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AMERICAN PSYCHOLOGICAL ASSOCIATION

COVER STORY

Inappropriate Prescribing

Research shows that all too often, Americans are taking medications that may not work or may be inappropriate for their mental health problems.

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June 2012, Vol 43, No. 6
Print version: page 36

Writing a prescription to treat a mental health disorder is easy, but it may not always be the safest or most effective route for patients, according to some recent studies and a growing chorus of voices concerned about the rapid rise in the prescription of psychotropic drugs.

Today, patients often receive psychotropic medications without being evaluated by a mental health professional, according to a study last year by the Centers for Disease Control and Prevention (CDC). Many Americans visit their primary-care physicians and may walk away with a prescription for an antidepressant or other drugs without being aware of other evidence-based treatments — such as cognitive behavioral therapy — that might work better for them without the risk of side effects.

"I would say at least half the folks who are being treated with antidepressants aren't benefiting from the active pharmacological effects of the drugs themselves but from a placebo effect," says Steven Hollon, PhD, a psychology professor at Vanderbilt University who has conducted extensive research on the effectiveness of antidepressants. "If people knew more, I think they would be a little less likely to go down the medication path than the psychosocial treatment path."

The use of psychotropic drugs by adult Americans increased 22 percent from 2001 to 2010, with one in five adults now taking at least one psychotropic medication, according to industry data. In 2010, Americans spent more than $16 billion on antipsychotics, $11 billion on antidepressants and $7 billion for drugs to treat attention-deficit hyperactivity disorder (ADHD). The rapid growth of all three classes of drugs has alarmed some mental health professionals, who are concerned about the use of powerful antipsychotic drugs by elderly nursing home residents and the prescription of stimulants to children who may have been misdiagnosed with ADHD. Psychotropic drugs are valuable tools in treating many mental health disorders, but inappropriate prescribing can cause serious harm. To help address those concerns, APA is developing clinical treatment guidelines that will help educate physicians, health insurers and the public about the best treatments available for common mental health disorders. APA also supports an integrated approach to health-care delivery in which primary-care and mental health providers work together to determine the best treatment plan for each patient.

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Prozac opened the floodgates

When Prozac (fluoxetine) was approved by the Food and Drug Administration (FDA) in 1987, it offered fewer side effects than other common antidepressants, leading to a burgeoning class of selective serotonin reuptake inhibitor antidepressants (SSRIs). Since the launch of Prozac, antidepressant use has quadrupled in the United States, and more than one in 10 Americans now takes antidepressants, according to the CDC. Antidepressants are the second most commonly prescribed drug in the United States, just after cholesterol-lowering drugs.

Most antidepressants are prescribed by primary-care physicians who may have limited training in treating mental health disorders. In the United States, almost four out of five prescriptions for psychotropic drugs are written by physicians who aren't psychiatrists (Psychiatric Services, 2009). And fewer of their patients receive psychotherapy than in the past. In 1996, one-third of patients taking antidepressants also received therapy. By 2005, only one-fifth of patients did, according to a study of more than 50,000 medical surveys that was co-authored by Mark Olfson, MD, professor of clinical psychiatry at Columbia University (Archives of General Psychiatry, 2009).

Lower clinician reimbursement rates for psychotherapy and higher out-of-pocket costs to patients most likely contributed to the declining use of therapy, the study found. "Antidepressants are overprescribed and underprescribed in the United States," Olfson says. "Many adults with major depressive disorder go for long periods of time without receiving treatment." At the same time, many people with mild depression are prescribed antidepressants even though they aren't likely to benefit from the drugs, he added.

A growing body of research suggests that antidepressants aren't as effective as many people believe. An analysis of all FDA clinical trials for four SSRI antidepressants found that the drugs didn't perform significantly better than placebos in treating mild or moderate depression, and the benefits of the drugs were "relatively small even for severely depressed patients" (PLoS Medicine, 2008). The study was led by Irving Kirsch, PhD, a clinical psychologist and researcher who is now associate director of the Program in Placebo Studies at Harvard Medical School. Some critics have challenged the study's methodology or cited other studies that support the efficacy of antidepressants.

Clinical studies of antidepressants also have some common limitations, including the subjective nature of depression rating scales and the difficulty in studying hospitalized or suicidal patients with severe depression, says Steven Paul, MD, a neuroscientist who heads the Appel Institute for Alzheimer's Research at Weill Cornell Medical College in New York City. Paul, who previously served as president of Lilly Research Laboratories, says several studies and his own clinical experience as a psychiatrist showed that a combination of antidepressants and cognitive behavioral therapy were the most effective method for treating depression. "Medication treatment is but one way to treat depression," he says. "It's not necessarily the best way or the only way."

Selective publication of clinical trials on antidepressants also could cause a bias about their perceived effectiveness, according to a study led by researchers at the Portland Veterans Affairs Medical Center (New England Journal of Medicine, 2008). The study examined 74 FDA-registered studies for a dozen antidepressants and found that most studies with negative results were not published in scientific literature or were published in a way that conveyed a positive outcome. The FDA studies showed that half of the drug trials had positive results, but 94 percent of the trials cited in published literature were positive.

Psychotherapy may be just as effective as antidepressants in many cases, without the risk of side effects and with lower instances of relapse, according to some studies. Hollon studied 240 patients with moderate to severe depression and found that patients who responded to cognitive therapy were significantly less likely to relapse into another bout of major depression than patients who responded to antidepressants and were later withdrawn from the drugs (*Archives of General Psychiatry*, 2005).

The study also found some enduring effects from cognitive therapy that may help prevent recurrence of depression. "Our impression is that patients initially need to apply the skills they learned during [cognitive therapy] treatment in a concerted fashion, but that these compensatory strategies eventually become second nature," the study noted. These strategies include having patients examine their negative thought patterns and the creation of a step-by-step plan to help cope with life stresses.

After reviewing the published literature, the National Health Service in England adopted cognitive behavioral therapy as a first-line treatment for mild and moderate depression because the risk-benefit ratio is "poor" for antidepressants. In 2011, the British government invested £400 million over the next four years to increase patient access to psychotherapy to treat depression and anxiety disorders. The effort includes plans to train up to 6,000 therapists in cognitive behavioral therapy.

For many patients, medications do not provide the same benefits and coping skills as psychotherapy, says APA President Suzanne Bennett Johnson, PhD. "Many patients don't want to take more drugs," she says. "Patients should be informed about the advantages, limitations and potential harm of all evidence-based treatments for their condition so they can make an informed choice. Too often, psychotropic medication is the only option that is offered."

The drug industry Health insurance reimbursements are higher and easier to obtain for drug treatment than therapy, which has contributed to the increase in psychotropic drug sales and a shifting of psychiatry toward psychopharmacology, says Daniel Carlat, MD, associate clinical professor of psychiatry at Tufts University and author of the 2010 book "Unhinged: The Trouble with Psychiatry."

"There is a huge financial incentive for psychiatrists to prescribe instead of doing psychotherapy," he says. "You can make two, three, four times as much money being a prescriber than a therapist. The vicious cycle here is that as psychiatrists limit their practices primarily to prescribing, they lose their therapy skills by attrition and do even less therapy."

The pharmaceutical industry has been very successful in marketing psychotropic drugs to physicians and the public. From 1996 to 2005, the drug industry tripled its spending on marketing, including a fivefold increase in direct-to-consumer advertising. Several studies have found that prescription drug ads don't adequately explain side effects and can adversely affect decisions by patients and doctors. In one study, American patients were more than twice as likely to request advertised drugs than patients in Canada, where most direct-to-consumer advertising is prohibited (*Canadian Medical Association Journal,* 2003). Patients who requested advertised drugs were nearly 17 times more likely to receive one or more new prescriptions than patients who did not request any drugs. The Pharmaceutical Research and Manufacturers of America says the ads help educate patients about treatment options. (The American Psychiatric Association's communications office declined to comment about issues related to inappropriate prescribing or potential ethical problems for psychiatrists who are paid by pharmaceutical companies to promote certain drugs through speaking or consulting fees.)

Aggressive marketing also has fueled the off-label prescription of antipsychotic drugs for a growing list of mental health disorders, including dementia, anxiety, depression and insomnia. While physicians can prescribe drugs off label for various conditions, pharmaceutical companies are prohibited by the FDA from promoting drugs for off-label uses. Over the past five years, Eli Lilly, Pfizer and several other drug companies have agreed to pay settlements totaling billions of dollars for prohibited off-label marketing of their drugs, including antidepressants and antipsychotics.

The rise of antipsychotics

The use of second-generation antipsychotics nearly tripled from 1995 to 2008 in the United States, ballooning to more than 16 million prescriptions for drugs such as aripiprazole (Abilify), clozapinel (Clozaril) and quetiapine (Seroquel). More than half of those prescriptions in 2008 were for uses with uncertain scientific evidence, according to a study from Stanford University and the University of Chicago based on more than 1,700 physician surveys (Pharmacoepidemiology and Drug Safety, 2011).

Of particular concern is the prescribing of antipsychotic drugs to vulnerable populations, including foster care children and elderly nursing home residents. Foster children are up to four-and-a-half times more likely to receive psychotropic drugs than other children covered by Medicaid, according to a Government Accountability Office report last year. The investigation of foster care programs in five states found that hundreds of children were prescribed multiple psychotropic drugs, including antipsychotic drugs at excessive dosages. Infants also were prescribed psychotropic drugs despite no scientific evidence supporting that use. In response to those findings, the GAO recommended the development of federal best-practice guidelines on the use of psychotropic drugs by foster care programs.

In nursing homes across the United States, antipsychotic drugs have been increasingly used to treat psychosis and other behavioral problems caused by dementia, even though studies have shown an increased risk of death for those patients who take the drugs. The medications also can cause serious side effects, including muscle spasms, metabolism changes, major weight gain and an increased risk of diabetes.

One in seven elderly nursing home residents had Medicare claims for antipsychotic drugs in 2007, and 83 percent of those claims were for off-label uses, according to an audit last year by the U.S. Department of Health and Human Services. The federal investigation also found that more than one in five Medicare claims for antipsychotic drugs didn't comply with federal guidelines prohibiting unnecessary or excessive medication of nursing home residents.

While antipsychotic drugs are a crucial and potentially life-saving treatment for schizophrenia, the evidence is much less conclusive for treating psychotic symptoms in patients with dementia, Paul says. "You're always going to use a drug in the context of what the benefits are going to be and weigh that against the risks," he says.

Some recent studies have found that cognitive behavioral therapy can help treat psychotic symptoms. In 2002, the National Institute for Health and Clinical Excellence in England recommended that cognitive behavioral therapy, as well as appropriate medications, be offered to all patients with schizophrenia based on a review of 20 randomized controlled trials. A University of Manchester study found that cognitive behavioral therapy led to clinically significant decreases in psychotic symptoms and longer periods in remission (*Psychological Medicine,* 2011).

The ADHD debate

The public debate about the potential overmedication of children with ADHD drugs has been more vocal than concerns about antipsychotics or antidepressants, in part because medicating children is an emotional issue. About 4 million children — or 8 percent of all youths in the United States — have been diagnosed with ADHD, and more than half of them take prescription drugs. The subjective nature of ADHD symptoms, along with varying reports about children's behavior from parents and teachers, has made it difficult for researchers to untangle the reasons for the increase in diagnosis of ADHD.

Stimulants such as methylphenidate (Ritalin) and mixed amphetamine salts (Adderall) generally have been safe and effective in treating ADHD symptoms in school-age children and some adults. But the use of stimulants by preschoolers has generated more controversy because of a greater risk of side effects and concerns about the drugs' impact on growth and brain development. (For more details, see the July 2011 Monitor.)

The American Academy of Pediatrics expanded its guidelines for the diagnosis and treatment of ADHD last year to cover preschoolers and adolescents, since the previous guidelines issued a decade ago were limited to children age 6 to 12 because of the then-available research.
The report recommends that preschoolers with ADHD receive behavioral interventions first, such as parent training in behavior management techniques. If those interventions fail, then methylphenidate may be considered only for moderate to severe symptoms.

Expanding prescription privileges
Some mental health professionals support granting prescription privileges to appropriately trained psychologists as one means of reducing inappropriate prescribing. By offering both therapy and medications, a prescribing psychologist could choose the best approach for the patient, these advocates say.

"The right to prescribe is also the right to unprescribe," says Elaine Levine, PhD, a prescribing psychologist who teaches psychopharmacology courses at New Mexico State University. "We have to recognize there are times when psychotropic drugs can be life-saving and very helpful. We need to be able to use them to really help people and minimize the overuse of medications."

Prescription privilege programs for psychologists have been approved in New Mexico, Louisiana, Guam and the armed forces as well as Indian Health Service and the US Public Health Services. APA has been working with a number of other states to enable psychologists to prescribe. Among those states, legislators in Arizona, Hawaii, Montana, New Jersey, Ohio, Oregon, Tennessee and Utah have also recently considered bills that would allow prescription privileges for psychologists, but the measures have been opposed by the American Medical Association and American Psychiatric Association over concerns that inadequate training of psychologists could jeopardize patient safety. Supporters of prescriptive authority for psychologists are quick to point out that there is no evidence to support these concerns.

Patients also must be willing to invest the time and energy in therapy if they want treatment that isn't centered on drugs, Carlat says. "From the standpoint of consumers and patients, it's very attractive on different levels to take a pill to solve your problems," he says. "But we haven't gotten to a point where a pill alone can resolve most people's depression or anxiety."

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