to *The New York Times*, nearly 14 million ADHD drug prescriptions were written for Americans ages 20 to 39 in 2011, more than double the rate of 2007.

Given the proliferation of such drugs, it is perhaps unsurprising that the U.S. has experienced rampant misuse and abuse of the stimulant medications, with the number of related emergency room visits more than doubling from 2005 to 2010. Young people are at the center of this dangerous trend of stimulant abuse: In one study of college students, 8 percent reported taking the drugs illicitly, mainly to improve academic performance.

Students, who feel pressure to perform at a high level academically; physicians, who respond to patients' pleas; and the pharmaceutical industry, which conducts incessant drug-marketing campaigns, all drive a dramatic increase in the prescription and illicit use of these substances.

Risks of ADHD treatments

There are two main categories of medications used to treat ADHD: nonstimulants and stimulants. Nonstimulants, such as atomoxetine (brand name: Strattera) come with a number of serious side effects, but, according to the Food and Drug Administration (FDA), they may be less likely to be abused than stimulants and

are effective in treating ADHD.

Some stimulants also are effective at treating ADHD, but they are addictive and far more commonly abused by young people due to their more potent and fast-acting effects. Most stimulants are amphetamines (such as the most widely abused drug among college students, amphetamine-dextroamphetamine, the active ingredients in Adderall), which are structurally and functionally similar (in one case, even identical) to street methamphetamine. Their addictive potential has led them to be classified as Schedule II drugs by the Drug Enforcement Administration (DEA). This means that under the federal Controlled Substances Act, the medications must be obtained from a DEA-licensed practitioner, prescriptions must be limited to a 90-day supply and the patient must return to the physician for further assessment to obtain refills.

Even when stimulants are used properly under a doctor's supervision, they carry several potentially fatal risks. Cardiovascular effects include increased heart rate and blood pressure, and the medicines are thus contraindicated in patients with serious heart problems. A 2006 study concluded that approximately 1 in 400 patients exhibit psychotic behavior or suicidal thoughts while taking the medicines. The drugs also cause seizures and driving impairment, and they interact dangerously with numerous other medications.

Little is known about the long-term side effects of stimulants, because most controlled studies of the drugs have lasted no more than one to two years. What is known, however, is that the

misuse and abuse of addictive stimulants result in thousands of visits to the emergency room per year. Abuse of the medications can lead to depression, mood swings, sleep deprivation, heart irregularities and severe withdrawal symptoms. Overdoses of methylphenidate or amphetamines have resulted in death and such life-threatening complications as prolonged seizures, tears in the aorta (the body's largest artery) and heart arrhythmias. In addition, stimulants have been reported anecdotally to act as a "gateway" drug to the abuse of other prescription medications, such as painkillers or sleeping aids.

Overdiagnosis of ADHD

Some of the increase in stimulant use in young adults may be attributable to children and adolescents with ADHD who continue the medications into adulthood. Based on the Health Resources and Services Administration's National Survey of Children's Health, the percentage of children ages 4 to 17 diagnosed with ADHD increased from 7.8 percent in 2003 to 9.5 percent in 2007 and up to 11 percent by 2011. Another national survey showed that

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Genetic Testing for Breast Cancer: Is It Right for You?

In May 2013, the actress Angelina Jolie announced in a column in *The New York Times* that she had undergone a preventive double mastectomy (removal of both breasts) after learning that she carries a defect of the BRCA1 gene, a genetic mutation that sharply increased her risk of developing breast cancer. Then in June, the U.S. Supreme Court ruled that a biotech company could not hold a patent on the BRCA1 and BRCA2 genes, effectively opening up patient access to affordable testing for all genetic mutations.

These stories have thrust the BRCA genes into the spotlight and led many women to consider testing themselves for these relatively rare genetic mutations that have been linked to several forms of cancer. For a small group of women, BRCA testing may help identify life-saving treatment. Yet for most, genetic testing will not lead to helpful information about the risk for breast cancer but is likely to trigger needless anxiety and perhaps even unnecessary removal of healthy organs. You can make smart decisions about testing by understanding BRCA mutations and available treatment options, as well as knowing what to expect from the test.

What is a BRCA mutation?

Normal BRCA1 and BRCA2 genes help prevent cancer by creating proteins that act as tumor suppressors by repairing damaged DNA. This in turn prevents further DNA mutations that can lead to cancer. Scientists have documented more than 500 forms of mutations to these BRCA genes, or changes to the gene sequencing. In most cases, these mutations disable the DNA-repairing protein, preventing it from performing its repair function and increasing the risk that the carrier of the mutation will develop certain types of cancer. However, not all BRCA mutations are negative: Some changes may

Identifying High Genetic Risk From Family History

The USPSTF recommends genetic counseling for women who meet any one of these criteria.

For all women:

- Two immediate family members (such as a sister, mother or daughter) with breast cancer, one of whom was diagnosed at age 50 or younger.
- Three immediate or second-degree family members (such as an aunt, grandmother or niece) on either side of the family diagnosed with breast cancer at any age.
- Both breast cancer and ovarian cancer among immediate or second-degree family members on either side of the family.
- An immediate family member with bilateral breast cancer (cancer in both breasts).
- Breast cancer in a male relative.

For women of Ashkenazi Jewish ancestry:

- An immediate family member with breast cancer.
- Two second-degree family members on the same side of the family with breast or ovarian cancer.

have no effect on protein function or cancer risk, and at least one form actually *reduces* the risk of cancer.

The child of a parent with a BRCA mutation (mother or father) has about a 50 percent chance of inheriting

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the mutation. BRCA mutations are extremely rare in the general population. Researchers have estimated that roughly 1 in 300 to 800 women carry such mutations. However, individuals with family histories indicating a high risk of cancer are far more likely to carry the gene. Also, certain ethnic groups are more vulnerable: Among Ashkenazi Jewish men and women, an estimated 1 in 50 carry the gene.

People with harmful BRCA mutations have a dramatically increased risk of breast and ovarian cancer. Among the general population, women have only about a 13 percent lifetime risk of developing breast cancer. By contrast, among BRCA mutation carriers, the lifetime risk of breast cancer is 40 to 85 percent. For ovarian cancer, the lifetime risk among the general population is 1.5 percent, whereas the lifetime risk is between 25 to 65 percent for BRCA1 mutation carriers and 15 to 20 percent for BRCA2 mutation carriers. An individual person's risk may be higher or lower based on that person's own family history or lifestyle choices. Cancer risk is lower among those who live a healthy lifestyle, including exercising regularly, eating healthfully, reducing alcohol consumption and avoiding cancer-causing drugs.

However, having a healthy BRCA gene does not mean freedom from cancer risk. In fact, most women who develop breast or ovarian cancer do not have these mutations. Some may have other genetic mutations making their families more susceptible to cancer. More often, women diagnosed with cancer will have no family history of cancer at all and no identifiable genetic risk factors. Overall, only about 5 percent of women with breast cancer and 4 to 11 percent of women with ovarian cancer carry a BRCA mutation.

Interventions for those who test positive

Before you undergo any type of screening, always ask, "Is an effective treatment available for me if I test posi-

For women who have never had breast cancer, the question of whether to get tested depends on family history and an individual evaluation of cancer risk and treatment options.

tive?" In the case of BRCA carriers, surgery is an effective treatment for preventing cancer, either double mastectomy (the surgery selected by Jolie) or removal of the ovaries with or without the fallopian tubes. Though effective, these surgeries are not without risks, and individuals may choose to delay surgery for various reasons, such as concerns about the health impact of early menopause or on the ability to have children.

Preventive removal of the ovaries and fallopian tubes reduces the risk of ovarian cancer by more than 80 percent. (The risk of being diagnosed is not entirely eliminated because women still get cancer in the abdominal cavity, which is sometimes diagnosed as ovarian cancer.) It also can reduce the risk of breast cancer when performed in younger women without prior breast cancer, although that benefit diminishes as women approach menopause. There also is evidence that preventive surgery reduces the risk of mortality. However, the procedure does not eliminate all risk of cancer and involves substantial risks, including impact on childbearing as well as premature estrogen deficiency (which may increase the risk of cardiovascular disease and other conditions) and exacerbated symptoms of menopause. These risks increase in younger women, and it may be reasonable for many young women to delay undergoing surgery until closer to the age of menopause.

Preventive removal of both breasts leads to a more than 90-percent reduction in breast cancer risk, although it is not yet clear whether this procedure leads to overall improvements in survival. The primary risks of the procedure include complications from the surgery itself or from breast implants if the patient chooses to have breast reconstruction.

Some women choose to undergo intensive annual or biannual screenings for breast cancer using Magnetic Resonance Imaging (MRI) or mammography. Though intensive screening can detect cancer, its effect on mortality is unknown, and it may lead to a high rate of unnecessary additional testing and surgery through the identification of false positives. Excessive exposure to radiation through repeated mammography screenings also slightly increases a woman's risk of developing breast cancer.

Tamoxifen and raloxifene are two drugs the Food and Drug Administration approved to reduce the risk of cancer in some groups. However, these drugs have not been sufficiently tested to show whether they reduce the risk of cancer in women with BRCA mutations, and there is some evidence that tamoxifen is not effective among carriers of a faulty BRCA1 gene. Both drugs also are associated with substantial risks: Raloxifene is associated with an increased risk of blood clots, as well as hip and other fractures, and tamoxifen increases the risk of blood clots and endometrial cancer.

What to expect from the test

In those who suspect they may carry a BRCA mutation that is known to be harmful, testing for the mutation can help identify high-risk patients and allow them to make appropriate decisions about preventive treatment. In rare cases, testing also may help relieve anxiety by revealing that a woman does not carry a mutation previously detected in a member of her family. Women who have avoided inheriting a family mutation have about the same low risk of ovarian cancer as the general population. They also have a lower risk

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BRCA, from page 3

of breast cancer than those who carry the mutation, although some studies suggest that they could remain at higher risk than people with no family history of breast cancer (this residual risk may be due to other genes in the family that contribute to cancer risk).

Yet cases such as these are rare. It is far more likely that a test will be uninformative than yield a concrete negative or positive result. In the most common scenario, a patient with a family history of cancer receives test results showing normal BRCA genes but is unable to rule out other, unrelated genetic mutations that could have caused her family's cancer history. This could occur when other members of the patient's family have not yet been tested for BRCA mutations or have all tested negative themselves.

Unhelpful results also may occur in rare cases in which tests reveal a BRCA mutation that has not been studied well enough to understand its effect on cancer risk. A patient with this mutation cannot know whether the mutation increases the risk of cancer or has a neutral or even protective effect.

Patients can experience increased anxiety as a result of testing, particularly if results are uninformative, which may lead to unnecessary additional screening, prophylactic surgery or other excessive treatment. For example, in one study of subjects undergoing BRCA testing, about 12 percent of the patients who received uninformative test results had their ovaries and fallopian tubes removed, and 2 percent of those with "true negative" results (confirmed absence of a known family mutation) also underwent this surgery. Many, if not most, of these surgeries were unnecessary, given that the lifetime risk of developing ovarian cancer for these women was either unknown or equal to the general population (1.5 percent).

Until recently, genetic testing for BRCA mutations was a costly process with potentially far-reaching implica-

tions for a patient's health insurance coverage. Two recent changes to the legal landscape have the potential to profoundly change these economic concerns.

First, the Supreme Court's June 2013 decision to strike down two patents on the BRCA1 and BRCA2 genes opened the door to companies wishing to manufacture generic BRCA tests at lower costs. The price of a single test, previously between \$3,000 and \$4,000, is likely to fall dramatically with the recent ruling.

Second, under the Affordable Care Act, new health insurance plans are required to cover BRCA testing as a form of preventive care for individuals at heightened risk of carrying the gene due to family history. Insurers also are prevented from raising rates or denying insurance to patients who test positive, based on a 2008 law preventing discrimination related to genetic test results. However, insurers may still decline to pay for related procedures, such as fertility treatments for women who wish to preserve their eggs before undergoing surgery or other preventive treatment.

Should I consider testing?

Patients who have been diagnosed with certain types of breast cancer should consider genetic testing in collaboration with their cancer treatment team. For women who have never had breast cancer, the question of whether to get tested depends on family history and an individual evaluation of cancer risk and treatment options.

The U.S. Preventive Services Task Force (USPSTF), an independent panel of experts that evaluates the best evidence on preventive health services, has recommended that women at high risk of cancer due to family history seek genetic counseling to help them make an informed decision about whether to test for BRCA mutations. There is no expert consensus on exactly who should be considered sufficiently high-risk to warrant genetic counseling. However, the USPSTF has identified specific

patterns of family history that can help women decide whether to seek genetic counseling. (See the box on page 2).

The USPSTF has estimated that only about 2 percent of adult women in the general population meet one of these criteria for increased risk. For the remaining 98 percent of women who do not meet these patterns, there is very low risk of carrying a harmful BRCA mutation. These women are still at risk of developing breast cancer that is not associated with a BRCA1 or BRCA2 mutation, but genetic testing is not likely to provide useful information to help them make treatment or prevention decisions. The USPSTF therefore recommends against genetic screening for these women.

Several companies advertise genetic testing for other mutations besides BRCA mutations. These tests are generally not as helpful in guiding treatment decisions because less is known about the impact these mutations have on cancer risk. As a result, the tests may cause women to undergo unnecessary prophylactic surgery or other high-risk preventive treatments.

Patients considering any form of genetic testing should ask their doctor for a referral to a health care provider who offers genetic counseling. Genetic counseling, if done correctly by a trained expert, can help women make informed decisions, improve their knowledge and perception of the absolute risk for breast and ovarian cancer, and reduce anxiety.

BRCA testing is not for everyone and should be considered only by patients with a firm understanding of what to expect. For a small number of patients at high risk for breast cancer, this test may be a critical step toward reducing cancer risks and living a longer, healthier life. ♦

ADHD, from page 1

prescribed stimulants to individuals under the age of 19 increased from 2.4 percent in 1996 to 3.5 percent by 2008.

There are undoubtedly severe cases of attention disturbances, in which the new diagnoses represent an increased awareness among physicians and parents of significant mental illness. However, it is certain that the difficulty of diagnosing a vague condition such as ADHD has contributed to the jump in diagnoses over time. Many, if not most, of the new cases likely result from more dangerously liberal diagnostic standards within the medical community.

As the National Institute of Mental Health (NIMH) points out, anything from a middle-ear infection to a mild disruption in a child's living situation can lead to symptoms similar to those of ADHD. The NIMH alludes to the situational and often transient nature of some of the symptoms that make up the criteria outlined in the official diagnostic guidelines. The agency notes that a child could qualify as an ADHD patient in one setting (e.g., school) while returning to "normal" childhood behavior once home and therefore advises that physicians pay "close attention to the child's behavior during different situations," which some physicians may not do, given time constraints.

The often deep-seated social or economic causes of ADHD-like symptoms lead to further overdiagnosis. According to a 2011 national survey conducted by the Centers for Disease Control and Prevention, children living in poverty or in a single-parent home were substantially more likely than other children to be diagnosed with ADHD or a learning disability.

Gender, race and geographical region are all potential factors in diagnosis and treatment for ADHD. According to a 2011 study, boys are three times more likely to be prescribed a stimulant compared with girls; whites are most often treated with a stimulant compared with other ethnicities; and in the Northeast, prescriptions increased from 2.7 percent in 2002 to 4.6 percent

in 2008 compared with no increase in the Western states in that period.

Profiting from overuse

As with other psychiatric conditions, the pharmaceutical industry has exploited the diagnostic and therapeutic uncertainties of ADHD to maximal effect. Prior to the last decade, ADHD medications were approved only for children and adolescents, but this changed following Strattera's 2002 approval for the treatment of adult ADHD. Four stimulants were then approved for use in adults within the next six years. This change opened the door for college students everywhere (as well as anyone 18 and older) to become potential new patients.

By 2008, the market research firm Datamonitor was highlighting the commercial potential of this new market of adult ADHD patients in a press release aimed at the drug industry: "Immature adult market continues to offer greatest commercial potential. ... Estimated to be twice the size of the pediatric ADHD population, the highly prevalent, yet largely untapped, adult ADHD population continues to represent an attractive niche to target." The firm then exhorted companies to undertake the tried-and-true strategies of disease creation and disease promotion to realize this potential: "Manufacturers would benefit from lobbying national medical agencies into developing much-needed diagnostic and treatment guidelines, in order to increase the awareness of proper diagnostic practices and increase the diagnosis rates of ADHD in adults."

Over the last decade, companies have worked incessantly to expand the market for lucrative stimulant medicines from children to adults. Expensive direct-to-consumer ad campaigns (complete with billboards in Times Square) have proliferated. Industry-backed organizations that masquerade as patient-advocacy groups, social-media marketing and even mass public disease-screening opportunities have all worked to generate demand for ADHD

drugs to adults, young and old.

By 2011, the investments were paying dividends, with prescriptions for ADHD in young adults almost tripling over the previous four years. Stimulant sales for all age groups more than doubled over the past five years, from \$4 billion in 2007 to \$9 billion by 2012.

Illicit drug use

In February 2013, *The New York Times* began a series of articles and student testimonials on the prevalence of stimulant misuse in high school and college students. In case after case, students reported using the pills as a way of getting ahead academically and fulfilling high expectations to succeed.

Stimulants are notoriously easy for young people to obtain without a prescription. One common method is to make arrangements with (or exert pressure on) classmates holding a prescription. Studies have found that 16 to 29 percent of children and college students with stimulant prescriptions who had been asked to give, sell or trade away their medications admitted to actually having done so at some point in the past. A recent survey of 334 college students showed that 76 had been prescribed stimulants for ADHD at some point. Of these, 29 percent had sold or given their medication to others. The going rate for illicit ADHD medicines on college campuses is anywhere from \$5 to \$10 per pill.

If they can't borrow or buy the medicines from others, students may visit a campus doctor and fake symptoms to obtain their own prescriptions. In one of the articles on the topic in *The New York Times*, high school students discussed how easy it was to fool doctors by using a few canned complaints of trouble studying or restlessness. For their part, health care practitioners sometimes facilitate this practice by diagnosing ADHD on the basis of a single questionnaire.

Students reported that once they got the pills, they would use them to help

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Robotic Hysterectomy: Newer, But Not Necessarily Better

A recent *Journal of the American Medical Association (JAMA)* study documented that between 2007 and 2010, there was a significant increase in U.S. hospitals' use of robot technology to assist in hysterectomy (surgical removal of the uterus) for benign, or noncancerous, disorders.

Robotic surgery is a new medical technology that has been rapidly embraced and promoted by many hospitals in what has been described as a "technology arms race," and hysterectomy is one of several procedures for which this new technology has been developed and marketed over the past several years.

Many hospitals eager to attract patients, compete with other nearby hospitals and increase revenue advertise that their doctors use the newest technologies available, implying that these technologies represent significant advances in medicine that are better than older treatments. Too often, however, new technologies are introduced into clinical practice without having undergone rigorous clinical testing comparing them to older, more proven treatments. As a result, many new medical technologies are widely and rapidly adopted without evidence that they are safer or more effective than their predecessors. Indeed, the *JAMA* study showed that robotic hysterectomy was more expensive than laparoscopic hysterectomy but offered no advantage in terms of medical complication rates.

About hysterectomy

Approximately 600,000 women in the U.S. undergo a hysterectomy annually, making it one of the most frequently performed surgeries. The majority of hysterectomies are for benign conditions, most commonly including symptomatic leiomyomas (also called "fibromas"), endometriosis and uterine prolapse (bulging of uterus into or outside the vagina).

There are four hysterectomy tech-

niques available: vaginal, abdominal, laparoscopic and robotic. A vaginal hysterectomy involves removing the uterus through incisions made within the vagina, whereas an abdominal hysterectomy involves removal of the uterus through a large incision in the abdominal wall. Laparoscopic hysterectomy is considered a minimally invasive procedure that involves making small incisions in the abdominal wall through which fiberoptic scopes and surgical instruments are inserted to remove the uterus. Robotic hysterectomy, also minimally invasive, is very similar to laparoscopic surgery but involves a surgeon sitting at a video console to control the robotic instruments inserted via small abdominal incisions.

The technique chosen for a hysterectomy is influenced by many factors, including the size and shape of the vagina and uterus, the scope of the disorder (whether it extends beyond the uterus), the need for other surgical procedures (such as for urinary bladder prolapse), the surgeon's training and experience, the nature of the surgery (elective or emergency), and the preference of the patient.

A recent systematic review of 34 randomized clinical trials of abdominal hysterectomy, vaginal hysterectomy and laparoscopic hysterectomy, involving a total of 4,495 subjects, demonstrated that vaginal hysterectomy had the best outcomes from among these three techniques. The review also found that for patients who are not candidates for a vaginal hysterectomy, laparoscopic hysterectomy offers some advantages over an abdominal approach, including a faster return to normal activities, shorter hospital stay, less blood loss and fewer wound infections. However, laparoscopic surgery takes more time and is associated with higher rates of injury to the urinary tract (bladder and ureter, the tubes that drain urine from the kidneys into the bladder).

Percentage of Hysterectomies by Technique, 2007 Versus 2010

Technique	1st Quarter 2007	1st Quarter 2010
Abdominal	53.6%	40.1%
Vaginal	21.7%	19.8%
Laparoscopic	24.3%	30.5%
Robotic	0.5%	9.5%

In 2005, robotic devices for hysterectomy surgery were first cleared by the Food and Drug Administration (FDA) for marketing in the U.S. under a process known as 510(k) premarket notification. Under this regulatory process — a process long criticized by Public Citizen's Health Research Group as being inadequate for ensuring the safety and effectiveness of medical devices — the manufacturer of the device was not required to provide data from clinical trials demonstrating that the robotic device was safe and effective for use in performing hysterectomy. Instead, the manufacturer only had to demonstrate that the device was "substantially equivalent" or similar to another device already on the market. The few randomized clinical trials comparing robotic and laparoscopic hysterectomy conducted after FDA clearance of the robotic device revealed that robotic surgery for treatment of benign gynecologic diseases was not safer or more effective than laparoscopic surgery. However, these studies were small, involving a total of 158 subjects.

Overview of the *JAMA* study

To examine the trend of robotic hysterectomy and to better compare laparoscopic and robotic hysterectomy, researchers at Columbia University conducted a large observational study, published on Feb. 20, 2013.

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fuel an all-night study session. Some even snort the medicine for quicker effects immediately before walking into an exam. Those who abuse stimulants often report improved academic performance, partly explaining the dramatic rise in the drugs' popularity. As the number of students using the pills has increased, a "race to the bottom" can emerge, in which more and more students start popping pills just to keep pace with supposedly higher-performing colleagues, who may be doing the same.

Such a dynamic may be heightened in highly competitive programs, such as medical school. Two recent surveys of medical and other health professions students found that approximately 10 percent of students reported having used a prescription stimulant illegally, mostly to help them study. There are potential public health implications once these students graduate and begin seeing patients: Reports of prescription drug misuse are five times higher among physicians than in the general public.

ROBOTIC, from page 6

The researchers used a medical database containing comprehensive clinical and demographic data on all inpatient admissions from more than 600 acute care hospitals across the U.S., including approximately 5.5 million patient discharges, or roughly 15 percent of all hospitalizations in the U.S. Using this database, the researchers identified all women ages 18 and older who underwent a hysterectomy for benign disorders between January 2007 and March 2010. The patients were classified into one of the four hysterectomy techniques discussed above. Demographic data, such as age, year of surgery, race and insurance status, and reason for the hysterectomy were collected for each patient. The hospital in which the surgery was performed and the number of surgeries performed at each hospital and by each surgeon also were recorded.

The researchers then collected data on

Setting limits

In response to stimulant overuse and abuse, many college campuses have become reluctant to diagnose ADHD. Some have attached conditions and provisions to stimulant prescriptions being written. For instance, California State University, Fresno, requires students to sign a formal contract agreeing to submit to drug testing, to see a mental health professional every month and to not share their pills. In the contracts required by the University of Alabama and Marist College, students must pledge to not misuse the pills or share them with others. A handful of colleges and universities have even decided to "get out of the ADHD business" altogether, as one student health director told *The New York Times*. Some universities forbid their staff clinicians from making an ADHD diagnosis or prescribing stimulants, and instead refer students to off-campus providers.

Public health officials also have been promoting appropriate stimulant use, emphasizing the detrimental effects of misuse and advocating for more stringent policies around stimulant prescrip-

mortality rates and complications that occurred during or after the surgery. Finally, the researchers calculated the actual costs of the surgical procedures.

JAMA study results

The researchers identified 264,758 women who underwent hysterectomy at 441 hospitals across the U.S. from 2007 to 2010. Of these, a total of 123,288 (46.6 percent) underwent an abdominal hysterectomy, 54,912 (20.7 percent) had a vaginal hysterectomy, 75,761 (28.6 percent) had laparoscopic surgery and 10,797 (4.1 percent) had robotic surgery. The table on page 6 provides the percent of hysterectomies for each technique for the first quarters of 2007 and 2010. During the study period across all hospitals, the use of abdominal and vaginal hysterectomies declined (by 13.5 and 1.9 percent as a share of all hysterectomies, respectively), while laparoscopic hysterectomies increased (by

6.2 percent) and robotic hysterectomies increased significantly (by 9 percent).

Conclusion

The overuse and abuse of prescription stimulants by young adults from high school through graduate school is now at epidemic proportions. Though laudable, the efforts thus far to address this vast problem appear insufficient to stem the nationwide tide of misuse.

The drug industry and the medical community are both to blame as suppliers of the drugs, which have addicted — and killed — untold numbers of the nation's youth. Unless we address the undue pressure on students from high school onward and, more broadly, the socioeconomic roots of ADHD symptoms in so many children and adolescents, the epidemic will likely worsen. ♦

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HRG Works for You!

Our latest work involves generic drug labeling, censorship of an expert on clinical trial ethics and a dangerous diabetes drug

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

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

Our latest research-based consumer advocacy includes:

- **Generic Drug Labeling: A Report on Serious Warnings Added to Approved Drugs and on Generic Drugs Marketed Without a Brand-Name Equivalent — 6/20/2013** — The majority of prescriptions in the U.S. today are filled with generic drugs, making prescription drugs more affordable for patients. Yet many potential hazards are not discovered until years after drugs have been on the market, and under current Food and Drug Administration (FDA) regulations, generic drug manufacturers can do little to warn doctors and patients about newly discovered information, putting patients at risk. In this report, Public Citizen lists the 53 drugs approved by the FDA more than 10 years ago that have required new black-box warnings over the past five years. The report also provides a list of more than 400 drugs for which the brand-name product is no longer sold. As this issue of *Health Letter* goes to press, the FDA has announced that it is beginning the process of granting our petition to make it much easier for generic drug companies to warn doctors and patients about newly discovered dangers.
- **Letter to Health and Human Services (HHS) Secretary Kathleen Sebelius Regarding the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT study) and Censorship of an National Institutes of Health (NIH) Expert — 6/13/2013** — Public Citizen was deeply troubled to learn that NIH has silenced an expert within the agency who has previously raised serious concerns about the ethics of clinical trials with designs that are very similar, if not identical, to that of the SUPPORT study involving extremely premature babies.
- **Testimony to FDA Drug Safety and Risk Management and Endocrine and Metabolic Drugs Advisory Committees Regarding Rosiglitazone Safety — 6/6/2013** — Public Citizen argues that not only should the current restrictions on the use of the diabetes drug rosiglitazone (Avandia) not be lifted, the drug should be removed from the U.S. market given its unique risks and the absence of any unique benefits. Among older patients with diabetes, rosiglitazone is associated with a significantly higher risk of heart failure and death compared to pioglitazone.

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

Product Recalls

May 29, 2013 – June 24, 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

MAXILOSS Weight Advanced, 225 mg proprietary blend of herbs, supplied in 36-count capsules per each green and blue box. Volume of product in commerce: 600 boxes. All lots, all expiration dates. Marketed without an approved NDA/ANDA: Product contains sibutramine, a previously approved FDA drug removed from the U.S. marketplace for safety reasons, making it an unapproved new drug. OLAAX International.

Rugby Natural Iron Supplement, ferrous sulfate, 5 gr (325 mg), 100 tablets. Volume of product in commerce: 19,944 bottles. Lot #: 12G468, expiration date 07/2014. Label mixup: Bottles of ferrous sulfate actually contain meclizine HCl (indicated for motion sickness). Advance Pharmaceutical 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

Levothroid (levothyroxine sodium tablets). Multiple dosages, multiple lots, multiple expiration dates. Contact your pharmacist. Volume of product in commerce: unknown. cGMP deviations: After quality review of stability failures in previous lots, there is insufficient data to determine that other lots are not affected. Lloyd Inc. of Iowa.

Levoxyl (levothyroxine sodium) tablets. Multiple dosages, multiple lots, multiple expiration dates. Contact your pharmacist. Volume of product in commerce: unknown. Subpotent drug: The products were below specification for potency at the expiry stability point. King Legacy, a wholly owned subsidiary of Pfizer.

Lloyd Thyro-Tab. Multiple dosages, multiple lots, multiple expiration dates. Contact your pharmacist. Volume of product in commerce: unknown. cGMP deviations: After quality review of stability failures in previous lots, there is insufficient data to determine that other lots are not affected. Lloyd Inc. of Iowa.

Metronidazole Tablets, USP, 500 mg, multiple pills-per-bottle counts. Multiple dosages, multiple lots, multiple expiration dates. Contact your pharmacist. Volume of product in commerce: unknown. Failed tablet/capsule specifications: Some tablets had the potential to not conform to weight specifications. Physicians Total Care, Inc.

Ropinirole Hydrochloride Tablets, USP 4 mg, 100-count bottle. Volume of product in commerce: 3,048 bottles. Lot #: ZRMB11004, expiration date 09/13. Labeling: Label error on declared strength. Unopened bottles of ropinirole USP 3 mg tablets were found to be incorrectly labeled as ropinirole USP 4 mg tablets. Mylan Pharmaceuticals Inc.

The following over-the-counter medications manufactured by TG United, Inc., have been recalled due to cGMP deviations. These products are underdosed or have an incorrect dosage regime:

AMBI 2CPM/15DM/5PEH, Antihistamine, Nasal Decongestant, Fruit Candy Flavor, 16 fl. oz. bottle

AMBI 3BRM/15DM/30PSE, Antihistamine, Cough Suppressant, Nasal Decongestant, Berry Vanilla Flavor, 16 fl. oz. bottle

AMBI 3BRM/30DM/50PSE, Antihistamine, Cough Suppressant, Nasal Decongestant, Berry Vanilla Flavor, 16 fl. oz. bottle

AMBI 12.5 CPD/100GFN/30PSE, Antitussive, Expectorant, Nasal Decongestant, Raspberry Flavor, 16 fl. oz. bottle

AMBI 12.5 CPD/120GFN/5PEH, Cough Suppressant, Expectorant, Nasal Decongestant, Berry Vanilla Flavor, 16 fl. oz. bottle

AMBI 15DM/100GFN/5PEH, Antitussive, Expectorant, Nasal Decongestant, Grape Flavor, 4 fl. oz. bottle

AMBI 20DM100GFN10PEH, Antitussive, Expectorant, Nasal Decongestant, Grape Flavor, 16 fl. oz. bottle

AMBI 25DPH/7.5PEH, Antihistamine, Nasal Decongestant, Fruit Candy Flavor, 16 fl. oz. bottle

AMBI 25CPD/200GFN, Antitussive, Expectorant, Berry Vanilla Flavor, 16 fl. oz. bottle

AMBI 40PSE/400GFN/20DM, Cough Suppressant, Expectorant, Nasal Decongestant, 100 count bottle

AMBI 40PSE/400GFN, 100-tablet bottle

Brompheniramine/Pseudoephedrine DM, Antihistamine, Cough Suppressant, Decongestant, 16 fl. oz. bottle

BroveX PSE, Antihistamine, Nasal Decongestant, 100-count bottle

BroveX PSE DM, Antihistamine, Cough Suppressant, Decongestant, 100-count bottle

BroveX PSB Liquid, Antihistamine, Decongestant

BroveX PSB DM Liquid, Antihistamine, Decongestant

DRUGS AND DIETARY SUPPLEMENTS (CONTINUED)

Cardec DM Drops, Decongestant, Antihistamine, Antitussive, 1 fl. oz. bottle

Cardec Drops, Antihistamine, Nasal Decongestant, 1 fl. oz. bottle

CPM / PSE Drops, Antihistamine, Nasal Decongestant, 1 fl. oz. bottle

CPM / PSE DM Drops, Antihistamine, Cough Suppressant Decongestant, 1 fl. oz. bottle

Dallergy Chewable Tablets, Antihistamine, Nasal Decongestant, 100-count bottle

ED A-HIST Tablets, Antihistamine, Nasal Decongestant, 100-count bottle

Lusair Liquid, 1 pint bottle

Maxifed DM, Expectorant, Nasal Decongestant, 100-count bottle

Maxifed-G, Expectorant, Nasal Decongestant, 100-count bottle

Mesehist DM, Antihistamine, Antitussive, Decongestant, 16 fl. oz. bottle

Mesehist WC, Antihistamine, Antitussive, Decongestant, 16 fl. oz. bottle

NoHist Tablets, Antihistamine, Nasal Decongestant, 100-count bottle

Poly Hist Forte, Nasal Decongestant, Antihistamine, 100-count bottle

Poly-Vent DM Tablets, Cough Suppressant, Expectorant, Nasal Decongestant, 60-count bottle

Poly-Vent IR, Poly-Vent DM Tablets, Expectorant, Nasal Decongestant, 60-count bottle

Ryddex G Tablets, Decongestant, Expectorant, 100-count bottle

TG 40PSE/400GFN Tablets, 1,000-count bottle

TL-DEX DM, Cough Suppressant Decongestant, Expectorant 16 fl. oz. bottle

TL Hist DM, Antihistamine, Decongestant, Cough Suppressant, 16 fl. oz. bottle

TL-Hist PD Drops, Antihistamine, Nasal Decongestant, 1 fl. oz. bottle

Tri-Dex PE, Antihistamine, Antitussive, Nasal Decongestant, 16 fl. oz. bottle

Trigofen Drops, Antihistamine, Decongestant, 1 fl. oz. bottle

Trigofen DM Drops, Antihistamine, Cough Suppressant, Decongestant, 1 fl. oz. bottle

Z-Dex Pediatric Drops, Cough Suppressant Decongestant, Expectorant 16 fl. oz. bottle

Z-Dex Syrup, Decongestant, Antitussive, Expectorant, 16 fl. oz. bottle

ZoDen DM Drops, Antihistamine, Cough Suppressant, Decongestant, 1 fl. oz. bottle

ZoDen PD, Antihistamine, Nasal Decongestant, 16 fl. oz. bottle

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

Aztec Light Chandeliers. The fixture loop that connects the hanging chain to the lamp can fail during use, causing the chandelier to fall from the ceiling and injure bystanders. Kichler Lighting's Home Center Division (Aztec) at (800) 554-6504 or www.kichler.com.

Baby Bath Seats. The bath seats fail to meet federal safety standards, including the requirements for stability. Specifically, the bath seats can tip over, posing a risk of drowning to babies. BeBeLove at (888) 464-1218 or www.bebeloveusa.com.

Cedar Lake Propane Heater/Cooker. The regulator on the heater/cooker malfunctions when a user switches from a cooking to heating option, or vice versa, the gas propane turns to liquid, which can flare easily and pose a fire hazard. Texsport at (800) 231-1402 or www.texsport.com.

DiveAlert and DiveAlert PLUS Signaling Devices. The signaling device can malfunction when used and restrict the diver's air flow, posing a drowning hazard. DiveAlert at (800) 275-4332 or www.divealert.com.

Easton Axis Arrows. The arrows can break when fired and hit unintended targets, including the user and bystanders. Easton Technical Products at (888) 380-6234 or www.axisrecall.com.

Gerber® Bear Grylls Parang Machete with Stitched Sheaths. The Parang machete can cut through the stitching of the sheaths when the blade is taken from or replaced in the sheath, posing a laceration hazard. Gerber Legendary Blades at (877) 314-9130 or www.gerbergear.com.

Idea Baby Bath Seats. The bath seats fail to meet federal safety standards, including the requirements for stability. Specifically, the bath seats can tip over, posing a risk of drowning to babies. Chelsea & Scott at (866) 271-4536 or www.onestepahead.com, and Buy Buy Baby at (877) 328-9222 or www.buybuybaby.com.

Jeep Liberty Strollers. The inner tube of the tire on the stroller can rupture, causing the wheel rim to fracture and fly off as a projectile, posing a risk of bodily injury and property damage. Kolcraft at (800) 453-7673 or www.Kolcraft.com.

"Joanna" Girl's Sandal. The metal flower on the shoe can detach, posing a choking hazard. Stride Rite at (800) 365-4933 or www.striderite.com.

LYDA Jumbo Cups. The cups can break when hot liquid is poured into them, posing a burn hazard. IKEA at (888) 966-4532 or www.ikea-usa.com.

CONSUMER PRODUCTS (CONTINUED)

Metal Halide Lamps. The internal wiring can arc, causing the lamp to catch fire or the glass to shatter. This poses fire and laceration hazards. Philips Lighting Company at (800) 372-3331 or www.philips.com/recall.

Paddywax Fragrance Diffusers. The label on the diffusers violates the Federal Hazardous Substances Act (FHSA) by omitting the presence of petroleum distillates. Petroleum distillates pose an aspiration hazard if swallowed. Paddywax at (888) 442-3088 or www.paddywax.com.

Portfolio and Transglobe Nine-Light Chandeliers. The mounting loop that holds the chandeliers to the ceiling can break, causing the

chandelier to fall, posing an impact injury hazard to consumers. Bel Air Lighting at (888) 803-0509 or www.regcen.com/belair.

Salsa Bicycle Forks. The bicycle fork can bend above the disc brake mount, posing a fall hazard to the rider. Salsa Cycles at (877) 774-6208 or www.salsacycles.com.

Target-Mins™ Iron Supplement Bottles. The packaging is not child-resistant as required by the Poison Prevention Packaging Act. The supplement tablets inside the bottle contain iron, which can cause serious injury or death to young children if multiple tablets are ingested at once. Country Life at (800) 645-5768 or www.countrylifevitamins.com.

ROBOTIC, from page 7

with private health insurance underwent robotic surgery more often than those with Medicare, Medicaid or no insurance. Patients treated at larger hospitals and at metropolitan medical centers also were more likely to have a robotic procedure.

The investigators compared outcomes and costs in a sample of 4,971 patients who underwent robotic hysterectomy with an appropriately matched sample of an equal number of patients who underwent a laparoscopic procedure. Matching took into account patient demographic and clinical factors (age, year of diagnosis, race, marital status, insurance status, reason for the surgery, other concomitant procedures and other diseases) and hospital factors (location, bed size, and hospital and surgeon hysterectomy volume). There were no significant differences in the rates of complications during and after surgery for the two patient groups. There also were no deaths in either group. However, laparoscopic hysterectomy patients were more likely than robotic surgery patients to have hospital stays longer than two days (25 percent versus 20 percent, respectively), whereas the total cost of the surgery was lower for the laparoscopic hysterectomy than the robotic procedure (an average of \$6,700 versus \$8,900, respectively).

Implications of the study

Too often, new medical technologies are adopted and aggressively promoted by hospitals before evidence has been obtained from well-designed clinical trials demonstrating that the new technologies are as safe, clinically effective and economical as older, more established treatments. The use of robotic technology for hysterectomy is an example of such circumstances.

In considering potential causes of the rapid adoption of robotic hysterectomy, the *JAMA* study authors noted:

- Robotic surgery may be easier for surgeons to learn than the laparoscopic technique because it is more similar to traditional open abdominal surgery;
- Robotic techniques may allow a minimally invasive approach for more technically demanding surgeries that would otherwise have required the more invasive, open abdominal hysterectomy.
- Extensive marketing of robotic surgery to surgeons, hospitals and medical consumers may contribute to increased use of the technology.

An editorial commenting on the hysterectomy study in the same *JAMA* issue noted that the “national fascination with technology and innovation” also likely affects the rapid expansion of the use of robotic hysterectomy. Slick marketing campaigns by hospitals

and surgeons that offer robotic surgery clearly take advantage of this.

Continuing along these lines, the *JAMA* editorial noted the following:

Considerable debate surrounded the emergence of direct-to-consumer advertising of prescription drugs in the 1990s. Robotic surgery takes this marketing to a higher level with advanced campaigns not only by industry, but also by surgeons and the hospitals that own the machines. Such consumer-directed advertising is not without merit if it uses consumer awareness to advance underused medical discoveries that benefit the population. However, when the innovation being advertised is of questionable advantage, direct-to-consumer promotion may only fuel unnecessary utilization.

We agree with the editorial writers.

Although there may be a subset of patients needing a hysterectomy who could benefit from robotic surgery, well-designed clinical studies have yet to identify such patients. Today, many patients are undergoing the more expensive robotic hysterectomy without evidence that it is improving patient outcomes. Until such evidence is obtained, patients considering hysterectomy should avoid being swayed by the advertising campaigns promoting robotic hysterectomy. ♦



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Outrage of the Month: Pay for Delay

The more we learn about the lucrative scheme of “pay for delay,” in which brand-name drug companies pay generic companies to delay marketing of a drug, the more outrageous it becomes. In the scheme, generic companies profit by agreeing to delay the introduction of their lower-priced version, and brand-name companies profit by having an artificially prolonged time to maintain their market exclusivity, at much higher prices. But what is lucrative for these companies is extremely costly, even unaffordable, for patients who must pay higher prices for an extended time.

A new report by the nonprofit advocacy organizations California Public Interest Group and Community Catalyst examines the consequences for patients of 20 widely used drugs for which pay-for-delay schemes were employed. Among the drugs studied were Cipro (ciprofloxacin), Lipitor (atorvastatin) and Nexium (esomeprazole). For the 15 medications studied for which the delay is now over, the price disparity after the delay period shows the extent of savings that are unavailable while the delay period is in place. For example, a prescription for brand-name antibiotic Cipro costs \$346, but generic ciprofloxacin costs only \$23, and a prescription for Lipitor costs \$205, while generic atorvastatin is only \$18. The brand-name drugs studied cost an average of 10

times more than their generic equivalents, but as much as 33 times more, and the payouts on these drugs have delayed the introduction of generic versions for an average of five years, but for as long as nine years. Since 2005, generic versions of 142 drugs have been delayed this way.

Although many federal bills banning pay for delay have been proposed since 2006, none of them have succeeded, largely due to drug industry opposition. But a vital ray of sunshine comes via the recent Supreme Court decision in *Federal Trade Commission v. Actavis*. This ruling upheld the Federal Trade Commission’s right to challenge patent settlements that would result in pay-for-delay deals because of the significant anticompetitive effects these schemes can have. In this case, the payment from the brand-name company to the generic company was said to be between \$19 million and \$30 million annually until 2015. The decision did not flatly ban any such payment by brand-name companies, but it implied that much smaller payments might be allowed.

The decision stopped short of an outright ban but is likely to significantly reduce the size and occurrence of pay-for-delay deals and thereby hasten the time for less-expensive generic drugs to reach the millions of patients who will be much more able to afford them.