To Prescribe or Not to Prescribe: Eleven Exploratory Questions

Richard B. Stuart
University of Washington

Elaine E. Heiby
University of Hawaii at Manoa

Many psychologists believe that gaining prescription authority (RxP) would benefit them, their patients, and the field. Prescribing could extend the boundaries of psychological services, but doing it responsibly requires many changes in knowledge acquisition and clinical practice. Since organized psychology is firmly committed to this change, the 11 questions presented here are intended to help individual clinicians decide whether they should seek prescriptive authority. The questions address significant challenges in obtaining the necessary education about human biology; the ways in which organ systems are affected by drugs; methods of prescribing and monitoring treatment results; and preparing for a possible increased risk of malpractice actions. Those considering the pursuit of prescribing authority will also want to determine whether the few psychologists who can currently prescribe drugs have used their authority safely and effectively. In addition, it is important to realize that to meet high standards of care for psychological services, prescribers must both keep abreast of the evolving body of psychological theory and research and devote equal or greater time to maintaining the most current knowledge about the predictable effects of drugs. The latter task is difficult due to common flaws in drug research and flaws in the policies and procedures used by the FDA to regulate drugs. Psychologists should be prepared to adjust their practices to meet these and other challenges *before* they put pen to the prescription pad.

Many people consult psychologists for help with problems that are widely believed to respond positively to medication. Careful evaluation of each patient and the predictable effects of each drug are needed to determine whether the most cost-effective intervention is to offer psychotherapy, prescribe drugs, or recommend a combination of the two by a single provider or two collaborating professionals (Bietman, Blinder, Thase, Riba & Safer, 2003). These decisions are more complicated than many of those commonly made by psychologists.

Unfortunately, "there has never been a full debate on [prescription authority] that was open to all interested members of APA" (Bush, 2002b, p. 2). Attempts to survey psychologists' opinions about the wisdom of prescription authority yielded results that are consistent with investigators' biases; this is reflected in the way in which questions are framed and samples selected. In general, surveys have revealed that majorities of psychologists in non-probability samples in North America endorse their profession's pursuit of the authority to prescribe medication along with offering psychotherapy, although most indicated that they would not choose to do so themselves (Bush, 2002a; Waters, 2001). Despite variability in the strength of the data, findings like these have fueled the commitment by organized psychology to obtain prescription authority for psychologists. To this end, the American Psychological Association (APA) incorporated the American Society for the Advancement of Pharmacotherapy as its 55th Division and created a new journal, *Experimental and Clinical Psychopharmacology*. In addition, the APA committed considerable time and money to support efforts to lobby for legislation that would permit psychologists who obtained additional training to prescribe in the Territory of Guam in 1998 and the states of New Mexico and Louisiana in 2002 and 2004, respectively. Similar proposals are also being considered in at least 19 other states, including Georgia, Missouri, Connecticut, Tennessee, and Hawaii (Gill, 2006).

Passionate arguments have been offered that both support and oppose the pursuit of prescribing privileges

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Please address correspondence to: Richard Stuart, P.O. Box 236, Edmonds, WA, 98020 (e-mail: rstuart@seanet.com).

for psychologists (e.g., Albee, 1998, 2005; Bell, Digman, & McKenna, 1995; Bush, 2002a; DeNelsky, 1996; Hayes & Heiby, 1996; Heiby, 2002; Heiby, DeLeon, & Anderson, 2004; Kim & Silvana, 2006; Robiner, Bearman, Berman, Grove, Colon, Armstrong, et al., 2002, 2003; Wagner, M.K., 2002; Westra, Eastwood, Bouffard, & Gerritsen, 2006; Yates, Wiggins, Lazarus, Scully, & Riba, 2004). Advocates suggest that one competitive market for traditional psychological services would be improved if psychologists had authority to prescribe drugs, believing that building new clientele would help to offset stagnant reimbursement rates for their traditional services. Beyond the economic incentive, they posit that prescription authority would allow psychologists to expand the array of services that they offer and make psychopharmacologic intervention more available to rural and other underserved populations, at a potentially lower cost than when psychopharmacology is delivered by physicians. They speculate that by prescribing, psychologists could gain greater respect from other health-care providers and an elevated professional status. If psychologists were to prescribe, proponents believe that—patients could receive an integrated service from a single provider who presumably knows them well and who potentially could see them frequently. Proponents also contend that psychologists could not only prescribe well, but by doing so in conjunction with their other psychological skills, they could offer a higher quality of service than do primary care physicians who have traditionally prescribed the majority of psychopharmacological medications (Schulberg & Burns, 1988).

Opponents of prescription authority believe that worries about the future of psychology are misplaced. The Bureau of Labor Statistics (2007) expects the "employment of psychologists . . . to *grow faster than average* [italics added] . . . through 2014, because of increased demand for psychological services in schools, hospitals, social service agencies, mental health centers, substance abuse treatment clinics, consulting firms, and private companies." Along with Pollitt (2003), they question whether psychologists who are now concentrated in urban areas will relocate to offer service in rural communities, and suspect that rather than offering lower-cost services, psychologists who prescribe will raise their fees to amortize the cost of additional training. Opponents acknowledge that the mental health services provided by general practitioners in many rural communities should be improved (Geller & Muus, n.d.). However, they also believe that improving the psychotropic prescribing skills of these general practice physicians by following the recommendations of the Accreditation Council of Graduate Medical Education (Bazaldua et al., 2005) and the American Academy of Family Physicians (2001) is a more direct and cost-effective way to improve mental health services than by introducing a new subspecialty in psychology and struggling to overcome the reluctance of many groups to define problems as psychological rather than medical that are not faced by traditional medicine practitioners (Sawyer, Gale, & Lambert, 2006). Opponents to prescription authority for psychologists recognize that psychotropic drug use is increasing at the same time that utilization of psychotherapy is decreasing (Olfson, Marcus, Druss, & Pincus, 2002); however, they believe that it would be more prudent to reverse this trend by improving the effectiveness of traditional psychological intervention and by educating prospective patients about their benefits. Opponents argue that drugs treat symptoms of mental diseases, not their underlying (often environmental) causes, which could undermine any attempts to treat the disease with psychotherapy or behavioral changes. Some are also concerned that over-reliance on psychotropic drugs can prolong patient distress and inadvertently raise healthcare delivery costs (Henk, Katzelnick, Kobak, Greist, & Jefferson, 1996). Although opponents recognize that every intervention, including psychotherapy, has the potential to cause harm (Lilienfeld, Fowler, Lohr, & Lynn, 2005), they also recognize that because psychologists' are typically well-trained in psychotherapy, they are more likely to be able to avoid harm caused by psychotherapy than that caused by psychopharmacology in which they are comparatively less well-trained.

Opponents also believe that psychologists who prescribe will be able to meet only some of their patients' medication needs. For example, prescribers who treat patients with complex mental disorders often find that entire sessions are needed to collect enough data to prudently adjust medication regimens. This could limit the time they can devote to psychotherapy, and in some cases, might even necessitate referral to another therapist who can address psychotherapeutic issues. Other patients may request different therapists because they are more comfortable separating discussion of their physical and mental problems. In other situations, it may be beneficial to have perspectives from two clinicians in identifying a plan for successful intervention. These and other challenges highlight the likelihood that a single prescribing psychologist may not be the optimal arrangement for a subset of complex patients. Moreover, to the extent that their practices would begin to focus on medication—as has happened to psychiatrists

(Luhrmann, 2000)—the range of services that prescribing psychologists offer could actually narrow. In addition, given the conflict that has arisen between psychiatrists and primary care physicians (Dworkin, 2006), other psychiatrists (Barrett, 2002) and nurses (International Society of Psychiatric-Mental Health Nurses, 2001), opponents fear that prescribing could disrupt long-standing collegial relationships between psychologists and physicians.

It is also possible that prescribing authority will significantly dilute the identity of psychology, much as it has diluted psychiatry (Luhrmann, 2000). To preserve their identities, professions must differentiate themselves from each other in meaningful ways. Diffusion of boundaries inevitably leads to dilution of identity and, in turn, a loss of diversity in perspectives that fuels adaptive changes in mental health services. Evidence for the extent of this threat to the core identity of psychology is found in the facts that for the foreseeable future, physicians and/or nurse practitioners will have to supervise prescribing psychologists, making this the only area of psychological practice for which supervision by non-psychologists is essential.

Opponents also believe that granting prescribing authority for psychologists would expose the profession to an unprecedented level of commercialism and malpractice allegations. They also argue that the high cost of training to prescribe will divert resources that are needed to help psychology grapple with concerns shared by more psychologists, radically changing its agenda for the future. In summary, opponents believe that both the field and individual practitioners are at risk of being economically harmed, rather than helped, by the adoption of prescription privileges. Accordingly, they believe that it is wiser for psychologists to continue to invest in the development of "integrated, collaborative modes of practice" (Bush, 2002b, p. 682), rather than pursue the questionable benefits of "one-stop shopping" for mental health services by a discipline that has had remarkably little experience and education directly related to prescribing.

Both advocates and opponents of prescribing privileges for psychologists generally support their positions with passionate if not always plausible arguments. Thoughtful discussion of the topic has been undermined by advocates who, for example, portray the opposition as "not grounded in or based on any objective fact" (Caccavale, 2002, p. 623), despite the paucity of data supporting prescription privileges for psychologists (e.g., Robiner et al., 2003), or equate reservations about prescribing authority with being "opposed to change of any sort in the discipline" (Sammons, Paige, & Levant, 2003, p.206). Contrary to these invectives, it is important to construe questions as the way in which responsible decision-makers seek and organize information needed for informed choices. In that spirit, the questions raised here are aimed at helping psychologists make more informed decisions about the level at which they wish to integrate psychopharmacology into their practices. The issue is not whether drugs should be used, but rather whether psychologists can become as well equipped as other health care professionals to prescribe them safely.

The Nature of Drugs

Drugs are compounds that are introduced into the body to prevent or treat a physical disorder. For centuries, various substances were regarded as drugs because they either had or were hoped to have desirable effects. It has been estimated that only one in 6,000 compounds that were believed to have therapeutic value reach the market (Pisano, 2007). Drug manufacturers cease work on many of these compounds because they do not prove effective in internal testing. Other compounds fail to gain the approval of the Food and Drug Administration (FDA) and are returned to manufacturers, who may then attempt to reformulate the drug, expand its drug-trial testing, or abort the project. Drugs "may increase or decrease the normal function of tissues or organs, but they do not confer any *new* functions on them; the effects of drugs are quantitative, never qualitative" (Walsh & Schwartz-Bloom, 2005, p. 29). Some drugs stimulate functions, such as creating antibodies to combat infectious diseases. Others inhibit functions; such as selective serotonin reuptake inhibitors (SSRIs) that prevent certain cells from absorbing the serotonin that is needed elsewhere to reduce anxiety, aggression, or depression. Still others are palliatives that reduce the severity of symptoms such as fever and inflammation. Although most psychoactive drugs currently do not address the underlying causes of disorders, when properly used, some drugs do-reduce or eliminate presenting complaints sufficiently to enhance patients' well-being. Moreover, some drugs under development may in the future alter DNA in a way that could alter the underlying mechanisms of disease (Sibille & Hen, 2001).

As pharmacology evolved, it became possible to study illnesses biologically and concoct remedies chemically. Due to the rapid growth of the molecular understanding of biology pharmacology has moved in the past decade "from an empirical discovery science to a

hypothesis-driven approach based on rational or systematic design principles" (Buehler & Rashidi, 2005, p. 276). Nevertheless, many applications of medications arose serendipitously when substances developed for one purpose were found to accomplish others. Some of these applications were discovered during drug testing. For example, Botox was originally developed to treat eye disorders but was found to relax wrinkle-causing muscular contractions. Viagra was developed as a vasodilator and unexpectedly was found to enhance erectile function. In psychopharmacology, chlorpromazine was originally developed to reduce surgical shock, but subsequently was found to have a calming effect that could be helpful in controlling psychosis. Lithium, neuroleptics, antipsychotics, tricyclics and monoamine oxidase inhibitor antidepressants were all discovered serendipitously. "These agents were not engineered to have selective actions, but instead to produce a wide range of central biochemical effects that generally affect more than one neurotransmitter system simultaneously, resulting in multiple repercussions" (Janicak, 1999, p. 5). These multiple impacts extend beyond their psychopharmacologic effects in ways that may be problematic for patients.

Other uses of drugs can be derived from "off-label" clinical trials in which clinicians prescribe them for conditions other than those deemed to be empirically substantiated by the United States Food and Drug Administration (FDA). Because so few drug-development research studies include children, off-label prescription for children is quite common (Hill, 2005). As an example, a lower dose of sildenafil, the core constituent of Viagra, has been introduced as Revaltio for the treatment of pulmonary hypertension in adults as well as children (Senior, 2005). Similarly, a derivative of thalidomide, Thalomid, which was originally approved as a last-resort treatment for a skin condition associated with leprosy, is being used off-label in the treatment of multiple myeloma and other oncological conditions (Center for Public Integrity, 2005b). If their effectiveness and safety are substantiated, these applications may be added to drug labels. However, if they prove harmful, manufacturers and prescribers could face legal action.

Drug development has had a profoundly positive impact upon human health and well-being. Deadly diseases like smallpox, pneumonia, influenza and tuberculosis have either been eradicated or are generally now treatable in all but the most vulnerable people. Many psychotropic drugs have enabled individuals who otherwise would have been incapacitated by illness to remain personally, socially, and occupationally productive.

Although the benefits of certain drugs used in specific ways is undeniable, so too is the fact that many generally beneficial drugs have unintended adverse effects. Unfortunately, some agents that have been perceived to be safe and therapeutic while under development have, with further testing, proven to cause more harm than is acceptable based on more extended cost-benefit analyses (Marti-Ibanez, 1962). The risk of negative effects underscores the need for prescribers to have broad knowledge of human physiology, pathophysiology, morbidity, and pharmacology far beyond just understanding of narrower subsets such as psychopharmacology. Moreover, they need to be able to identify adverse effects that may be associated with medications, even if the unwanted effects emerge in organ systems other than those targeted by the drug that they have prescribed. The need for broad knowledge and clinical experience is even greater when one appreciates the unpredictability of the way medications affect each individual. .Reducing this uncertainty is one of the major challenges in pharmacology.

Eleven Challenges in Clinical Psychopharmacology

The addition of prescribing privileges to psychologists' scope of practice would require major changes in professional training, knowledge, and practice. Advocates presumably will want to make these changes in an ethically responsible manner to protect their patients from harm (American Psychological Association, 2002). However, when drugs are part of the treatment, it can be more difficult to ensure necessary safeguards than when psychologists exclusively provide their psychotherapeutic methods. The questions listed in Table 1 offer a perspective on some of the necessary changes if psychologists are to prescribe medications responsibly and competently. Questions 1, 2, and 11 are of special concern to psychologists while the remaining questions pose challenges for all who prescribe.

1. *At what level would you like to integrate psychopharmacology into your practice?* Given the current prominent role of drugs in mental health services, all practicing psychologists must have at least a rudimentary awareness of the potential benefits and risks of psychopharmacology. This, of course, does not mean that all psychologists should prescribe. According to the original APA Ad Hoc Task Force on Psychopharmacology (1992), knowledge about medication and its effects could be integrated into psychologists' practices at any of three levels (Smyer et al., 1993). *Level 1* would allow all psychologists to offer services informed by an aware-

Table 1

Eleven Questions Relating to the Readiness to Prescribe Drugs

1. At what level would you like to integrate psychopharmacology into your practice?
2. How will you deal with the limitations that are likely to be placed on your prescribing authority?
3. How will you minimize the risk of a misdiagnosis that leads you to prescribe the wrong drug?
4. How will you minimize the risk of making prescription errors that lead to adverse drug events?
5. How accurately will you be able to predict the effects of the drugs that you prescribe?
6. How will you find the accurate information needed for sound decisions about drugs?
7. How will you avoid choosing a drug that is generally correct for the diagnosis but incorrect for a given patient?
8. How will you gain access to the resources that you will need to adequately assess patients before prescribing drugs, and then to monitor medication effects?
9. How will you be able to resist the pressure to prescribe unnecessary drugs?
10. How will you prepare for the increased risk of being sued for malpractice due to patient reactions to a drug that you prescribed?
11. Do you know enough to make a data-based decision about prescribing authority now?

ness of the neurobiology and neurochemistry of human behavior. To meet this standard, limited coursework in neuroscience and psychopharmacology would be required in the predoctoral training of licensed psychologists. *Level 2* calls for more intensive training for those who plan to enter collaborative practice with medical providers. This standard could be met through the pursuit of interdisciplinary training with physicians and nurses as a means of gaining both knowledge and interprofessional understanding.

Level 3, the highest level of training considered by the APA Ad Hoc Task Force, (1992) is independent prescribing, akin to some of the activities of psychologists in the Psychopharmacology Demonstration Project (PDP) developed by the Department of Defense (American College of Neuropsychopharmacology, 2000). Because the first iteration of this program—requiring two years of coursework comparable to the first two years of medical school—was perceived as inefficient and too demanding for trainees, a one-year didactic program was introduced for later entrants to the PDP. It included: 712 hours of instruction that included: medical school courses (pharmacology [102 hrs.], clinical pharmacology [21 hrs.], clinical medicine II [121 hrs.], and clinical concepts [100 hrs.]); modified medical school courses (anatomy and cell biology [48 hrs.], neuroscience I, II [91 hrs.]), biochemistry [57 hrs.], physiology [39 hrs.], pathophysiology [60 hrs.], and health assessment [39 hrs.]); and a 34-hour seminar on clinical pharmacology. This was followed by a full year of clinical training, split between inpatient and outpatient services, supervised by psychiatrists. Trainees were evaluated by examinations administered independently by the American College of Neuropsychopharmacology. Before being eligible to practice independently, trainees' work was closely monitored for up to two years by psychiatrists. Some of the limits to ascertaining how well psychologists' prescribing experiences in the PDP would generalize to more general populations of psychologists and patients include: (a) their patients had been medically screened before referral to the psychologists and were seen in military hospitals rather than private offices; (b) their patients were adults between the ages of 18 and 65 (i.e., they did not treat any children or older adults whose medical conditions and healthcare are likely to be more complicated); and (c) the psychologists were limited to an abbreviated formulary. Whereas PDP graduates were assessed as generally competent to prescribe, the Department of Defense terminated the program on the basis of its high cost relative to its benefits

The PDP program has been criticized for several omissions, such as its failure to require both undergraduate courses in basic sciences and calculus and a passing score on the Medical College Admission Test (MCAT). Trainees' failure to meet these requirements may help to explain why their grades on coursework had to be "normalized." And even that did not prevent them from underperforming nurse anesthetists in some areas. (American College of Psychoneuropharmacology, 2000). The PDP model has been criticized for offering "less than half the training of other prescribing professionals" (Heiby, DeLeon, & Anderson, 2004, p. 340) and therefore ought not be construed as being on par with other prescribers.

Rather than enhancing prescribers' performance by building on this program and abiding with the recommendations (i.e., prerequisites and curriculum) of its own Ad Hoc Committee (1992), the APA incredulously elected to *lower* the bar for training requirements to offer "just enough knowledge and skill to enable psychologists to prescribe" (Newman, 2000). In effect, the APA (1996) appears to have decided to lower the cost of training while hoping not to lose quality and depth of training proportionately. It did this by endorsing a program of only 300 hours of coursework that includes: neuroanatomy, nerurophysiology, and neurochemistry (25 hrs. each.); pharmacology and clinical pharmacology (30 hrs. each); psychopharmacology (45 hrs.); developmental psychopharmacology (10 hrs.); chemical dependency

and chronic pain management (15 hrs.); pathophysiology (60 hrs.); introduction to physical assessment and laboratory exams (45 hrs.); psychotherapy/pharmacotherapy interactions and pharmacoepidemiology (10 hrs. each); professional, legal and ethical issues (15 hrs.); and computer-based aids to practice (5 hrs.). The clinical practicum requires trainees to assume responsibility for 100 diverse patients, with a minimum of *two* hours of weekly supervision. There are negligible guidelines for supervision including the extent of supervised care required for any of the patients. In contrast, the APA internship accreditation requires one year of predoctoral clinical supervised experience, including at least *four* hours of supervision per week, and one year of postdoctoral supervised clinical experience. Formulation of the APA pharmacology training guidelines would appear to be based on the dubious notion that prescribing drugs safely requires but a small fraction of the training and supervision needed to develop skills within psychologists' current scope of practice. This seems to be a dangerous oversimplification of the challenges of competent prescribing.

Changes to the guidelines for clinical psychopharmacology practice have recently been proposed by the Board of Education Affairs and the Committee for the Advancement of Professional Practice (BEA/CAPP) Task Force (2007). Among others, they include an increase from 300 to 400 hours of instruction and a shift to competency-based instruction that emphasizes knowledge, performance, problem solving and self-reflection. At the same time that the curriculum is strengthened, the clinical component might be weakened. Because trainees have had difficulty finding suitable clientele and supervision, there has also been discussion of reducing the amount of hands-on experience and direct supervision required. Even if the curriculum is expanded, when compared to the original Department of Defense program, the APA training protocol might be construed as "PDP-Lite" because it requires less than half of the formal instruction and only a small fraction of the clinical training. The training is offered currently through postdoctoral certificate and degree (Master of Science in Psychopharmacology) programs offered by approximately 11 organizations. It would be interesting to compare the resources for these programs (e.g., curriculum, library, faculty, laboratory facilities) with those of institutions that train prescribers in other disciplines. None of the programs appears to be associated with medical schools and some appear to lack a university affiliation.

Although the APA does not yet accredit these psychopharmacology programs, the Academy of Medical Psychology (n.d.) is attempting to develop accrediting mechanisms that will set higher standards for psychopharmacology training, minimize conflicts of interest between regulators and those whose performance is being assessed, and have adequate resources for meaningfully monitoring training. This could prove to be an especially challenging process given institutional differences in the amounts of distance-learning and campus-based instruction, library and laboratory resources, clinical opportunities, and supervision resources. In addition, it is hoped that an accrediting organization will set stringent standards for faculty background, which is currently a vexing problem because few psychologists have substantial experience in prescribing. The same challenges in determining acceptable levels for psychopharmacology training are faced by regulating bodies (i.e., boards) in states that have enacted legislation allowing psychologists to prescribe (i.e., Louisiana and New Mexico). The regulatory process psychologists with prescription authority is complicated by the fact that there is little infrastructure for this purpose. Board members have had little experience in discriminating between adequate and inadequate knowledge of psychopharmacology and between competent and incompetent prescribing practices.

The states in which psychologist prescribers might work will also require those psychologists who have completed advanced training in psychopharmacology to pass a national examination. Thus far, the most prominent test is the Psychopharmacology Examination for Psychologists (PEP), a 150-item multiple-choice test (only 4% of which addresses research issues) administered by the College of Professional Psychology, a unit of the American Psychological Association Practice Organization (2007). Currently, the New Mexico Psychologist Examiners (2007) requires that the PEP must be passed at a level recommended by the APA. In Louisiana, the Louisiana State Board of Examiners of Psychologists determines the acceptable score on the proficiency examination.

The statutes adopted by the various states that could enable psychologists to prescribe are likely to be variants of this pattern, with domain-specific differences. For an overview of current legislation in all U.S. jurisdictions, see Pope (2007). Changes in the model legislation proposed by the BEA/CAPP Task force can be found at: http://www.apa.org/ed/graduate/comment_review.html). For example, New Mexico (New Mexico Legislature, 2002) requires at least 450 hours of classroom instruction in areas such as neuroscience, physiology, laboratory assessment, and psychopharmacology; at least 80

hours of practicum instruction on assessment; and at least 450 hours of pharmacotherapy in which no fewer than 100 patients are treated under the supervision of a psychiatrist or other appropriately trained physician. Louisiana (2004) also requires that prescribing psychologists pass a national proficiency examination and obtain 30 hours of continuing education in psychopharmacology annually. Other legislative differences among states enabling legislation may include: increasing the academic and/or clinical training requirements; narrowing the scope of disorders that psychologists can treat psychopharmacologically and/or the formulary of medications that they can prescribe; defining the parameters of their required collaboration with medically trained professionals; the amount of continuing education required; and the periodic independent reexamination of their knowledge and skills. Such requirements are intended to address legislators' concern that regulatory mechanisms protect their constituents from harm. One example of a potential increase in the amount of training is suggested in the Hawaii Legislative Reference Bureau's report on prescriptive authority for psychologists (Merrick, 2007). It concludes that:

> No postdoctoral training program in psychopharmacology that meets APA training recommendations has been externally evaluated and deemed successful . . . [therefore] the Legislature may wish to consider requiring a training model that requires minimum classroom and clinical training requirements no less rigorous than the PDP program training model and a scope of practice and formulary for graduates that is no broader than limitations applied to PDP program graduates. (p. 76)

In summary, those who wish to pursue Level 3 practice should be cautious in spending their training dollars. In addition to the current tuition costs of approximately $405 per credit, additional expenses include the cost of paid supervision/consultation and the opportunity cost of revenue lost due to the hours devoted to continued education and clinical training. This could prove particularly burdensome when added to the expense of obtaining a Ph.D. or Psy.D. It would be wise to study very carefully the specific, and potentially unique requirements of any jurisdiction in which one hopes to practice. Programs that meet these requirements should then be evaluated closely to determine the competence of the faculty and availability of clinical training opportunities. Especially in the absence of accrediting mechanisms, programs are likely to vary in their merit and their ability to meet the needs of individuals. Finally, some registries and other prescription-promoting organizations advertise that those earning certificates through their auspices will be grand-parented into prescriptive authority wherever they apply. Such claims, of course, cannot be validated, and in fact may not be substantiated because they depend upon predictions of the actions of authorizing legislative bodies, all of which will govern as they see fit. Neither legislatures nor regulatory boards have a responsibility to comply with the claims of commercial educational ventures. Similarly, legislatures, governors, and regulators are not compelled to accept the APA's determination of whether psychologists should prescribe, nor its guidelines regarding training for prescriptive authority.

2. *How will you deal with the statutory limitations that are likely to restrict your prescribing authority?* Psychologists have long been trained to treat a broad range of problems with a variety of talking therapies. In contrast their prescribing practice is likely to be more narrowly defined and dependent upon supervision and/or consultation with other prescribers, including non-psychologists. Due to the gravity of some illnesses and the nature and complexity of the drugs that they require, some disorders that are amenable to drug therapy will require the intervention of, or at least close supervision by, medically trained professionals. These include diagnoses such as severe post-partum reactions, somatization disorders, severe anorexia and bulimia, certain schizophrenia spectrum disorders, organic mental disorders, and various substance abuse problems. It will be necessary to develop protocols that help psychologists recognize when it may be appropriate for them to prescribe versus when it is prudent or necessary to refer patients whose medication management challenges exceed their own competence.

Psychologists are likely to be limited in the range of drugs that they can prescribe. Three classes of FDA-approved drugs exist in the United States: over-the-counter drugs that are available without prescription; "legend" drugs that are available by prescription only; and "scheduled" drugs, controlled substances that can be prescribed only by those holding a license from the Drug Enforcement Administration (DEA) (2007). The DEA confers authority to prescribe scheduled drugs and regulates and monitors every prescription for their use. States can grant psychologists the authority to prescribe only-legend drugs that have been approved for mental health applications. However, only the DEA can confer the authority to prescribe scheduled drugs (e.g., schedule II drugs like stimulants and schedule IV drugs like benzodiazapines and hypnotics), and it is highly improbable that psychologists will gain this authority.

These limitations could put psychologists in the position of extensively screening new patients but having to refer some elsewhere because they cannot provide the necessary drugs. It could even require referral of some of psychologists' current patients whose needs would be better met by drugs that the psychologist cannot prescribe, resulting in "fragmented care . . . [that] diminishes the efficacy of the drug treatment" (Simon & Shuman, 2007, p. 96) . In these situations, patients whose needs might have been met through consultation with a single prescribing provider could find it necessary to consult two or more clinicians. Accordingly, formulary limitations may at times preclude psychologists from substituting for more broadly trained medical prescribers even in rural areas or when working with underserved populations.

3. *How will you minimize the risk of a misdiagnosis that leads you to prescribe the wrong drug?* There is at present considerable overlap in diagnoses for which specific classes of drugs are prescribed; for instance, neuroleptics are used in the treatment of psychoses and bipolar disorders, as augmentation for the treatment of certain forms of depression, and to help control aggression and improve sleep. Accurate diagnosis contributes to the selection of the most suitable drug. For example, one would hardly want to prescribe a neuroleptic when an antidepressant might better meet a patient's needs. The DSM-IV-TR (American Psychiatric Association, 2000) provides the standard nomenclature for this purpose. A product of group discussion rather than programmatic research, the DSM-IV contains lists of symptoms and time frames that have varying levels of empirical support (Beutler & Malik, 2002). Given the fact that symptoms are observed or self-reported problems, most of which can be manifestations of multiple biological problems, a DSM-IV diagnosis creates, at best, a hypothesis about possible underlying disorders—but not proof of their existence. Tucker (1998), one of the major contributors to the development of the DSM series, observed that, "if the patient's symptoms fit the criteria for a major depressive disorder, this tells us that the predominant symptoms are those of depression. It does not tell us the etiology of the depressive symptoms, so a differential diagnosis of the potential causes of these symptoms is still necessary" (p. 133). He added that a DSM-IV-TR diagnosis ". . . tells us nothing about the genetics and significant family relations of the patient . . . [or] about the patient's story" (p. 133). This is of particular importance to psychologists who normally think of behavior in developmental and situational contexts. They try to understand the meaning and function of patients' problematic behavior as well as the sources of their vulnerability and resilience. Syndromal classification discourages this comprehensive assessment in favor of one in which the "actions of individuals are object-like collections that indicate an underlying disease entity . . . to the point of excluding psychological categorical systems" (Hayes & Heiby, 1996, p. 200).

Problems arise when the DSM-IV becomes the core of assessment, particularly in the context of psychopharmacology. Luhrmann (2000) described the way in which the training of psychiatric residents is often narrowed to a primary focus on deciding whether patients are suitable for drugs to reduce problems such as anxiety, depression, or psychosis, diverting their attention from other aspects of their patients' conditions. Psychologists who prescribe may or may not be able to maintain a more holistic perspective on their patients. Attempting to do so will extend the time and effort that must be devoted to assessment. Psychologists will also have to cope with an emerging trend: a move away from the categorical designations of the current clinical nomenclature to a more dimensional approach (Widiger & Trull, 2007). Because it is probably easier to prescribe drugs for categories than dimensions, psychologists may have to have to develop a new approach to prescribing if they are to stay in step with developments within psychological assessment.

In addition to the problems inherent in the exclusion of potentially psychologically relevant details, when clinical labeling is over-weighed, misdiagnosis is always a possibility for at least four reasons. First, although the DSM-IV categories strive for objectivity, a certain amount of subjectivity colors all interpersonal judgments. Therefore it should not be surprising that the kappas—statistics that measure agreement among observers beyond that which could occur by chance (Hulley, Cummings, Browner, Grady, & Newman, 2007, p. 201)—have been found to be generally acceptable, *but not perfect*, when comparing raters' assessment of diagnostic categories based on the use of structured diagnostic interviews (e.g., Zanarini et al., 2000). (Parenthetically, it is also of note that the same investigators found greater inter-rater agreement for dimensional versus categorical assessment, a finding that supports psychologists' moving toward use of the former as an alternative to the latter.) That means that some risk of misdiagnosis is inherent in the use of the DSM-IV, with errors potentially leading to the prescription of inappropriate drugs. Second, the same symptoms may be manifestations of different disorders. For example, a patient's hyperactivity might be a manifestation of

Attention-Deficit/Hyperactivity Disorder (ADHD) or of the manic stage of bipolar disorder. In this example, prescribing stimulants would help the former problem but exacerbate the latter. Third, diagnoses of psychological problems generally depend heavily on patient self-report. Patients may over- or under-report symptoms. Therefore, to enhance their assessments, providers will need to develop ways to verify the accuracy of DSM-IV diagnoses and the completeness and validity of the databases upon which their assessments depend. This would be of particular concern when prescribing inappropriate drugs that could lead to dangerous or irreversible harmful effects (e.g., tardive dyskinesia). Finally, it is entirely possible that classifiable symptom patterns may result not from an underlying mental disorder but from the interaction between two or more prescribed or self-selected drugs (Preskorn, 1999). If this occurs, medicating the manifest disorder could lead to delays in recognizing or treating potentially serious iatrogenic conditions.

To minimize diagnostic errors, prescribing psychologists will need access to resources that will help them avoid misinterpreting the roots of presenting symptoms. This is especially concerning in light of psychologists' remarkably abbreviated medical training and limited education in the physical sciences. In addition to needing more effective training and collaboration with other health professionals, access to ongoing supervision is essential. So too is ready access to resources such as sites like Wrong Diagnosis (www.wrongdiagnosis.com/intro/common.htm) and others listed in Table 2. However, though such resources may be helpful, they are hardly replacements for medical school and residency training or for non-doctoral education that is highly relevant to prescribing (e.g. nurse practitioner training).

4. *How will you minimize the risk of making prescription errors that lead to adverse drug events (ADEs)?* Every request for psychopharmacology requires careful evaluation of a patient's medical history. Once a drug has been prescribed, there is a need to collect detailed diagnostic data, such as the level of the drug in the blood and indications of the impact of the drug on non-targeted organ systems, as a basis for choosing one of the six follow-up actions in managing psychoactive medications. These actions include: discontinuing the drug; continuing the drug as originally prescribed; altering the dosage of the original drug; continuing the original drug and adding one or more others; replacing the original drug with one or more others; and/or adding one or more adjunctive therapies (e.g., ECT, broad spectrum lights for seasonal affective disorder, or some form of psychotherapy and/or behavior therapy). The need for great care with each of these actions is illustrated by the estimate that when reducing or terminating antidepressants, as many as 78% of patients experience withdrawal reactions that may mimic their original illness (Glenmullen, 2005).

Table 2

Sources of Information about Drugs

1. The most authoritative information about medication effects and interactions can be found at the website of the British National Formulary (www.bnf.org), a joint effort by the British Medical Association and the Royal Pharmaceutical Society of Great Britain. It is arguably easier to navigate and probably less influenced by drug manufacturers than the website of the FDA (www.fda.gov).
2. The *Physician's Desk Reference* (*PDR*) is updated annually. It consists entirely of package inserts for which manufacturers are charged a publication fee. Therefore the completeness and accuracy of the data are limited. Because the information is arranged by manufacturer rather than by application, it is difficult to compare medications. The absence of pricing data also limits the utility of the volume.
3. Guidelines based on evidence-based medicine source (e.g. the National Guidelines Clearinghouse [www.guidelines.gov], the Institute for Clinical System Improvement [www.icsi.org], and the Vanderbilt Center for Evidence Based Medicine [www.ebm.vanderbilt.edu]). Useful general recommendations are provided that may or may not suit a given patient.
4. Information about drug side effects and adverse drug reactions can be found and reported at the following sites: www.fda.gov/medwatch/; http://vaers.hhs.gov; www.medlineplus.gov.
5. Reviews of prescribing preference (e.g. Kornluh, et al., 2001). Reveals common but not necessarily best practice.
6. Print handbooks (e.g. Fuller & Sajatovic, 2004; Walsh & Schwartz-Bloom, 2005). Such references provide recommendations that are limited by the authors' knowledge and interpretation of the underlying research, dated by publication delays. When real-time updates are provided, these resources increase in value.
7. Web handbooks and downloadable sources, e.g. www.nursepdr.com/, www.1ww.com/product/?1-58255-259-2, www.pdr.net/Home/Home.aspx, www.lexi.com/lesistore/servlet/Controller?a-sca&t=CE. Value may be added by frequent updates.
8. Newsletters, such as *The Medical Letter* (www.medicalletter.org/). Some are based on meta-anlayses and are free of commercial information. However they may be limited by flaws in the underlying research that may not be obvious in second-hand reports.
9. Websites offering general information, such as www.nlm.nih.gov/medldineplus/druginformation.htm,www.ncbi.nlm.nih.gov/entrez/query.fcgi, and www.cochrane.org/index0.htm. Such resources provide vast amounts of information but their methodology is not well evaluated.
10. Information about clinical trials, such as . This website provides information about a range of medical research. Like other websites, the methodology is not well evaluated.
11. Consumer-oriented sites, such as www.worstpills.org/. Sites like this are a useful source of secondary analyses that are accessed by both patients and professionals.
12. Regularly updated drug information available on handheld devices, such as Epocrates (http://epocrates.com/) and UpToDate (http://www.utdol.com/utd/store/index.do).

Adjustments in drug regimens are often motivated by the wish to switch from one drug with an untoward set of side effects to another that hopefully will cause fewer side effects and be equally or more therapeutic. Such regimen shifts, along with original prescriptions, require comprehensive knowledge of the probable side effects of the drug in general, and of their impact on patients with special characteristics, such as those who are pregnant, have other medical conditions, or are younger or older than participants in the original evaluations of the drug. That, in turn, requires detailed information about patients' current physical and mental health, environmental influences upon their behavior, and their personal and family history of reactions to each drug that they consider taking. Failure to collect and use this information properly can compromise the quality of the treatment or even cause permanent harm.

The term adverse drug event (ADE) has been defined as: "Any error in identifying an indication for, prescribing, omitting, transcribing, compounding, dispensing, administering, assessing, and documenting a patient's capacity to understand and correctly use medication, teaching proper use, or monitoring and documenting a patient's response to medication" (Grasso, Rothschild, Genest, & Bates, 2003, p. 393). ADEs have been increasingly implicated as leading causes of substantial morbidity and mortality, estimated to account for at least 1.4 million emergency room visits in 2004 and 2005 (Anonymous, 2007) and 100,000 deaths per year (Lazarou, Pomeranz, & Corey, 1998). Among the morbid complications are movement disorders, neuroleptic malignant syndrome, serotonin syndrome, obesity, insulin resistance, sexual dysfunctions, cardiac arrhythmias and various pathogenic drug interactions. The effects of the psychotropic drugs that some psychologists seek to prescribe are not limited to those aspects of the nervous system that patients wish to modulate; they can wreak serious undesirable effects throughout the entire body. Errors in prescribing psychotropic drugs by medically trained professionals accounted for 12.3% of the deaths due to ADEs reported to the FDA (Chyka, 2000). One half (Bates et al., 1995; Gurwitz, et al., 2003) to three quarters (Bates et al., 2001) of these iatrogenic effects were deemed attributable to preventable prescribing errors. Errors resulting in fatalities were associated with mistakes such as improper dose, wrong drug, and wrong route of administration, all of which are due to procedure and information deficits that could have been avoided (Bazaldua et al., 2005). For example, in a primary practice study, "25% of patients reported drug complications, and 63% [of these] were attributed to physicians' failure to respond to medication-related symptoms" (Bazaldua et al., 2005, p. 100).

Errors were found in decisions in each of the "five rights of prescribing: the right drug, right dose, right route, right time, and right patient" (Benjamin, 2003, p. 768). Prescribers' lack of knowledge (Dean, Schachter, Vincent, & Barber, 2002) and resulting reliance upon subjective judgment (Krishnan, 2003) can lead to their failure to follow evidence-based guidelines (Meagher & Moran, 2003), elevating the risk of ADEs. Prescribing errors are particularly prevalent when psychotropic drugs are used because prescribers often base their diagnoses on patients' self-reports and fail to elicit other types of essential information, such as whether patients take the drug as directed, take drugs recommended by other professionals, or have made diet or other life style changes that could affect the action of the prescribed drug. Errors are also attributable to confusion about drug names (Filik, Purdy, Gale & Gerrett, 2004), and inattention to drug interactions (Ciraulo, Shbader, Greenblatt, & Creelman, 1995) and/or drug-delivery formulations (Lesar, 2002). Of course, such problems are compounded by patients' failure to use the drugs as prescribed (Cohen, 2003).

The prevention of ADEs is not a simple matter. It requires, among other things: knowledge of the probable effect of the prescribed drug and its interaction with all the other prescribed and self-selected drugs, or even with certain foods the patient takes; precision in writing prescriptions as the prescriber intended them to be written; careful medical and behavioral monitoring of the drug's effect; and great effort to motivate patients to comply with therapeutic directions. Adoption of an integrated electronic prescribing and drug management system could significantly reduce some of the causes of serious medication errors (Gulchelaar, Colen, Kalmeijer, Hudson, & Teepe-Twiss, 2005), albeit at the cost of additional training and expense for prescribers (Tamblyn et al., 2006). It should be recognized that even when such systems are successfully implemented, they cannot reasonably be expected to make up for deficits in prescribers' knowledge and/or insufficient clinical experience.

Another potential adverse health outcome that is not normally included in the discussion of ADEs occurs when a patient's symptoms are relieved before the underlying disorder has been diagnosed. (This is also a common concern for physicians who are often cautious about curbing a fever without knowing its cause.) Because many patients who request therapy present with both physical and psychological problems, health professionals who prescribe psychotropic drugs face the

risk of missing underlying medical illnesses; "endocrine disorders, diabetes, malignancies, heart disease and infections are but a few of the common illnesses that may present with psychiatric symptoms" (Yates et al., 2004). Psychopharmacology is particularly vulnerable to this risk because of its focus on symptoms. Although the use of drugs frequently produces welcome relief, this may come at the cost of allowing underlying illnesses to remain untreated. For example, anxiety in the elderly may be caused by: situational factors such as grief and mourning; drugs such as caffeine, alcohol, bronchodilators, hypotensive agents, diuretics, etc.; psychiatric or neurological illnesses such as major depressive disorder, Alzheimer's disease, seizure disorders, postconcussive syndrome, etc.; and physical illnesses, including respiratory and cardiac disease, anemia, gastrointestinal syndromes and metabolic and endocrine disorders (Janiack, 1999, p. 333). Prescribing an anxiolytic drug may relieve symptoms while allowing the core problem to remain undiagnosed and fester. In addition to the required careful attention to the prescribing process, clinicians must be vigilant over time to be sure that one or more undiagnosed illnesses are not the avoidable source(s) of ADEs.

5. *How accurately will you be able to predict the effects of the drugs that you prescribe?* Drug effects result from the interaction of multiple factors. In the simplest terms, pharmacodynamics refers to what medications do to the body while pharmacokinetics refers to the ways in which the body responds to drug. These processes are mediated by pharmacogenetics, (genetically linked medication-response patterns), and chronopharmacy (the timing of the body's reactions to medications). Given the high cost of many drugs that some third-party payers may be reluctant to meet, pharmacoeconomics is another major concern that affects drug selection and resulting treatment outcomes. And because the FDA does not require drug manufacturers to include all potential patient populations in drug trials, and because it does little to monitor the effects of drugs after they have been approved, pharmacoepidemiology (Strom, 2006), that is, the study of "the use of and the effects of drugs in large numbers of people" (p. 3), is an additional body of research that prescribers must track.

The way in which these processes interact is often difficult to predict. In general, "predictability has been notoriously difficult in biology" (Buehler & Rashidi, 2005, p. 19). The challenge is even greater when drugs are involved because much remains to be learned about the mechanisms of their action. Medication reactions are never simple because the actions of every compound differ across individuals and even within individuals over time. Although medications are intended to have a main effect, as a rule they generally affect multiple biological processes and organ systems. As Stahl (2002) noted:

> Chemical messengers sent by one neuron to another can spill over to sites distant to the synapse by diffusion. Thus, neurotransmission can occur at any compatible receptor within the diffusion radius of the neurotransmitter, not unlike modern communication with cellular telephones, which function within the transmitting radius of a given cell. This concept is called the *chemically addressed nervous system*, where neurotransmission occurs in chemical "puffs." The brain is thus not only a collection of wires but also a sophisticated "chemical soup." (p. 5/6)

In essence, labeling these diverse reactions as "side" effects is misleading because they are actually unintended direct effects of the drugs that, in theory, may be predicted. Lithium is an excellent example: it "is initially distributed in the extracellular space and then accumulates in varying degrees in different organs . . . e.g. brain, kidney, thyroid, bone . . . liver, muscle. Lithium is not bound to plasma proteins and distributes nearly evenly in the total body water space" (Burton, Schentag, Shaw, & Evans, 2006, p. 800). It can potentially alter the function of every site that it reaches.

When medications have functions unique to one organ and have delivery systems that transport the substance only to that site, their effects are specific. But when medications can impact multiple organs and delivery systems are nonspecific, diverse reactions are likely. For example, first generation antipsychotics had high rates of neurologic side effects, including extrapyramidal signs and tardive dyskinesia. Even second generation antipsychotics that have a lower risk of neurologic impact have been associated with weight gain and blood chemistry changes associated with a dangerous metabolic syndrome (Lieberman et al., 2005). Other medications, like certain antidepressants, can pass through the placental barrier and cause teratogenic effects in the fetus. Because of this vast complexity, it is very difficult to predict the exact effect of medications in general, and psychotropics in particular. Nevertheless, when clinicians prescribe medications, they may be held accountable for negative outcomes, even when they are neither intended nor anticipated. Since psychologists are trained to focus primarily on the nervous system, they may be limited in their understanding of the effects of the drugs that they prescribe on other organ systems, and are poorly equipped to diagnose the adverse effects, thus raising the risk of ADEs.

6. *How will you find the accurate information needed for sound decisions about drugs?* Understanding the ways that drugs affect the human body requires knowledge in many basic areas including biology, chemistry, biochemistry and physics, as well as functional knowledge in traditionally medical areas including anatomy, endocrinology, genetics, histology, neurology, pathology, and pharmacophysiology. Unlike physicians and other prescribers, psychologists historically have lacked background in these areas (Robiner et al., 2002, 2003). The critical task of keeping abreast of developments in such diverse fields is also daunting. Despite their comparatively extensive training in these areas, physicians sometimes prescribe medications without recognizing the reported contraindications. For example, Lasser et al. (2006) found that 7% of prescribers ignored black-boxed drug-drug, drug-disease, or drug-laboratory warnings of potentially serious harmful effects. This highlights the need for prescribing practice to be based on as thorough knowledge base as possible of the expected main and potentially adverse side effects of each drug. Because new information about a given drug can become available at any time, with no one source necessarily reporting all of the relevant data, it is necessary to consider recommendations from multiple sources.

Some useful sources of information about drugs are listed in Table 2. In using all of these sources, three cautions should be borne in mind. First, the absence of reported evidence about adverse medication effects does not mean that they do not occur; it merely means that such effects have not yet been reported. It is even more critical that while some published reports of drug trials offer valuable information, others suffer from misleading claims and/or omit relevant information that can be essential in choosing a medication. Finally, some look to the *Physicians' Desk Reference* (PDR) as a convenient compendium of authoritative information about drugs and their effects. However, the PDR primarily consists of package inserts that are manufacturers' descriptions of their products. "The PDR is not a comprehensive clinical text. Patient care may be compromised if [prescribers] rely on the PDR rather than the professional literature and the usual community standards of practice as their main source of clinical guidance" (Simon & Shuman, 2007, p. 87). This means that competent prescribers need to undertake broad searches of diverse sources of information about the drugs that they wish to prescribe, a task that poses considerable challenges and can consume large amounts of time and other resources.

The pharmaceutical industry profoundly influences the nation's scientific agenda by funding at least 60% of biomedical research, including 70% of the clinical trials in the United States (Studdert, Mello, & Brennan, 2004), and 90% of the clinical trials in the United Kingdom (Ferner, 2005). Funding may intentionally or inadvertently affect results, given the finding ". . . that conclusions of trials were significantly more likely to recommend the experimental drug as the treatment of choice if trials were funded by for-profit organizations" (Als-Nielsen, Chen, Glund, & Kjaergard, 2003). Despite the fact that most scientific journals try to curb bias in the articles they publish, the financial viability of many outlets depends upon advertising and reprint purchases by pharmaceutical manufacturers (Krimsky, 2003; Smith, 2003). In fact, some large pharmaceutical companies either own the journals in which their reports appear or pay the authors of these studies for their work (Egger, Bartlett, & Juni, 2001). Some articles have been ghostwritten, with named authors not even seeing the data upon which the publications were based (Healy & Cattell, 2003). In addition, professional interest in a particular medication may be proportionate to the number of print sources that describe its use. However, rather than being a measure of the usefulness or efficacy of the drug, the number of articles reporting on it may be more a function of the revenues that pharmaceutical manufacturers are willing to spend to promote it. Marketing strategies may result in the relative overuse of some medications while other equally or even more effective alternatives languish (Melander, Ahlqvist-Rastad, Meijer, & Beermann, 2003). Such market factors can contribute to the impression that some entities in the pharmaceutical industry may put "profits before people" (Weber, 2006).

Despite growing consensus about the requisites of acceptable conduct and research design (Riegelman, 2000), the validity and utility of the results of some drug trials may be questioned on the basis of ethical violations (e.g., inadequate disclosure [Beresin, Baldessarini, Alpert, & Rosenbaum, 2003]) or design flaws (Hananff, Giraudeau, Baron, & Ravaud, 2006; Pampallona, Bollini, Tibaldi, Kupelnick, & Munizza, 2004; Rosenheck, 2005; Smith, 2003; Warner & Gluck, 2003). Table 3 lists some of the more common problems in drug research.

Establishing a cause-effect relationship between the administration of a drug and assessment of symptoms is challenging. The process is made even more difficult when large pharmaceutical companies withhold or distort relevant data (Avorn, 2005; Hiatt, 2006). Judson (2004) found some of the drug-study literature to be beset by two major ethical problems. Some authors fabricate results by deleting unfavorable data and/or by

distorting findings to make them appear more favorable. Other authors fabricate by simply making up findings. Fraudulent data may confound the research in some areas of investigation, and its negative impact can be incalculable when people's health and well-being are exposed to avoidable risks. Unfortunately, design flaws in psychopharmacology studies can be subtle and difficult to detect (Warner & Gluck, 2003). That the literature is vulnerable to error and bias is a concern for clinicians and consumers. For example, an exhaustive review of the literature on one class of antidepressants concluded with the admonition that:

> For anyone who relies on published data alone to choose a specific drug, our results should be a cause for concern. Without access to all studies (positive as well as negative, published as well as unpublished) and without access to alternative analyses (intention to treat as well as per protocol), any attempt to recommend a specified drug is likely to be based on biased evidence. (Melander, et al. 2003, p. 1173)

Although one might logically look to federal agencies for oversight and trenchant reviews of this research, four problems point to the need for caution. First, "the history of drug regulation parallels the history of major adverse drug reaction 'disasters'" (Strom, 2006, p. 3). Therefore, at least some drug regulation occurs after harmful drugs have been used by millions of Americans, resulting in more than 100,000 potentially avoidable deaths annually. As a second problem, the "United States has *no active drug-surveillance system* [italics added]," relying instead on the Adverse Event Reporting System that "captures only a small fraction of adverse events" (McClellan, 2007, p. 1702). Third, FDA approval is not an omniscient seal of safety for drugs. A memo from the Centers for Medicare and Medicaid Services (2005) warns that:

> When a drug is approved it is often not known how the drug will work in patients different from those studied for the FDA-approved indications, such as elderly patients with complex combinations of diseases or people with poor kidney function, or other patients for whom important benefits from the drug are suspected but have not been demonstrated. (p. 1)

This problem can be overcome by expanding the populations included in clinical trials and increasing the range of effects that are studied.

The fourth problem, however, is even more difficult to solve: it is the belief that due to flawed procedures, the FDA may inadvertently be complicit in the dissemination of false and/or misleading data about drugs. For example, federal funding of the FDA is inadequate, forcing the agency to depend on the pharmaceutical industry for 42% of its operating revenue (Horton, 2006). New laws that make the regulatory process faster greatly restrict the FDA's functioning, such as requiring only one Phase IV trial that evaluates the longer-term effects of medications (Piantadosi, 2005), making the collection of post-approval data essentially voluntary, and relaxing limits on incomplete direct-to-consumer advertising (Center for Public Integrity, 2005b). One disincentive for industry to promptly release information that might diminish patients' willingness to use their drugs is the

Table 3

Common Flaws in Clinical Trial Research

1. *Asking the wrong question.* When new drugs are proposed for a previously untreated illness, the classic efficacy, double-blind placebo control study is required. But when a new drug is proposed for an illness for which one or more other drugs are used, comparisons between the new and best current alternative are more relevant to clinicians' practices. These studies are a small minority of the reports on drug trials.
2. *Biased comparisons.* When comparison studies are published, the data are often forced by adjusting the doses of competing drugs to assure adverse reactions.
3. *Sampling errors.* Participants are selected for most studies only if they present with only the problem being studied. However patients in community practices often present with multiple problems. In addition, research samples are often demographically skewed and therefore may not be generalizable to the general population. Studies also often exclude specific groups (e.g. children, women, and the elderly) who might be adversely affected by the drug under study.
4. *Failure to measure salient side effects.* As an example, many of studies of antidepressants measure only depression despite general knowledge that antidepressants have multiple effects.
5. *Failure to adequately account for dropouts.* A significant number of participants drop out of drug studies and are not included in reports of the results. This precludes determination of whether and how they were helped or harmed by the drug in question.
6. *Extremely short trial periods.* When drug studies are very brief, their results may not accurately predict the effects associated with the typically longer durations of use in clinical practice.
7. *Lack of follow-up data.* Studies that do not continue to monitor participants' performance after active treatment ends preclude the possibility of systematically assessing adverse reactions that occur after brief trials end. Delayed adverse reactions may outweigh the benefits of short-term use of the drug as it was used in the original research.
8. *Acceptance of statistically significant low effect sizes that are clinically trivial* rather than adopting more clinically meaningful, moderate-to-high effect sizes as standards for accepting research results.
9. *Reliance upon post-hoc analyses.* The use of responses by subsets of participants to generalize the effects of drugs to these groups creates the opportunity for incomplete and potentially misleading predictions.
10. *The "file-drawer" problem.* The failure to publish adverse findings about drugs contributes to a failure to appreciate their possible iatrogenic effects, a problem that may be resolved with the requirement of a national drug database.

potential profit that they can make from continued use of their products. Moreover, totally inadequate regulation of conflicts of interest arguably puts the public's safety at risk (Center for Public Integrity, 2005a) For example, when Rezulin was given rapid approval for the treatment of adult-onset diabetes, adverse data were discounted by FDA staff who were simultaneously well-compensated consultants to Warner-Lambert, the company that developed the drug (Krimsky, 2003). Another example of the effects of lax standards occurred when the FDA approved dexfenfluramine (Redux) for the treatment of obesity. Only after many patients had used the drug did the public learn that the drug was associated with an average weight loss of only 6 pounds and that it could cause potentially fatal pulmonary hypertension, as well as other adverse long-term effects (e.g., cardiac valvulopathy). In addition, the manufacturers paid consultation fees to 10 of the 36 members of the FDA advisory panel that allowed the painkiller Bextra to remain on the market, and Vioxx to return to the market, despite evidence of the drugs' serious side effects (Harris, 2007). One may wonder whether these drugs might have been prevented from entering or withdrawn earlier from the market had the paid consultants voted differently.

Moreover, allegations that some FDA actions are motivated by political considerations rather than science further undermine the credibility of its actions (Wood, Drazen, & Greene, 2005). The FDA's flawed policies have engendered public distrust of certain agency rulings (Horton, 2006; Healy, 2005). It has even been alleged that rather than promoting good science, the FDA defends "a minimal standard that would be unacceptable anywhere else in research" (Avorn, 2005, p. 959).

To correct this and related problems, the Institute of Medicine recently made 25 recommendations for change in the operating policies of the FDA in general, and the Center for Drug Evaluation and Research in particular (Baclu, Stratton, & Burke, 2006). The goals of the proposed policies were to articulate, streamline, and improve the effectiveness of agency procedures. However, not only are the recommendations yet to be implemented, they have been found to lack adequate control of commercial influences and legal mandates through which the agency can enforce scientifically sound decisions when they are rendered (Horton, 2006).

Even when the FDA takes a step forward, it may be at the expense of several steps backward. For example, prescribers and patients alike habitually do not read labels because they can be so inscrutable. To remedy this situation, the FDA recently required drug package inserts to feature a highlighted summary of the most important indications and concerns (Anonymous, 2006). A label that meets this requirement will be much more accessible but it may also be a:

> . . . regulatory time bomb that could severely limit the accountability of companies [by immunizing them] from liabilities for unanticipated injuries resulting from the use of their products...[They would receive this protection] even if a company failed to warn prescribers or patients adequately about a known risk, unless a patient could prove that the company intentionally committed fraud—a very hard legal test to meet. (Avorn & Shrank, 2006, p. 2010)

In another recent policy change, the FDA limited members of its advisory panels to a maximum of $50,000 per year in consultation fees paid by the manufacturers of the drugs that they are charged with regulating, a restriction that could be waived at the discretion of the Commissioner (Harris, 2007). Added to an existing rule that panel members hold less than $100,000 in stock in these same companies, this change falls far short of eliminating the potential conflicts between personal and public interest. This change in regulations appears to have been brought about by mounting public pressure and the wish of the FDA to undertake self-regulation rather than have to submit to new Congressionally-mandated controls. Others believe that meaningful changes are most likely to depend upon litigation by those injured by its rulings (Kesselheim & Avorn, 2007). It is likely that only a sweeping change in policy will overcome the impression that the FDA's relationship with pharmaceutical industry may be more one of patron than of regulator.

Due to the combination of flawed research designs and lax governmental oversight, both health care professionals and consumers would be well-advised to remain cautious in reviewing the results of medication-outcome studies and FDA rulings. Because such criticisms have been covered by the media, it is theoretically possible that providers could be held responsible for adverse outcomes of the drugs that they prescribe on the assumption that they should have had the wisdom to understand the limitations in the guidelines and literature that influenced their choices. Psychologists who prescribe will have to navigate the maze of accurate, missing, and inaccurate information about drug effects. Given the recent finding that many psychotherapists are not even aware of the results of outcome studies in their core area of interest (Boisvert & Faust, 2006), it will be a daunting challenge for them to also keep abreast of the rapidly changing psychopharmacology research and broader medical literature that pertains to the effects of psychopharmacologic drugs.

7. *How will you avoid choosing a drug that is generally correct for the diagnosis but inappropriate for a given patient?* Even when diagnostic groups are well-defined, the myth of uniformity suggests that it is hazardous to assume that all individuals within the group will respond similarly. The risk of errors due to this fallacious assumption is as great in psychopharmacology as in every other area of clinical endeavor. Within gross diagnostic categories are subgroups that require different management strategies. For example, rapid-cycling bipolar patients may respond better to anticonvulsants than to lithium; and atypical depressives may respond better to monoamine oxidase inhibitors than more frequently prescribed SSRIs.

Drug effects have been shown to vary significantly across ethnic and demographic groups presenting with the same complaints. Culture influences definitions of illness and the choice of remedial options as well as the ways that members of different ethnic groups define symptoms. A symptom that one group considers a serious somatic concern might be viewed as a trivial psychological complaint by a different group. As the field of pharmacogenomics evolves, so too does recognition of the tendency of ethnic groups to respond differently to some drugs. For example, ethnic differences have been observed in the levels of the P-450 (CYP) enzyme systems that metabolize most psychotropic medications, the percentage of dopamine receptor blockades, and the level of plasma proteins that transport medications (Pi & Simpson, 2005). The resulting impact on responses to medications can be profound. For example, "opium from China is one of the oldest pain-relieving drugs—or is it? White people tend to feel [opium's] sleep-inducing and analgesic, pain-stopping effects, whereas the Chinese and other Asian peoples react to it more often with euphoria and hallucinations" (Haeger, 2000, p. 15). In addition, culture contributes markedly to the reasons that patients do or do not take medications as prescribed (e.g., Fleck, Keck, Corey & Strakowski, 2005).

Providers' biases can also influence the way in which patients are assessed and treated (Smedley & Smedley, 2005). For example, African Americans who are depressed or alcoholic may be misdiagnosed as schizophrenic; they are also less likely to receive second-generation medications (Pi & Simpson, 2005). Despite their importance, ethnic differences receive little systematic attention in drug research, compromising the general applicability of available data.

Many other factors, such as the failure to control for the stage of illness, medical history or response to comparable drugs, and lifestyle, contribute to varied responses to medications by participants in drug trials. In addition, drug trials often do not include the full range of patients with which the drug will be used. These groups include children and adolescents (Couzin, 2004) and the elderly (Janicak, 1999), as well as women (Correa-De-Araujo, 2005; Jensvold, Halbreich, & Hamilton, 1996), particularly those who are pregnant (Gjere, 2001). For example, overprescribing medications for the elderly can lead to behavioral disturbances that are falsely attributed to aging (Hayes & Heiby, 1996). Another prescribing dilemma arises when women develop mental illnesses during their childbearing years because some psychotropic drugs can affect their ability to conceive and pose risks of birth defects, premature delivery, and so on. Finally, there is the problem of the unreported use of other prescribed medications or street drugs. In one instance, Wachtler (1997), a former New York judge, reported that he convinced:

> . . . one doctor to prescribe Tenuate, an amphetamine-like drug that I used to elevate my energy level and thereby mask my depression (I took 1,400 of them in a four-month period). And because I could not sleep, I was able to convince another doctor to prescribe a hypnotic called Halcion (I took 280 of them during the same four months). Still another doctor gave me a prescription for Pamelor. And there were others. (p. 4)

As a result of this drug stew, Wachtler developed a drug-induced condition that was significantly worse than his original presenting complaint. Although this may be an extreme example, it is one that should draw attention to the need for both patients and prescribers to attend to any tendency for patients to shop for doctors who will inadvertently prescribe drugs that might, when combined, produce a near-toxic drug cocktail. Physicians who have seen many patients are more likely to recognize this problem than psychologists who, at least in the first years of prescribing, will not have had the opportunity to finely tune this skill. Use of alcohol and illegal drugs is also a common complication that may never be revealed to the prescribing clinician because patients do not consider it significant, are embarrassed to report it, and/or fear the legal and other consequences of disclosure.

8. *How will you gain access to the resources that you will need to adequately assess patients before prescribing drugs, and then to monitor their effects?* "Responsibly prescribing the consumption of powerful chemicals requires the study of organ systems and their mutual interdependence, not just the study of the behavioral impact of these chemicals" (Hayes & Heiby, 1996,

p. 202). Therefore, to minimize the risk of malpractice, prescribers have been advised to take a complete medical history and be certain that their patients have had adequate *physical* examinations, including all appropriate laboratory tests, prior to recommending the use of drugs (Simon & Shuman, 2007). This is necessary because of the multiple biological impacts of many drugs. In particular, medications usually affect and are affected by liver function and could potentially impact every cell in the body. Prescribing clinicians are therefore responsible for their patients' general health and for managing a range of adverse organic or side effects of the prescribed drugs (Hayes & Heiby, 1996; Janicak, 1999). As but one example, due to its wide distribution throughout the body and concentration in certain sites, when lithium is prescribed in treating bipolar disorder, it is necessary to monitor renal, thyroid, and cardiac functioning as well as general health using multiple blood assays and other laboratory procedures (Janicak, 1999). Serious illnesses can result from the failure to collect or correctly interpret these data. Psychologists have historically not been authorized to order such diagnostic tests and quantitative assays, and have negligible experience with the testing procedures and interpretation of results. It is not clear how widely the authority to order such clinically indicated assays will be incorporated into legislation that enables psychologists to prescribe.

Inexperience with drugs may lead to the naive assumptions that the "therapeutic range for most drugs has been well defined from carefully controlled clinical trials...[and] that concentrations in the therapeutic range will result in the desired clinical response" (Burton, Schentag, Shaw, & Evans, 2006, p. 4). Unfortunately, charts that plot dose-response and toxicity are not available for many drugs. For those drugs for which they do exist, the plots are at best probabilistic estimates that ignore "unpredictable intra-patient and inter-patient variability in the drug's pharmacokinetics" (ibid, p. 5). For example, one patient might absorb 90% of a given drug while another might absorb only 20% of the same dose of that same compound. It is therefore necessary to measure serum of drugs known to have adverse effects, despite the fact that serum levels do not necessarily correspond to expected levels at the site of action.

Responsible practice requires continuous monitoring of the direct and side effects of prescribed medications and their interactions with those drugs prescribed by other providers, self-selected over-the-counter and recreational drugs, and other substances. Extensive knowledge is required in managing psychotropic medications due to their impact on multiple organ systems and interactions with drugs prescribed for other purposes. Many widely used drugs require laboratory tests including, but not limited to: the blood level of the prescribed medication; creatinine level; liver function; pregnancy test; urinalysis; fasting glucose level; lipid panel; and electrocardiogram. Prescribers must not only know which tests to order but also how to interpret the results. Those who practice outside medical centers (e.g., in private practice) may find it difficult to obtain needed diagnostic data, such as measurement of concentrations of the medication in blood or plasma, or other parameters of health status.

9. *How will you be able to resist the pressure to prescribe unnecessary drugs?* The general public has been infatuated with "wonder drugs" since the advent of medications like penicillin and the Salk polio vaccine. The pharmaceutical industry has capitalized on this interest through massive advertising campaigns aimed at convincing people that psychoactive medications are the solutions to their various problems (Center for Public Integrity, 2005a). By its own account, the U.S. pharmaceutical industry spends $60 trillion per year to promote its products, with increasing emphasis on direct-to-consumer marketing. This is three times the amount spent on drug research and development (Pharmaceutical Research and Manufacturers of America, 2005).

Pharmaceutical companies begin their efforts to market psychoactive products by promoting the notion of "artificial happiness" (Dworkin, 2006). Happy is conflated with normal, and unhappiness with depression that includes sadness, worry, and disappointment. In effect, the public is coaxed to buy into the concept that if one is unhappy, one is ill and can therefore benefit from drug treatment. Contrary to well-established conceptions of emotions as sources of adaptive energy needed to motivate efforts to create opportunities for survival, minimize threat, and escape danger (de Sousa, 1987; LeDoux, 2002), the normal personality is misleadingly portrayed as having only positive emotions. In effect, everyday life is pathologized (Miller & Leger, 2005; see also Sommers & Satel, 2005), when common experiences that might otherwise have been effectively managed instead are labeled as symptoms of an illness. It is then a small step to recommend that sufferers seek the haven available through the advertisers' products. Rubin (2006) terms this process of creating a conceptualization of illness to sell drugs "commodification" (p. 86).

Although unflattering revelations about the drug industry have somewhat dampened public enthusiasm (Glenmullen, 2005), direct-to-consumer advertising has been extremely effective. Since its introduction in 1997, drug manufacturers have spent $4.2 billion on this type

of marketing. Surprisingly, the FDA reviews the authenticity of the claims in only a small sample of the ads, and often only after the ads have been disseminated (Horton, 2007). An ever-increasing number of patients arrive at clinics with a self-diagnosis and a request for a specific medication (Hollon, 2005), sometimes before prescribers have had an opportunity to study the newly marketed drug. In an ingeniously designed study, Kravitz et al. (2005) demonstrated that primary care physicians were likely to respond positively to patient-actors' brand-specific requests for antidepressants when presented with the symptoms of major depression. Moreover, a significant number of physicians were willing to prescribe medications for patient-actors who presented with the symptoms of adjustment disorders when psychotherapeutic intervention would have been the treatment of choice. Consequently, it is not surprising that benzodiazepines and antidepressants, which have been promoted as essential for coping with life's stresses, rank among the most widely used medications in the history of pharmacology (Gadsby, 2000). Many of the presenting stress reactions might have either remitted spontaneously or been resolved through brief psychotherapy. Children, too, have been targeted successfully. Parents and teachers have been prompted to request stimulants (Breggin, n.d.; Brody, 2006) and atypical antipsychotics (Olfson, Blanco, Liu, Moreno, & Laje, 2006) to modify a wide range of children's problems that can be responsive to non-pharmacological treatments.

Despite the fact that medications can help many patients overcome the ravages of severe depression, increasing numbers of providers may inadvertently undermine the adaptive resources of their patients by prescribing drugs that offer temporary symptom relief of problems often with counterbalancing undesirable side effects for which skill-building might well have provided more long-lasting solutions (Hollon, Stewart, & Strunk, 2006). For example, Nemeroff et al. (2003) reviewed the effects of drug treatment, cognitive behavior therapy, or a combination of the two in services to 681 depressed patients. They found that:

> Among those with a history of early childhood trauma (loss of parents at an early age, physical or sexual abuse, or neglect), psychotherapy alone was superior to antidepressant monotherapy. Moreover, the combination of psychotherapy and pharmacotherapy was only marginally superior to psychotherapy alone among the childhood abuse cohort. (p. 14293)

Exposing some depressed patients to the non-trivial cost and risk of potential side effects of medication is not necessarily in their best interests, even if they believe that medication is their preferred therapeutic option.

Research on the therapeutic potential of placebos warrants thoughtfulness about the necessity of using full-strength drugs with all patients. For example, Mayberg et al. (2002) demonstrated that placebos can lead to positive neurophysiological changes that sustain improved behavior. It has also been shown that placebo reactions contribute markedly to the benefits of active drugs. For example, it was found that: "if drug and placebo effects are additive, the pharmacological effects of antidepressants are clinically negligible" (Kirsch, Moore, Scoboria, & Nicholls, 2002, p. 1). Similarly, "more than half the studies comparing antidepressant treatment with placebos in children and adolescents with depression have not shown any benefit of the active compounds" (Ryan, 2005, p. 933). The same review also found a putative increase in the risk of suicide attempts by some adolescents treated with certain antidepressants, clearly an unwanted side effect that is not associated with placebos, justifying the sparing use of psychotropic drugs. Other research also suggests that clinicians may be well-advised to at least attempt other therapeutic interventions before exposing their patients to the risks associated with drugs. For example, compared with commonly prescribed psychotropic medication, cognitive behavior therapy alone was found to be an effective treatment for attention deficit hyperactivity disorder (Safren et al., 2005) and insomnia (Silversten et al., 2006) in adults, and behavior therapy combined with a placebo was found to be as effective as an active drug in the treatment of panic disorder (Barlow, Gorman, Shear, & Woods, 2000). Moreover, each of these studies documented attrition from therapy due to adverse side effects of the active drugs. This suggests that although prescribers may gain access to some new patients, they are at risk of losing others if they add drugs to traditional therapy. Accordingly, prudent practice may well involve offering patients with these and other disorders a course of nonpharmacologic therapy, moving to prescribed drugs only if desired outcomes cannot be achieved without them.

Prescribers often respond to requests for specific medication in three ways. They can refuse to prescribe, suggesting a trial of other therapeutic methods before resorting to drugs. They can prescribe the requested drug at the standard clinical dosage. While being sensitive to ethical practice, it may be reasonable at times to begin treatment with a very small dose of a prescribed drug and increase it only if needed. In clinical trial research, this strategy is termed "active drug run in" (Hulley et al., 2007, p. 173). Third, under some conditions, it may be

ethically acceptable to prescribe a placebo to capitalize on many patients' expectations that drugs generally provide relief (Horne, 1999; Walsh, Seidman, Sysko, & Gould, 2002).

Because many patients believe in the magic of the prescription pad and/or use prescribed medications as alternatives to illicit drugs as mood managers, they often strongly request drugs when the professional they consult has the authority to prescribe. Because the clinical interaction is such a human endeavor, clinicians may find it easier to acquiesce to patients' requests for drugs than to invest their time and risk potential aggravation by attempting to dissuade them. This is a particular problem for psychopharmacologists because "the diagnosis of psychiatric conditions and the response to psychiatric medication is so subjective and therefore so easily manipulated" (Glenmullen, 2005, p. 202). Of course, while the requested drugs may be helpful, they also may have harmful side effects, create dependency, and undermine patients' motivation to develop better personal coping skills.

A number of other factors may also motivate professionals to prescribe unnecessary, or overly expensive medications when less expensive alternatives are available. If providers are over-identified with their role as prescribers, they may believe that every patient should be medicated. They may be drawn to medication management because of the allure of a higher rate of hourly compensation than psychotherapy. They may continue using outmoded medications with which they are familiar because learning about alternatives takes time that could be put to other uses. Or, like their patients, prescribers may succumb to intense pharmaceutical industry advertising.

The process of influencing professionals begins early. Medical students are exposed to many forms of promotions. Although most students are aware of the fact that ads touting medications contain biased information, they are nevertheless influenced by them (Sierles et al., 2005). These promotions continue through residency and postgraduate education (Studdert, Mello, & Brennan, 2004; Wazana, 2000). More than 30,000 "detailers" are paid commissions for their success in influencing the prescribing practices of providers whom they visit regularly. In addition to inducements from pens and note pads to expensive outings, industry representatives rely heavily on food, flattery, and friendship (Moynihan, 2003). One also hopes that they are offered a fourth "F": facts. In addition, manufacturers offer to pay for endorsements, consultations, and opportunities to make presentations, all of which are geared to touting the superiority of their drugs.

One team of investigators (Ross et al., 2007) recently encountered many barriers to the discovery of this information in Vermont and Minnesota despite legislation that requires disclosure of these practices. They did, however, find that 16 drug manufacturers collectively paid at least $30,597,861 between 2002 and 2004 to influence the prescribing practices of physicians and other healthcare professionals. These incentives took the form of free meals, travel, and educational materials as well as lucrative consultation and lecture fees. To be sure, some percentage of the resulting prescriptions would have been written even if no incentives had been provided. However, the fact that the payments were offered and accepted provides sufficient justification for doubt about the appropriateness of many of these actions. As Ross et al. (2007) observed: "In contrast to many other professions, including education and law, medicine allows payments from a company to an individual who decides whether and how often to use products produced by the company" (p. 1216).

If his observations are accurate, Topol (2005) offered an unnerving illustration of what can happen when lax FDA regulations, aggressive drug marketing, and profit-oriented clinicians interact. In discussing Nesiritide, a drug that is used for short-term treatment of hospitalized patients with decompensated congestive heart failure, he wondered:

> How can a drug that is associated with higher rates of both renal dysfunction and death than placebo—and that costs 50 times as much as standard therapies and for which there are no meaningful data on relevant clinical end points—be given to more than 600,000 patients and be promoted throughout the United States for serial outpatient use, an indication not listed on the label? (p. 113)

His answer is that blurred boundaries between economic and clinical concerns can expose patients to harm. Not surprisingly, prescriptions for Nesiritide declined after reports of its adverse effects appeared in major medical journals (Hauptman, Schnitzler, Swindle, & Burroughs, 2006). It is noteworthy that the drug continued to be prescribed, albeit at a lower rate, and that recommendations for its removal from the market have still not been effectuated.

This example from medicine suggests that psychologists who prescribe will ultimately be exposed to comparable influences. There is no reason to believe that psychologists will be better able than physicians to resist the temptations and messages of marketing campaigns, particularly in light of the fact that physicians have had decades of experience in identifying and coping with

these inducements. To help prescribing psychologists resist mounting commercial pressures on diagnosis and treatment planning, effective firewalls would need to be erected by APA and other professional and state organizations. (Antonuccio, Danton, & McClanahan, 2003; Reist & VandeCreek, 2004). If the struggles within the medical community are any indication, psychology as a profession will face:

> . . . real or perceived pressures to relax scientific standards, inducements to become advocates (or shills) for industry, suppression of nonoptimal research results, incomplete or misleading descriptions and interpretations of trial results, and premature termination of clinical trials. Some institutions continue to accept contributions restricting traditional academic prerogatives in return for industry support of faculty research. (Cohen & Siegel, 2005, p. 1368)

The latter observation is particularly troubling if, for example, a company's offer to support research is contingent upon undertaking studies biased to produce outcomes consistent with corporate interests, as well as the willingness to avoid studies of competitive and possibly more effective alternatives. Both of these scenarios have occurred (Krimsky, 2003; Weber, 2005). It is probably wishful thinking that prescribing psychologists will be more adept than other professionals in meeting these challenges. Efforts to increase psychologists' ability to preserve their integrity would need to be buffered by amendments to the APA's *Ethical Principles of Psychologists and Code of Conduct* (2002).

10. *How will you prepare for the increased risk of being sued for malpractice due to patient reactions to a drug that you prescribed?* Medical malpractice is commonly in the news. The rate and cost of settlements has risen so sharply during the past decade that a growing number of insurance companies have cancelled their malpractice lines (Hartwig & Wilkinson, 2003). As a result, physicians are ending high-risk areas of their practice and looking for ways to protect their assets (Gilman, 2005). Most malpractice complaints are settled without going to trial, but the process of preparing a defense is expensive and unsettling. Verdicts can be emotionally and financially devastating. Although only 99 malpractice actions were filed against psychologists between September 2002 and July 2004 (Cohen, 2004), it is likely that this number will rise as the number of psychologists who prescribe increases. A frequent saying among clinical psychologists is: "You are only one litigious borderline patient away from ending your practice." Prescribing drugs for that patient could provide an even greater cause of action for a malpractice suit.

The potential for malpractice in prescribing drugs begins when the psychologist undertakes a legal duty by agreeing to offer a patient a certain standard of care. The plaintiff must then demonstrate that the care delivered did not correspond to that standard, and that demonstrable harm was suffered as a direct result of this substandard service (Fremgen, 2006). Regardless of whether any practice error has occurred, a patient who merely believes that harm has resulted from this service may seek compensatory, punitive, or nominal damages in the courts. Subsets of malpractice include: *malfeasance* that occurs when a wrong or illegal act is committed (e.g. practicing beyond the scope of one's license by prescribing a medication that the psychologist is not authorized to prescribe, or treating a patient whose needs exceed the provider's competence); *misfeasance* when an otherwise proper act is improperly performed (e.g. failing to recognize the implications of certain symptoms, choosing the wrong drug, or failing to take into account predictable side effects of the prescribed drug); or *nonfeasance* when a necessary act has not been performed (e.g., failing to obtain diagnostic or monitoring laboratory tests, or failing to inform patients about the expected effects of the drugs at issue). To prevail, plaintiffs must convince the court that there is greater than a 50% chance that the provider's action was the proximate cause of the injury and that the plaintiff is innocent of any contributory negligence. If psychologists' experiences parallel those of other health professionals, they would lose approximately 27% of these cases (Cohen, 2004). However, because plaintiffs' attorneys will try to establish the foundation for defendants' culpability in every possible way, making psychologists' limited pharmacology training relative to other prescribers and their debatable incompetence in attending to medical matters almost certainly subjects of scrutiny.

Despite the fact that many of the determinations in malpractice proceedings are subjective, litigation would be relatively straightforward but for two problems. First, no definitive, universally applicable protocols for medication treatment exist nor are likely to be developed, due in part to the difficulty in predicting medication effects. As Walker (2002) notes:

> Until we are able to completely understand how the human mind works, the legal questions surrounding Prozac and other psychotropic drugs will remain at issue. Because a complete understanding of the complexities that constitute the human neurological makeup is not likely to ever be fully achieved, the law must instead adapt to deal with these legal questions. (p. 801)

This lack of certainty opens the door to argument and exposes every medication decision to the risk of challenge in court. These predictions are further complicated by the unique way in which each patient responds to prescribed medication as a result of the interaction between internal dynamics, health status, the other medications and street drugs taken, and diet. It is an unusual clinician who assesses all of these areas. However, when something is alleged to have gone wrong, it will be asserted that needed tests were either not administered or, if so, that their results were not properly understood. Courts will be expected to decide whether the professional invested the level of resources necessary to evaluate the risks to which the patient was exposed, evaluated the risks carefully, and accurately conveyed the probable outcome to the patient.

The second complication in litigation proceedings is the elusiveness of professional standards for care. Based on a 1998 finding in the Supreme Court of Rhode Island (Sheeley v. Memorial Hospital 710 A.2d 161), defendants will claim that their services equaled or exceeded those that would have been rendered by minimally qualified professionals in the same specialty. In the past, support for this claim was drawn from the testimony of experts (Gutheil, Bursztajn, Brodsky, & Alexander, 1991). British common law, which strongly influenced American jurisprudence in this area, used the so-called "Bolam Test" (Bolam v Friern Hospital Management Committee [1957] 2 A11 ER 118) stipulating that doctors are innocent of malpractice if they act in accord with the standard methods used by others in their specialty. However, subsequent rulings in England (Jones, 2000) and Australia (Ebum, n.d.) have allowed courts to evaluate the logic of expert testimony prior to accepting it, and to resolve conflicts in expert testimony that are inevitable when supporting plaintiffs and defendants offer contradictory views. This has created new opportunities for plaintiffs to challenge defendants' assertions about standards of care. Moreover, well-recognized flaws in the literature and the fallibility of some FDA rulings weaken their utility in mounting a strong defense.

The provision of adequate information about the potential side effects of prescribed drugs is one area in which litigation can be expected. Prescribers have a duty to warn their patients about side effects, and failure to do so is a tort. For example, "a significant number malpractice lawsuits have been brought against psychiatrists by patients who developed TD [tardive dyskinesia, a generally untreatable movement disorder]" (Simon & Shuman, 2007, p. 91). In effect, these lawsuits are based on the premise that the prescriber did not obtain sufficient informed consent before prescribing the neuroleptic. These suits also typically allege that the doctor chose the wrong drug, prescribed an improper dose, kept the patient on the drug for an undue period of time, and/or failed to adequately monitor the effects of the drug so it could be terminated prior to the development of this highly undesirable side effect. Defense against these allegations is difficult because there are conflicting opinions about the proper use of potent antipsychotics; that is, there is not a single universally accepted standard of care.

In the courts, whereas prescribing psychologists would prefer that juries consider the standard to which their actions are compared be that of the "reasonable prescribing psychologist," the likelihood is that plaintiffs' attorneys would petition for the standard to be the reasonable *medical* prescriber, namely a psychiatrist who has undergone more extensive training. Such a more stringent standard would likely seem reasonable to juries, which may not fully understand the differences in training between psychologist prescribers and other prescribers (i.e., psychiatrists), and who might be empathic regarding the alleged harms perpetrated on consumers of prescribing psychologists' services possibly as a function of the prescribing psychologist's abbreviated training.

Even when psychologists do not commit torts, this would not immunize them from the risk of being sued. Neither would the absence of evidence that their medication practices differed from those of other prescribing psychologists or healthcare professionals. Indeed, prescribing psychologists' actions would always be subject to questions of whether gaps between their educations and those of other prescribers may have played a role in whatever action a dissatisfied party alleges has caused harm. Nor would innocence protect prescribers from the possible consequences if their insurance company decides to settle a case rather than go to trial. Should that occur, the psychologist would have to choose between having a record of malpractice and paying out-of-pocket the potentially large expense of a trial. Accordingly, psychologists who choose to prescribe drugs should do so with a full appreciation of the potential for litigation and the need for significantly more expensive malpractice insurance.

11. *Do you know enough to make a data-based decision about prescribing authority now?* Advocates of prescribing authority assert that: "empirical evidence supports the efficacy of granting prescriptive authority to clinical psychologists" (Cox & Ellis, 2003, p. 275). But careful reading of the literature suggests a far more cautious conclusion.

Since the movement to obtain prescribing authority for psychologists began more than 25 years ago, very few psychologists have been in a position to write prescriptions (Merrick, 2007). The PDP program attracted 13 participants, 10 of whom completed the program. Despite noted deficiencies in their knowledge of the basic sciences upon which psychopharmacology depends, various evaluations found those trained to have developed sufficient level skill to prescribe effectively. These results are qualified, however, by the facts: their military patients were all adults who had been prescreened for medical conditions; the training program was at least twice as rigorous as those proposed by the APA model (1996); psychologists used a carefully delineated formulary; and all orders were supervised by psychiatrists. By the end of 2006, other psychologists met the requirements in Guam (four, who are authorized to prescribe only in collaboration with a physician), New Mexico (four conditionally approved, still working under the supervision of a psychiatrist), and Louisiana (39).

As of September 30, 2006 it was reported that these prescribing psychologists have issued 20,000 prescriptions without adverse incident (Bolter, cited by Merrick, 2007, n. 25, p. 31). This claim should be questioned on a number of grounds. For example, it is not clear whether this is an independent valuation or prescribers' self-assessment, or whether enough time had elapsed after prescriptions were written for ADEs to be reported. More importantly, it is not known how many of these prescriptions were continuations of orders written by medically trained personnel or were co-signed by psychiatrists or other physicians. In addition, it is not known how many of these prescriptions were written by graduates of the PDP program as opposed to graduates of significantly less intensive training programs that follow the APA model. In summary, Gutierrez and Silk (1998) believed that the PDP experiment demonstrated that, "psychologists can be adequately trained to independently prescribe medication...at least within the military health care system. [But] these data must now be replicated in a variety of settings before an informed decision for or against prescription privileges can be made" (p. 221). Therefore, while Resnick and Norcross (2002) rejected "premature and inflammatory conclusions that prescribing psychologists pose a health risk and that proposed training programs are inadequate" (p. 270), it is equally premature and potentially dangerous to assume that the effectiveness of prescribing psychologists and the programs that trained them are able to deliver safe and effective service.

Data are also absent in other areas of concern. For example, the reluctance of people in rural areas to seek mental health services has been documented (Geller & Muus, n.d.). If prescribing psychologists did in fact migrate to rural areas, it is not known whether they would be able to overcome prospective patients' unwillingness to define their problems as psychological as opposed to medical, and seek psychologists' prescribing services. It is also not known whether the prescription services by psychologists will be more effective than those provided by physicians who have long-established relationships within their rural communities and for whom education about psychoactive medications has been steadily improving. Moreover, despite the fact that rural and underserved groups are emphasized in proponents' lobbying efforts to promote prescriptive authority, we know of virtually no plans to redistribute prescribing psychologists by, for example, deploying them to rural areas or underserved sections of cities.

Another interesting, although not unexpected, problem in the literature advocating prescribing authority is the amount of interpretive bias that colors proponents' perceptions. As but one example, Wiggins (Yates et al., 2004) boasted "collaboration between primary care physicians and psychologists significantly improved clinical outcomes in the treatment of depression over the generalists' usual care" (p.1422). However, when one reviews the research cited in support of this claim (Katon, Roy-Byrne, Russo, & Cowley, 2002; Katon, et al., 1995) one finds that it was *psychiatrists,* not psychologists, who provided the outcome-enhancing consultation. Proponents may hope that a similar pattern would emerge for psychologists, but in the absence of data, it remains a hope and should be regarded as speculative. Moreover, psychologists' collaboration with primary care physicians does not require that they obtain prescriptive authority.

The standards for the publication of research favoring prescription authority often lack methodological rigor. For example, in one study (Wiggins & Wedding, 2004), the authors attempted to survey the 644 members of the APA who were also trained as nurses, but only 370 (57%) responded. Of these, only 13 indicated that they prescribed drugs. None of the 13 reported that they had been charged in malpractice actions. Based on these scant data, from a different field (nurses have more extensive medical training than prescribing psychologists and are limited to dependent prescribing privileges), the authors extrapolated to conclude that psychologists can prescribe without adverse incident. Because the malpractice fees paid by licensed nurse-psychologists were lower than those commonly paid by psy-

chologists insured by the APA Insurance Trust, the authors also concluded that "the fears of sky-high premiums raised by those opposed to prescriptive authority are unfounded" (p. 150). It is quite a leap to generalize from a very small sample of nurse-psychologists to a population of psychologists who lack nursing training, but nevertheless gain prescriptive authority. It is hoped that as the history of psychologists' prescribing experiences unfolds, the quality of data and the logic used to evaluate it will improve.

Another issue raised by opponents of prescription authority is the possibility that biological concerns might overtake the pivotal role that psychosociocultural factors have played in psychological thinking, much as psychiatry has undergone periodic ideological change (Luhrmann, 2000). To address this question, Levine and Schmelkin (2006) collected survey responses from 241 of the 500-member sample generated by the Research Office of the APA. Although complete data were not reported, respondents valued psychological treatments more highly than biological intervention. This led the authors to conclude that psychological variables would not be sacrificed to biological factors among prescribers. However, because no participant in the study was able to prescribe, it is impossible to predict from this data set how they would react if or when they obtained the legal authority to do so.

In evaluating legislative trends regarding prescriptive authority for psychologists, it is premature to determine whether those jurisdictions that have allowed it thus far are pioneers in a growing trend or simply anomalies. It is unknown whether other states will follow in the steps of Guam, New Mexico, and Louisiana. Some may be willing to grant prescription authority to those holding certificates from watered-down programs; others may accept programs that adhere to the APA's controversial model; and still others may insist upon full PDP-style training, if they grant psychologists prescription authority at all. All of the states considering this issue face the same dilemma that confronts individuals who are weighing the pros and cons of prescribing. As Bush (2002b) phrased the problem: "no satisfactory precedents exist, either for designing suitable training programs or for predicting psychologists' performance as prescribers" (p. 3). Individuals who choose to seek prescribing authority are well advised to determine the requirements of the states in which they hope to practice, find a program that addresses these requirements, and ascertain the success of its graduates to gain the hoped-for privileges. No matter how hard they work to obtain prescriptive authority, they are likely to have to continue to endeavor to convince others about the adequacy of their training and competence.

Similarly, state psychological associations will need to assess whether the resources they would need to channel into advocacy in this matter would be well spent. One consideration is determining whether advancing the prescribing interests of some of their members is worth the expense of diverting resources from other issues that may be more important to the majority of their members. As it is difficult to change laws, efforts to do so should be concentrated on matters that are of importance to a majority of the APA membership. They will also want to determine whether the experiences of prescribing psychologists seem beneficial, costly, or irrelevant to the consumers of psychological services. It must also be wondered whether championing this matter will promote good will or divisiveness among their members, and whether it will lead to a sorting of psychologists into a two-tiered structure.

Conclusion

To meet unmet client needs and continue to improve their results, many psychologists choose to develop innovative psychotherapy skills. Some are now choosing to pursue what they see as practice enhancements by trying to obtain the authority to prescribe. Just as nurses have sought degrees in psychology to enhance their psychotherapeutic skills, it may be more reasonable for psychologists to seek

prescription authority by becoming nurse practitioners, or attending medical school, rather than through abbreviated training models. Those who prefer the route of psychopharmacology training programs for psychologists should be prepared to meet many challenges.

The 11 questions raised here were designed as a guide to help students and psychologists better weigh some of the costs and potential risks of prescribing against its hoped-for benefits. If psychology is to support the goal of obtaining prescription authority for psychologists it faces formidable challenges. For example, it would be necessary to develop new resources for training so that psychology's traditional mandates are not depleted through the diversion of resources. New training and practice protocols will need to be developed, a number of which fall outside the normal purview of psychology. Additional ethical guidelines will need to be developed that seek to insulate psychology from the problems of commercialization that have beset medicine in its effort to protect patients from potential harms. These challenges are new

to psychology as is the need to rely on the rulings of governmental agencies and a literature that is frequently unreliable. Neither clinicians nor the profession should rush into prescribing without fully understanding and preparing to meet these substantive demands.

Some might argue that psychologists should not be expected to solve the problems that still beset other professions that have far more experience in dispensing medications. But the fact that other professions have not met these challenges does not absolve psychologists from doing so. Instead, it should serve as a warning about the challenges of prescribing drugs responsibly. All patients face some inherent risks in the prescribing process. Because of relative deficits in training and experience related to managing medications, psychologists are likely to be more vulnerable to lawsuits when inevitable adverse outcomes occur. It is impossible to empirically assess these risks because there have been no large-scale efficacy studies, or even well-designed effectiveness research that objectively evaluates the benefits and risks of psychologists' prescribing practices. This puts psychology in the awkward position of being a scientifically based profession that is seeking to expand its scope based on a small pilot program (e.g., the PDP) that reaches well beyond the parameters of the available data. This fact has not gone unnoticed by observers in other professions. For example, Pollitt (2003), a psychiatrist, sees "psychologists seeking prescriptive authority [as] blinded by their own self-interest . . . willing to distort and totally disregard a multitude of opposing facts, placing patients at harm" (p. 512). And within psychology, it has been suggested that "if the fight to gain prescription authority continues and is won . . .clinical psychology will be in danger of regressing toward a pseudo-science funded by the deep pockets of pharmaceutical companies" (Goldenberg & Powlison, 2007, p. 24). Noting the inevitability of unanticipated risks, Albee (2005) predicted that the adoption of prescription privileges will be a "poison pill" for professional psychology. Before deciding to seek prescribing authority, psychologists are therefore cautioned to consider very carefully the figurative black-box label that applies to the practice of prescribing itself.

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