

Medical Ideals Not Always Easy to Live Up To

BY JOEL B. FINKELSTEIN

Contributing Writer

WASHINGTON — Easier said than done. That may be the take-away message from a study that revealed troubling gaps between physicians' attitudes and behavior when it comes to standards of professionalism.

A national survey of 3,500 primary care and specialist physicians found that 95% said physicians should report incompe-

tent or impaired colleagues. However, only 56% of those who had been in a position to do so, in fact, did.

"It's simply not acceptable that bad physicians aren't being reported to the proper authorities," said Dr. James N. Thompson, president and CEO of the Federation of State Medical Boards, at a press briefing to release the findings.

The survey also showed that 92% of physicians thought they should always report medical errors, but 31% admitted to not doing so on at least one occasion.

"Most physicians are trying to do the right thing, under increasingly difficult circumstances," said Dr. David Blumenthal, who is the director of the Institute for Health Policy at the Massachusetts General Hospital, Boston, and senior author of the study (Ann. Intern. Med. 2007;147:795-802).

Those circumstances include not only financial pressures, but also the seemingly constant threat of lawsuits, he said.

"I'm neither surprised nor disheartened by the study's outcome. It just shows that

doctors are people," said Dr. Ari Silver-Isenstadt, a pediatrician at Franklin Square Hospital Center in Baltimore.

For example, while 96% of physicians said that they should put the patient's welfare above their own financial interests, 84% had accepted food or beverages from drug company representatives. Smaller percentages admitted that they had received drug

samples, admission to CME events, consulting or speaking fees, travel tickets to sporting events and other industry provided perks.

Physicians may feel they are not influenced by such marketing, but even the appearance of a conflict can undermine patient trust.

"It took me awhile to recognize that I am just as vulnerable as any other Joe to advertising, but given my fiduciary responsibility to my patients, I have to be more vigilant," said Dr. Silver-Isenstadt, who recalled the novelty and allure of industry grants and gifts when he was new to the profession.

Despite everyday obstacles to profes-

sionalism, the authors took it as a hopeful sign that physicians have the right attitude. What is needed next is the ability to bridge that divide between attitude and action in a nonpunitive environment.

"We have to create a health care system that is safe for professionalism," said Dr. Blumenthal.

That is borne out by the work of both national groups and more local efforts, said Dr. Peter Cohen, a retired anesthesiologist who chairs the physicians health program for the Medical Society of the District of Columbia, which steps in when physicians are found to be abusing drugs or alcohol.

"We have hospitals reporting, patients reporting, colleagues reporting. They know that ... they are doing both the drug-abusing physician and society a favor, because these people do get into treatment and over 90% return to practice," said Dr. Cohen, who also is an adjunct professor of law at Georgetown University, Washington.

"It's not enough to just say 'woe is us, we've got a disconnect.' It's important that people look for the reasons behind the disconnect and do something about it. ... As more and more knowledge is gathered, the disconnect will begin to disappear," he said. ■

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(3% and <1%); Anorgasmia* (2% and <1%); *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflamed injury, anxiety. †Primarily ejaculatory delay. ‡Denominator used was for males only (N=225 Lexapro; N=188 placebo). †Denominator used was for females only (N=490 Lexapro; N=404 placebo). ‡Generalized Anxiety Disorder Table 3 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see TABLE 3). TABLE 3 Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder* (Lexapro (N=429) and Placebo (N=427)).

Autonomic Nervous System Disorders: Dry Mouth (9% and 5%); Sweating Increased (4% and 1%); Central & Peripheral Nervous System Disorders: Headache (24% and 17%); Paresthesia (2% and 1%); Gastrointestinal Disorders: Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%); General: Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%); Musculoskeletal: Neck/Shoulder Pain (3% and 1%); Psychiatric Disorders: Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%); Urge/Urge to Urinate Disorder†‡ (14% and 2%); Anorgasmia* (6% and <1%); Menstrual Disorder (2% and 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: inflamed injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. †Denominator used was for males only (N=182 Lexapro; N=195 placebo). ‡Denominator used was for females only (N=247 Lexapro; N=232 placebo).

Dose Dependency of Adverse Events The potential dose dependency of common adverse events (defined as an incidence rate of ≥25% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 4 shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. TABLE 4 Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=251); Insomnia (4%, 7%, 14%); Diarrhea (5%, 6%, 14%); Dry Mouth (3%, 4%, 9%); Somnolence (1%, 4%, 9%); Dizziness (2%, 4%, 7%); Sweating Increased (<1%, 3%, 8%); Constipation (1%, 3%, 6%); Fatigue (2%, 2%, 6%); Indigestion (1%, 2%, 6%); Adverse events with an incidence rate of at least 5% in either of the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. Male and Female Sexual Dysfunction with SSRIs Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Table 5 shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. TABLE 5 Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials (In Males Only: Lexapro (N=407) and Placebo (N=383); Escitalopram (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). (In Females Only: Lexapro (N=371) and Placebo (N=636); Libido Decreased (3% and 1%); Anorgasmia (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priligis has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from (1) Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1420 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in Tables 2 & 3, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring in one or more occasions in at least 1/1000 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients; Cardiovascular - Frequent: palpitation, hypertension. Infrequent: bradycardia, tachycardia, ECG abnormal, flushing, varicose vein, Central and Peripheral Nervous System Disorders - Frequent: light-headed feeling, migraine. Infrequent: tremor, vertigo, restless legs, shaking, twitching, disequilibrium, tics, carpal tunnel syndrome, muscle contractions/involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - Frequent: heartburn, abdominal cramp, gastroenteritis. Infrequent: gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General - Frequent: allergy, pain in limb, fever, hot flushes, chest pain. Infrequent: edema of extremities, chills, lightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemtic and Lymphatic Disorders - Infrequent: bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - Frequent: increased weight. Infrequent: decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - Frequent: arthralgia, myalgia. Infrequent: jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - Frequent: appetite increased, lethargy, irritability, concentration impaired. Infrequent: jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, anxiety attack, bruism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female - Frequent: menstrual cramps, menstrual disorder. Infrequent: menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only; N= 905 Respiratory System Disorders - Frequent: bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. Infrequent: asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - Frequent: rash. Infrequent: pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodules. Special Senses - Frequent: vision blurred, tinnitus. Infrequent: taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - Frequent: urinary frequency, urinary tract infection. Infrequent: urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, chorea-thetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoaesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepatitis, hypotension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, spontaneous abortion, Stevens Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

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Elderly Mental Health Care Services

To help communities provide support services for older adults' mental health needs, the Substance Abuse and Mental Health Services Administration is accepting applications for the Older Adults Targeted Capacity Expansion Grants. More information is at www.samhsa.gov/Grants/2008/sm_08_008.aspx.

Substance Abuse in Young Adults

The Substance Abuse and Mental Health Services Administration has released a national survey short report entitled "Depression and the Initiation of Cigarette, Alcohol, and Other Drug Use Among Young Adults." The report is based on statistics that were gathered from adults aged 18-25 years and suggests that mental disorders can cause substance abuse and vice versa. To download the report, visit <http://oas.samhsa.gov/2k7/newusers/depression.cfm>. To obtain free copies, call 877-726-4727.

Anti-Underage Drinking Comic Book

Spider-Man and the Fantastic Four superheroes will promote a message against underage drinking in a new video comic book for the Elks National Drug Awareness Program. The comic book, launched in collaboration with the Substance Abuse and Mental Health Services Administration, is available at www.elks.org/Marvel.cfm.

Resources on Co-Occurring Disorders

The Substance Abuse and Mental Health Services Administration's Co-Occurring Center for Excellence has published three new reports ("Services Integration:

Overview Paper 6," "Systems Integration: Overview Paper 7," and "The Epidemiology of Co-Occurring Substance Use and Mental Disorders: Overview Paper 8") to help mental health professionals treat people who have co-occurring substance abuse and mental disorders. The papers can be obtained for free by calling 877-726-4727.

Helping Older Adults Search Online

The National Institute on Aging is offering a free curriculum titled "Helping Older Adults Search for Health Information Online: A Toolkit for Trainers." Instructors can use this curriculum to teach elderly people how to find health information on the Web. The curriculum also contains easy-to-read health information from NIHSeniorHealth in different formats, including open-captioned videos and large type. To get more information, visit <http://nihseniorhealth.gov/toolkit>.

New Multilanguage Resources

The Substance Abuse and Mental Health Services Administration has released publications for non-English speakers. "What is Substance Abuse Treatment? A Booklet for Families" is now available in Chinese, Vietnamese, and Korean, as well as Russian and Spanish. This and other products, including booklets translated into Navajo, can be downloaded at www.kap.samhsa.gov/mli.

Spanish Language Web Site

The Centers for Disease Control and Prevention has relaunched its Spanish language Web site, CDC en Español, with new features. The site provides up-to-date information on health promotion and disease prevention topics of special interest

to Hispanic communities, including asthma, cancer, HIV/AIDS, immunizations, children's health, diabetes, and occupational hazards. CDC en Español receives more than 6 million visitors a year. The Web site address is www.cdc.gov/spanish.

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