Psychology in the Prescription Era

Building a Firewall Between Marketing and Science

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The pharmaceutical industry has contributed to many lifesaving innovations in medicine and has become one of the most successful industries in the world. As a result, pharmaceutical industry financial and marketing influences extend to federal regulatory agencies, professional organizations, medical journals, continuing medical education, scientific researchers, media experts, and consumer advocacy organizations. These extensive influences have created conflicts of interest that have undermined the credibility of medical research and education. As professional psychology pursues and achieves prescription privileges, it will likely be faced with increasing influences from the industry. To preserve the integrity of psychological science, the authors propose an aspirational "firewall" designed to separate industry marketing from the science of psychology.

Through their patients and the media, psychologists are frequently confronted with information about the latest psychotropic medication innovation. Sorting out scientific fact from marketing "spin" can be challenging to say the least (e.g., Vedantam, 2001). As professional psychology moves into a new era of prescription privileges (Daw, 2002), it will likely receive increasing direct financial and marketing attention from the pharmaceutical industry (Antonuccio, Burns, & Danton, 2002; Beutler, 2002), causing potential conflicts of interest that may affect the scientific database. Opponents of prescription privileges argue that our profession will be harmed by these influences (Antonuccio & Danton, 2003), whereas proponents argue that our high scientific standards will protect us (Levant & Sammons, 2003). The protection of our science is one area of the prescription privileges debate in which both sides may find common ground. The goal of this article is to detail the extent of pharmaceutical industry influence in medicine in general, and psychiatry in particular, and to propose an aspirational "firewall" between the drug industry and organized psychology to preserve the credibility and integrity of our science. While also acknowledging the importance of nonfinancial (e.g., interest in career advancement) conflicts of interest (Levinsky, 2002), we have narrowed the scope of this article to address the financial conflicts of interest related to the drug industry because they are more easily measurable, voluntary, and often unrecognized unless disclosed (Bekelman, Li, & Gross, 2003).

The pharmaceutical industry has contributed to many healing (e.g., antibiotics for infections and chemotherapy for certain cancers), life-enhancing (e.g., anesthesia and other medication for pain), and life-extending (e.g., insulin for diabetes and thrombolytic therapies for vascular disease) innovations in medicine. Partly as a result of this success, the industry generated more than $400 billion in annual revenue worldwide in 2002 according to pharmaceutical consulting firm IMS Health, with the United States accounting for about one third of all pharmaceutical sales (Louie, 2001). It is the most profitable industry in the United States in terms of return on revenues, return on assets, and return on equity (Fortune, 2000). From a business perspective, it is arguably the most successful industry in the world.

While many lives are saved by pharmaceutical innovations, many lives are also put at risk. For example, it has been estimated that as many as 100,000 hospitalized patients die each year in the United States from adverse prescription drug reactions (Lazarou, Pemeranz, & Corey, 1998). In an ambulatory clinical setting, adverse drug events are common and often preventable (Gandhi et al., 2003), especially among elderly patients (Gurwitz et al., 2003; Juurlink, Mamdani, Kopp, Laupacis, & Redelmeier, 2003). Some harmful reactions cannot be foreseen because the medications are only tested on an average of 3,000 people prior to approval, causing a reliance on postmarketing data to identify less common reactions (Friedman, 2002). Up to 20% of approved drugs subsequently require a new black box warning about life-threatening drug reac-

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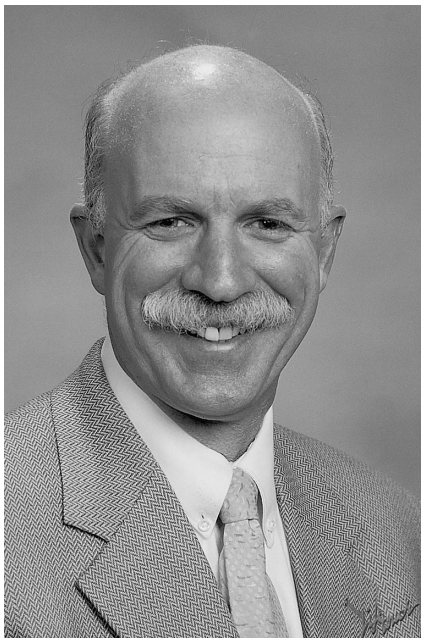

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tions or are withdrawn from the market (Lasser et al., 2002). Such medications can generate substantial revenue before being withdrawn. For example, seven potentially lethal drugs (among them the diet pill Redux and the diabetes medication Rezulin) generated more than $5 billion in sales revenue before they were ultimately withdrawn from the market between 1997 and 2000 (Willman, 2000).

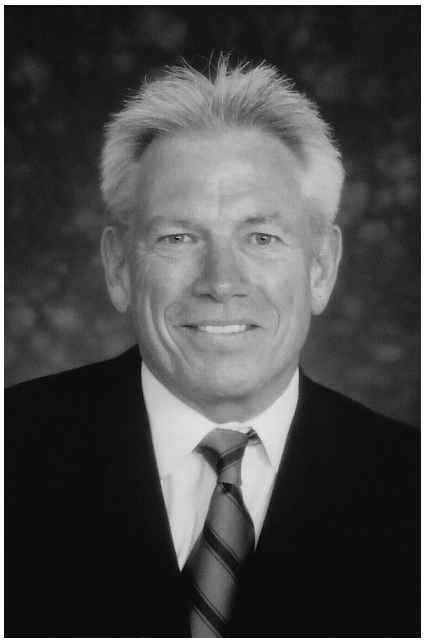
Although selective serotonin reuptake inhibitors (SSRIs) are widely thought to be extremely effective and safe, there is mounting evidence that their benefits have been overemphasized in the scientific literature (Antonuccio et al., 2002) despite clinically negligible advantages over inert placebo (Kirsch, Moore, Scoboria, & Nicholls, 2002). At the same time, side effects and withdrawal symptoms of SSRIs may have been underemphasized (Antonuccio et al., 2002; Fava, 2002). For example, a recent study (Gandhi et al., 2003) found that SSRIs were the class of drug most commonly involved in adverse drug events, often unaddressed by the physician, in a primary care outpatient environment. Other data suggest that patients who take SSRIs appear to be significantly more likely to engage in suicidal behavior than those randomly assigned to the older antidepressants or even placebo (Healy, 2003). In fact, at the time this article went to press, following similar action by the United Kingdom Department of Health, the U.S. Food and Drug Administration (FDA) had issued a warning against using paroxetine for major depressive disorder in anyone under age 18 because of the greater risk of suicidal behavior induction compared with placebo, while also cautioning about troublesome discontinuation effects (FDA, 2003). If this warning were ever extended to adults, the potential impact on revenues could be enormous. Also, the possibility of a causal link between antidepressants and breast cancer cannot yet be ruled out (Bahl, Cotterchio, & Kreiger, 2003; Moorman, Grubber, Millikan, & Newman, 2003), raising the stakes even more. All of this is to suggest that human lives depend on creating a scientific literature that is as unbiased and safety conscious as possible. The financial stakes directly compete with the safety risks and can create a threat to the integrity of the data underlying the medications that come to market.

Marketing Medications

With success comes considerable financial influence. According to IMS Health, the industry spent more than $19 billion in 2001 in U.S. advertising alone. The pharmaceutical industry spent almost $200 million on lobbying and campaign contributions in 1999 and 2000, more than any other industry (Wayne & Petersen, 2001). The industry has more lobbyists than there are members of congress (Wayne & Petersen, 2001), and it underwrites about 70% of all clinical drug trials in the United States (DeAngelis, Fontanarosa, & Flanagin, 2001).

The pharmaceutical industry does an outstanding job of marketing its products, and psychotropic drugs are no exception. As an example, in 1999, 3 of the top 10 best-selling pharmaceuticals were the SSRIs Prozac, Paxil, and Zoloft, accounting for combined revenues of $6.7 billion (Louie, 2001). The top selling drug category is that for antidepressants, and revenues generated by SSRIs are growing about 25% each year (Kroenke et al., 2001). Survey data suggest that as many as one in eight adult Americans has taken an antidepressant in the past 10 years, and an estimated 3.5 billion doses of SSRIs were consumed in 1999 alone (Langer, 2000). About 60% of those who had taken antidepressants indicated they had taken them for more than three months, whereas 46% indicated they had been on them for a year or more.

Many advertising strategies are well known and well documented. *Consumer Reports* has documented drug industry marketing strategies ("Miracle Drugs," 1992; "Pushing Drugs," 1992) that include but are not limited to the following: (a) giving free samples and information to doctors, (b) advertising in medical journals, (c) using "ask your doctor" media ads aimed directly at the consumer (see Mello, Rosenthal, & Neumann, 2003; Wolfe, 2002), (d) sponsoring promotional dinner meetings with substantial gifts or even cash provided for attendees, (e) paying consultants to speak at scientific meetings in which it is possible to circumvent FDA guidelines that require disclosure of side effects, (f) funding only those research projects that have a high likelihood of producing favorable results for a particular drug company's product (see Bodenheimer, 2000), (g) terminating negative studies before they are ready for publication, (h) involving large numbers of physicians in studies not intended to yield publishable information but simply designed to yield maximum product exposure, (i) including "look-alike" publication supplements (i.e., non-peer-reviewed articles underwritten by a drug company that appear in a special issue of a peer-reviewed journal) in professional journals, (j) offering to pay journalists to cover their products, (k) offering pre-



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packaged information for journalists in the form of video news releases that give the appearance of having been independently developed (e.g., Petersen, 2003c), and (l) helping to fund patient advocacy and other public interest groups so the consumer group appears to be publicly carrying the banner of a particular drug.

Of these strategies, perhaps direct-to-consumer advertising has had the most profound effect. Since 1997 when the FDA relaxed the rules for such advertising, the volume of TV ads has increased over sevenfold, prompting millions of American consumers to ask their physicians about a medical condition they had never discussed before seeing the ads (Rosenthal, Berndt, Donohue, Frank, & Epstein, 2002). In addition to calling attention to undertreated disorders, such drug advertising may help patients become more accepting of treatment. Although many physicians and patients find direct-to-consumer ads educational and useful, an analysis of 564 warning letters to drug manufacturers since 1997 ("Free Rein," 2003) revealed that these ads commonly minimize drug risks, exaggerate drug effectiveness, falsely claim one drug is better than another, suggest unapproved uses for existing drugs, or promote still experimental drugs. The analysis also found that doctors were exposed to four times as many messages deemed false or misleading by the FDA as were consumers. Not only does the FDA lack the authority to fine offending companies, but drug ads are not preapproved by the FDA and have often run their course before a warning letter is ever received.

An estimated 60 million consumers annually ask their doctors about medication they have seen advertised ("Free Rein," 2003). Most of the time doctors comply with the patient's request for prescription of a specific medication and write significantly more prescriptions for patients who request them than for those who do not ("Free Rein, 2003"). Sometimes it is difficult to distinguish legitimate news stories from advertising directed at consumers. For example, in 1999 a New York public relations firm coordinated an ad campaign involving newspaper, radio, TV, and Internet stories, along with testimonials from advocates and doctors who indicated that social anxiety was highly prevalent (Vedantam, 2001), which certainly seems to be the case (e.g., Heiser, Turner, & Beidel, 2003). The media campaign was so successful that social anxiety was mentioned in media stories over 1 billion times in 1999, compared with about 50 total stories in 1997 and 1998 (Vedantam, 2001). About 96% of the stories indicated that the antidepressant Paxil was the first and only FDA-approved medication for the treatment of social anxiety disorder (Vedantam, 2001). The public relations firm was working for the pharmaceutical company SmithKline Beecham (now GlaxoSmithKline), the maker of Paxil. Pharmaceutical companies also effectively hire celebrities to promote their products unbeknownst to viewers or pay for product placements in movies and TV shows (Petersen, 2002a). Some have even argued (e.g., Mintzes, Bonaccorso, & Sturchio, 2002; Moynihan, 2003a) that direct-to-consumer advertising is sometimes designed to attract patients within the normal range by marketing "diseases" like premenstrual dysphoric disorder, sexual dysfunction, and even relationship disorders to sell certain medications.

It is difficult to think of any arena involving information about medications that does not have significant industry financial or marketing influences. Industry financial ties extend to federal regulatory agencies, professional organizations, continuing medical education, researchers, media experts, and consumer advocacy organizations. Such widespread corporate interests may contribute to self-selecting academic oligarchies, narrowing the range of acceptable clinical and scientific information or inquiry (Fava, 1998; Marks, Swinson, Basoglu, Noshirvani, et al., 1993). This can lead to legal, professional, or even personal attack, directly or indirectly financed by the industry for those who deliver information or produce data that conflict with corporate interests (e.g., Boseley, 2002; Deyo, Psaty, Simon, Wagner, & Omenn, 1997; Healy, 2002; Marks, Swinson, Basoglu, Noshirvani, et al., 1993; Monbiot, 2002; Nathan & Weatherall, 2002; Rennie, 1997). For example, Marks, Swinson, Basoglu, Kuch, et al. (1993) conducted one of the most carefully designed and executed studies ever done on the treatment of panic disorder with agoraphobia. Initially Upjohn, the maker of Xanax (alprazolam), supported the design, execution, analysis, and quality assurance of this multisite study comparing (a) alpazolam plus exposure, (b) alprazolam plus relaxation (psychological placebo), (c) placebo plus exposure, and (d) placebo plus relaxation (double placebo). At some point it was discovered that the results were going to favor exposure plus relaxation and that the alprazolam actually seemed to interfere with treatment outcome. Marks, Swinson, Basoglu, Noshirvani, et al. (1993b, p. 792) wrote that

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monitoring and support stopped abruptly when the results became known. Thereafter, Upjohn's response was to invite professionals to critique the study they had nurtured so carefully before. The study is a classic demonstration of the hazards of research funded by industry.

Another troubling example of constraints on academic freedom in psychiatry involved psychiatrist David Healy, who publicly presented data linking SSRIs to increased risk for suicidal behavior in a subset of susceptible patients (Healy, 2002, 2003). This resulted in the rescission by the university of an already accepted job offer for him to head a depression research unit at the University of Toronto. This led to an outpouring of support for Dr. Healy from other scientists around the world (Axelrod et al., 2001) and a lawsuit filed by Dr. Healy for breach of contract, libel, and a first ever suit for breach of academic freedom. The suit was resolved by representatives of the university clarifying what had happened and responding to the issues of libel and breach of academic freedom by making Dr. Healy a visiting professor. At the heart of what had happened were representations to the university by academics with close contacts to industry. In such an environment, large doses of integrity, courage, and stamina may be required if one decides to present data that conflict with corporate interests.

Conflicts of Interest Within the Federal Government

The pharmaceutical industry also has demonstrated links to government agencies such as the FDA (Cauchon, 2000; Horton, 2001; Kranish, 2002; Willman, 2000), the British version of the FDA called the Medicine Control Agency (Boseley, 2003), and the National Institutes of Health (Cimons, 1999). A *USA Today* investigation (Cauchon, 2000) found that 54% of expert consultants hired by the FDA had a direct financial interest in the drug or topic they were asked to evaluate. There were roughly 300 experts serving on 18 advisory committees that make recommendations (usually followed by the FDA) about new medications. *USA Today* found that from January 1, 1998 through June 30, 2000, 92% of the meetings had at least one member in attendance who had a financial conflict of interest. At 55% of the meetings, half or more of the FDA advisors had financial conflicts of interest. Although federal law generally prohibits the use of experts with financial conflicts of interest, the FDA waived this restriction more than 800 times during the time period under investigation.

It is thought that relaxing FDA standards in recent years has led to approval of more dangerous medications and ultimately more drugs requiring withdrawal from the market due to lethal side effects (Lasser et al., 2002). Unfortunately, of the 13 dangerous drugs withdrawn from the market from 1992 to 2002, none filled an otherwise unmet medical need (Seligman, 2002), raising the question about whether the benefit of speedier approval exceeds the risk. Some have argued that the speedier approvals have come in exchange for user fees (fees paid by the pharmaceutical companies to offset the increased financial burden of the approval process) implemented over a decade ago (Sigelman, 2002). It might be argued that this arrangement creates a potential conflict of interest for a regulatory body at least partially dependent financially on the companies it is supposed to regulate.

Further complicating matters is that many newly marketed medications are just single isomers (i.e., one of a set of mirror image molecules) of existing medications without any safety or efficacy advantages over the older versions (Relman & Angell, 2002). Some examples in psychiatry include dexmethylphenidate (Focalin) for methylphenidate (Ritalin) and escitalopram (Lexapro) for citalopram (Celexa).

Advertising to Professional Organizations

In 2000, the American Psychiatric Association received over $13 million from the pharmaceutical industry, more than the roughly $10 million generated by dues-paying members (Vedantam, 2002) and representing about 30% of its budget (Pfeiffer, 2001). The April and May 2002 issues of the *American Journal of Psychiatry*, the flagship journal of the American Psychiatric Association, had more than 25% of the pages devoted to appendices, primarily advertising for psychotropic medications or drug-company-sponsored continuing education. Such journals typically generate considerable profits for their parent organizations and risk losing advertising revenue if they publish articles critical of their advertiser's products (Abassi & Smith, 2003; Pellegrino & Relman, 1999). For example, in 1992, the *Annals of Internal Medicine* published a study (Wilkes, Doblin, & Shapiro, 1992) showing that new drug advertisements in journals were often misleading regarding safety and effectiveness. The journal editor ultimately resigned under pressure at least in part because the journal lost up to $1.5 million in advertising revenue when the drug

companies stopped advertising as a result of the published article (Altman, 1999). Although such advertising may serve an educative function, many ads lack adequate quantitative information and can indeed be misleading (e.g., Loke, Koh, & Ward, 2002; Villanueva, Peiro, Librero, & Pereiro, 2003).

Professional meetings also provide opportunities for advertising efforts. At the 1999 fall meeting of the American Psychiatric Association, about 17% of all presenters listed affiliations with the pharmaceutical industry in the conference brochure, though disclosure policies may underestimate conflicts of interest (e.g., Krimsky & Rothenberg, 2001). To its credit, organized psychiatry has a long established mechanism for disclosing to the public these potential conflicts whereas organized psychology is only beginning such efforts. The American Psychological Association (APA) Council of Representatives approved a motion in 1997 to have the APA send disclosure forms to authors and presenters. The APA began using such forms (http://www.apa.org/journals/acorner.html#pubforms) in 2001, although there are still some gaps in their use and in public acknowledgment of disclosed conflicts. Drug company support for the APA is currently less than 0.4% of the operating budget (S. Graves, personal communication, February 24, 2003), although the potential for greater interest and support from the industry is likely as psychologists continue to achieve prescriptive authority. Also, there is at least some industry support for APA divisions (e.g., the brochure project at http://www.brochureproject.org/), something the organization does not track.

Education or Advertising?

It has been estimated that pharmaceutical companies annually spend up to $13,000 per physician promoting medications (Christensen & Tueth, 1998; Wazana, 2000). Although there may be a valuable educational component to these efforts, they are primarily designed to get physicians to increase their prescription of the advertised medication (Relman & Angell, 2002). A recent phenomenon involves Medical Education Services Suppliers (MESSs), private companies that provide medical education designed to modify physician-prescribing practices. Public Citizen (Ross, Lurie, & Wolfe, 2000) estimated that in 1999 the MESS industry had an income of $643 million. Of this sum, $289 million was earned through providing grand rounds ($115 million), symposia ($114 million), and publication-related activities ($60 million). This often takes the form of unrestricted educational grants. Although drug companies are not supposed to influence the content of lectures supported by unrestricted grants, there is always the possibility that the list of eligible speakers will be restricted to individuals or organizations that they believe are likely to treat their products favorably (Relman, 2003).

Most companies pay for medical education from their marketing budgets, a fact that speaks for itself (Relman & Angell, 2002). Despite assertions to the contrary, there is no doubt that continuing medical education (CME) courses have an impact on physician prescribing practices. In a meta-analysis of 29 studies, Wazana (2000) found that company-sponsored courses mentioned positive effects of the companies' medications 2.5 to 3 times more often than other courses. Physicians prescribed the sponsors' medications 5% to 19% more often afterward. It should be noted that such a change in practice may reflect attendance at a workshop about any clinical procedure and may not be limited to workshops underwritten by the drug industry.

Advertising tailored to the individual physician also takes place. The American Medical Association (AMA) assigns a medical education number to all new medical students to track them throughout their careers (Stolberg & Gerth, 2000). The AMA generates up to $30 million annually by selling master lists of nearly 850,000 physicians along with detailed prescriber profiles to private pharmaceutical marketing companies (Kowalczyk, 2003). After office visits, sales representatives enhance the profiles by adding data regarding hobbies and possible "perks" of interest. Companies can track the prescribing practices of doctors throughout their careers. While this can serve an important safety function by allowing doctors to be alerted to dangerous prescribing habits, it also allows the targeting of physicians for promotions that are tailored to their specific prescribing practices and interests.

Physicians begin meeting with pharmaceutical representatives in medical school and continue at a rate of about four times per month (Wazana, 2000). One study suggested that as many as 13% of the statements made in such interactions are inaccurate, all in favor of the drug being promoted, and physicians generally fail to recognize the inaccuracies (Ziegler, Lew, & Singer, 1995). General practitioners who meet with drug industry representatives at least once a week express a greater willingness to prescribe medications that are not clinically indicated if the patient requests it (Watkins et al., 2003). There is even evidence of some physicians allowing pharmaceutical sales representatives into their exam rooms to meet with patients, review medical charts, and recommend medications in a "shadowing" program designed to promote medication for uses unapproved by the FDA (Tanner, 2003). Concern about such influence has led to new ethical guidelines on physician–industry relationships (Coyle, 2002), and the AMA has even undertaken an education initiative, ironically underwritten by the drug industry, to educate physicians about the ethical issues involved in receiving gifts from the industry. There may be some parallels that can be drawn between pharmaceutical company support of ethics training and the tobacco industry efforts to support youth smoking prevention programs (Farrelly et al., 2002; Landman, Ling, & Glantz, 2002), both designed in part to forestall legislation that would restrict industry activities. In June 2002, Vermont became the first state in the country to require all pharmaceutical companies to report physician gifts that are worth more than $25 (Seglin, 2002). Unfortunately, social science research suggests that even small gifts can have substantial biasing effects, and recipients of gifts are subject to an unconscious, unintentional self-serving bias that may lead them to conclude that they themselves are not influenced while their colleagues certainly are (Dana & Loewenstein, 2003).

Evidence from recent court proceedings reveals how such marketing efforts can transform an epilepsy drug like gabapentin, with a limited market, into a "blockbuster" drug with sales revenues from prescriptions (78% written for unapproved uses) over $2 billion in 2002 (Petersen, 2003a, 2003b). Court documents show that to promote "off label" uses (including for treatment of mood disorders and attention deficit disorder), the drug manufacturer Parke-Davis (later acquired by Pfizer) (a) hired doctors as "consultants" to attend dinner conferences, (b) hired third-party companies to produce seminars supported by "unrestricted grants" while Parke-Davis actually controlled the content, (c) provided "educational grants" to demonstrated gabapentin advocates (i.e., doctors who prescribed gabapentin at high rates or programs that were willing to host speakers supportive of gabapentin), (d) provided technical or "ghost" writers while paying physician "authors" honoraria for at least 20 "scientific" articles in 1996, and (e) created speakers bureaus made up of doctors who recommended gabapentin at teleconferences, dinner meetings, consultants meetings, and educational seminars. Although this is one of the most well-documented cases, it is not likely isolated. At the time this article was prepared, settlement talks were under way in the gabapentin case. It is in this context that universities such as the University of California, San Francisco, medical reform groups, and student associations are attempting to redefine and disentangle marketing and science by considering strategies like ending free lunches and removing drug representatives from academic environments (Abassi & Smith, 2003; Moynihan, 2003b, 2003c).

Industry Ties to Research

There are widely acknowledged publication biases (e.g., Blumenthal et al., 1997; Callaham, Wears, Weber, Barton, & Young, 1998; Chalmers, 2000; Gilbody & Song, 2000; Lexchin, Bero, Djulbegovic, & Clark, 2003; Misakian & Bero, 1998; Rennie, 1999; *The Lancet*, 2001; Wise & Drury, 1996), often related to conflicts of interest (Campbell, Louis, & Blumenthal, 1998; Cech & Leonard, 2001; Chopra, 2003; DeAngelis et al., 2001; Fava, 2001; Lo, Wolf, & Berkeley, 2000), that favor pharmaceutical industry products (Als-Nielsen, Chen, Gluud, & Kjaergard, 2003; Bekelman et al., 2003). In fact, these biases have so eroded the credibility of the medical literature (Quick, 2001), including the psychiatry literature (e.g., Torrey, 2002), new proposals call for stringent accountability guidelines (e.g., Davidoff et al., 2001; Moses & Martin, 2001) that attempt to ensure researcher independence in study design, access to data, and right to publish. So far there has been minimal adherence by American medical schools to the standards embodied by these guidelines (Schulman et al., 2002).

It has been noted that data may be withheld or delayed if they reflect unfavorably on the sponsor's products (Blumenthal et al., 1997). For example, the publication of data (from a study sponsored by a nicotine patch manufacturer) showing the nicotine patch to be ineffective without behavioral counseling (Joseph & Antonuccio, 1999) was delayed for several years after favorable safety data from the same study were published (Joseph et al., 1996), not an isolated delay in the nicotine replacement literature (Vergano, 2001). In the antidepressant literature, an indirect estimate of publication bias is possible by examining the FDA antidepressant database for medications in the initial approval process when all data from every study must be submitted, whether the study is ultimately published or not. Several independent analyses of the FDA antidepressant database have shown that study medications had a significant advantage over inert placebo in less than half (as few as 43%) of randomized controlled trials (Khan, Khan, & Brown, 2002; Kirsch et al., 2002; Laughren, 2001). In the published literature, antidepressants are significantly more effective than inert placebos in about two thirds of studies (Thase, 1999). Such a pattern would be consistent with a failure to publish results from as many as 35% of antidepressant trials (mostly those showing no advantage to the antidepressant), which is somewhat higher than previous estimates of up to 20% (Gram, 1994). The discrepancy between the FDA database and the published literature may also reflect duplicate publication, selective publication, or selective reporting as has recently been found in SSRI studies submitted to the Swedish drug regulatory authority (Melander, Ahlqvist-Rastad, Jeijer, & Beermann, 2003). We are unaware of any database comparable with the FDA database requiring the mandatory reporting of all data on new psychosocial interventions that would offer the same glimpse at potential publication bias in the psychosocial literature. The problem of publication bias has led to proposals for an international registry of all initiated trials (Dickersin & Rennie, 2003).

Roughly one quarter of biomedical investigators have industry affiliations, and roughly two thirds of academic institutions hold equity in startup companies that sponsor research at the same institutions (Bekelman et al., 2003). About half of medical school faculty serving on human subjects review boards at academic medical centers have served as industry consultants (Campbell et al., 2003). One study (Krimsky, Rothenberg, Stott, & Kyle, 1998) examined research conducted by 1,000 Massachusetts scientists who were lead authors on articles published in major scientific and medical journals during 1992. The report concluded that more than a third of the articles had lead authors with a financial interest in the research (defined as investment in a related patent, on a scientific advisory board of a related biotechnology company, or serving as an officer or major shareholders in a commercially related firm), even without considering honoraria and consultancies. Another study found that the vast majority of authors of clinical practice guidelines had financial relationships (mostly undisclosed in the guidelines) with companies whose drugs were considered in the guidelines (Choudhry, Stelfox, & Detsky, 2002). Even leading bioethicists, whose objectivity is crucial to their role as ethical watchdogs, have developed financial conflicts in the form of consulting fees, contracts, honoraria, and salaries from the drug industry (Elliot, 2001). Conflicts of interest can occur at the level of the individual scientist or at the level of the academic institution itself, resulting in calls for divestiture and oversight by

an independent review panel (e.g., Johns, Barnes, & Florencio, 2003).

Some top journals require disclosure of financial conflicts of interest. For example, the *New England Journal of Medicine* revealed that 11 of the 12 authors of an article about the efficacy of nefazadone and behavior analytic therapy (Keller et al., 2000), had financial ties to Bristol Myers Squibb, the drug's manufacturer. In fact, the authors' ties with companies that make antidepressant medications were so extensive that the journal decided to summarize them on the *New England Journal of Medicine* Web site rather than take up journal space to detail them fully (Angell, 2000). The journal even had trouble finding psychiatric researchers who met their standard of independence from manufacturers of antidepressants to write an accompanying editorial (Angell, 2000). In fact, because the editors of the *New England Journal of Medicine* concluded that they cannot find enough experts without financial ties to the drug industry, the journal recently relaxed its strict policy against financial conflicts of interest by editorial and review authors (Drazen & Curfman, 2002), bringing it in line with most other top medical journals. This example gives a clear indication of just how pervasive the industry ties are. This is a challenging and important issue, because it has been long established that public relations firms for major drug companies are willing to pay professionals to write articles such as editorials designed to favor their clients' products (Brennan, 1994).

Industry support is shifting from academic medical centers to private research companies called *contract research organizations* and *site-management organizations*, both of which have grown tremendously in recent years (Bodenhemier, 2000). In 1991, 80% of industry money for clinical trials went to academic medical centers; in 1998, only 40% went to academia (Bodenheimer, 2000). Subtle biases in industry-funded research may influence the results that are produced (Bodenheimer, 2000; Safer, 2002). Drug company marketing departments may rule out funding studies that might reduce sales of their products. The companies may design studies likely to favor their products. A new medication may be tested on a healthier population than the population that will actually receive the drug. A new medication may be compared with an insufficient dose of an older one. Clinical trials may use surrogate end points or "markers" instead of clinical end points (e.g., measuring blood pressure as a surrogate for heart attacks or measuring suicidal ideation as a surrogate for suicidal behavior) or certain data analysis strategies (e.g., last observation carried forward instead of observed cases; see Kirsch et al., 2002) to get the most favorable outcome. In drug company studies, investigators may receive only portions of the data. In fact, industry sponsorship has been associated with restrictions on publication and data sharing (Bekelman et al., 2003). Drug companies have even been hiring advertising companies that are buying or investing in other companies that perform clinical trials of experimental drugs in an attempt to get "closer to the test tube" (Petersen, 2002b).

There are several other questionable practices that can bias the scientific literature toward products favored by the marketing departments of such companies (Bodenheimer, 2000). As in the gabapentin case, professional medical writers ("ghostwriters") are often paid by a drug company to write an article but not be named as an author. Sometimes a clinical investigator ("guest author") will appear as an author on a paper on which he or she did not contribute or analyze the original data. This practice is akin to a celebrity endorsement of a product or idea and might be more appropriately considered advertising than science. In one study, 19% of articles had guest authors who did not sufficiently contribute (i.e., did not help conceive the study, analyze the data, or contribute to the writing), and 11% had ghostwriters who were not named as authors (Flanagin et al., 1998). Healy (2001) estimated that up to 50% of review articles about new drugs in respectable Medline journals appear as supplements (i.e., are not adequately peer reviewed), are ghost written, or are written by company personnel. Such supplements and reprints of actual articles can be a rich source of revenue for scientific journals. Sometimes an apparently independent journal can have strong undisclosed editorial ties to industry that can influence content and emphasis of articles that appear in the journal (Letter to Academic Press, 2002). One study found that in journals with policies calling for disclosure of conflicts of interest, only 0.5% of authors made such disclosure (Krimsky & Rothenberg, 2001), most likely reflecting poor compliance with such policies. As yet, there are not enough data to evaluate the impact of ghost writing on the literature. However, because the ghost writers generally work for the marketing departments of the drug companies themselves, it is probable that the articles may selectively report data that favor the manufacturer's product (Healy & Catell, 2003).

Potential Methodological Biases

Recent methodological analyses of randomized controlled trials (RCTs) suggest that design flaws and reporting omissions are associated with biased estimates of treatment outcome (Moher, Schultz, & Altman, 2001). This has led to the publication of the CONSORT (Consolidated Standards of Reporting Trials) statement, developed by an international group of clinical trial specialists, statisticians, epidemiologists, and biomedical editors (Moher et al., 2001). The CONSORT statement, adopted by many leading medical journals, specifies design and reporting standards for selection criteria, intervention details, randomization, blinding procedures, and intent-to-treat analyses in RCTs.

Some of the methodological biases are subtle and woven into the fabric of study design. For example, in antidepressant research, it is common to use a *placebo washout* procedure prior to randomization (Antonuccio, Danton, DeNelsky, Greenberg, & Gordon, 1999). This procedure typically involves a 1- to 2-week single blind trial during which all prospective subjects are placed on placebo. Any patients who improve during this washout period are excluded from the study before randomization. Such a procedure may subtly favor the drug condition by,

among other things, eliminating placebo responders before the study even starts (Antonuccio et al., 2002).

The double blind in antidepressant studies is likely to be unintentionally penetrated owing to the pattern of side effects in the active and inactive drug conditions (Greenberg & Fisher, 1997; White, Kando, Park, Waternaux, & Brown, 1992). Research clinicians routinely educate themselves and patients about potential side effects as part of the standard informed consent process. Further, these studies tend to rely on measures by clinicians who often have a major allegiance or stake in the outcome, resulting in larger differences than with patient-rated measures (Greenberg, Bornstein, Greenberg, & Fisher, 1992; Moncrieff, 2001). Efforts to ensure the integrity of the blind tend to diminish estimates of drug efficacy. For example, a review of the Cochrane database of antidepressant studies using "active" placebos (i.e., placebos with side effects, making side effect differences more difficult to detect) found very small or nonsignificant outcome differences, suggesting that trials using inert placebos may overestimate drug effects (Moncrieff, Wessely, & Hardy, 2001).

Also, antidepressant studies do not adequately evaluate the efficacy of medication alone because most of these studies allow the prescription of a sedative (Kirsch et al., 2002; Walsh, Seidman, Sysko, & Gould, 2002). If patients in the drug condition are more likely to take sedatives or antidepressants with sedative properties, this could distort results because there are at least 6 points on the Hamilton Depression Rating Scale that favor medications with sedative properties (Moncrieff, 2001). Many of these studies provide concurrent supportive psychotherapy, giving a distorted picture of the effectiveness of these medications in a typical managed primary care environment wherein mental health support may be offered on a more limited basis or even not at all (Antonuccio et al., 2002).

Klein (2000) and Quitkin (1999) have argued that because antidepressants have been established as effective in the treatment of depression, trials that do not find a statistical advantage of antidepressants over placebo lack "assay sensitivity" (i.e., the ability to detect specific treatment effects). In other words, they argue that something is wrong with the sampling or methodology of such trials and the results should be discounted or discarded. If that logic had been applied to the recent meta-analysis of the FDA antidepressant database (Kirsch et al., 2002), more than half of the studies would have been discarded, a strategy that would have seriously distorted the overall results (Antonuccio et al., 2002; Otto & Nierenberg, 2002).

Media Coverage of Pharmaceutical Products

Media coverage of medications tends to include inadequate or incomplete information about risks, benefits, and costs (Steinbrook, 2000). Many newspaper articles and television reports also omit relevant information about the financial connection between the experts interviewed for the story and the drug companies sponsoring the research. One study of media stories about three commonly prescribed medications (prevastatin, alendronate, and aspirin) found that of 207 stories surveyed, only 47% mentioned potential adverse drug reactions and only 30% mentioned costs (Moynihan et al., 2000). Of the 170 stories citing an expert or a scientific study, 85 (50%) cited at least one expert with a financial tie to the drug manufacturer. However, these financial ties were disclosed in only 39% of those 85 stories. These findings are consistent with other recent data showing that news releases about new studies from the top medical journals typically fail to note industry funding when it is known to exist (Woloshin & Schwartz, 2002). It is important to note that these practices may be a result of sloppy journalism and not necessarily deception on the part of medical experts.

The Internet has become the new marketplace for many public relations firms, and in a strategy called *viral marketing*, there is even evidence of infiltration of professional electronic mailing lists in an effort to shape ideas favorable to the products of their corporate clients or to attack their perceived opponents (Monbiot, 2002). There are now many free literature review services available online to help sort through the vast amount of new biomedical information available through journals and the Internet. Many are underwritten by the pharmaceutical industry. As an example, the Internet site called Literature Review Service on Depression was underwritten by Solvay Pharmaceuticals, the maker of the antidepressant fluvoxamine. The Internet sites Depression Resource Center and Web MD Health are at least partially underwritten by Eli Lilly and Company, the maker of Prozac. Although valuable information may be provided, a question may be raised about whether such a service may offer a selective review of information relevant to the product of its sponsor or the sponsor's competitors.

Consumer Advocacy Organizations

Grass root organizations are ostensibly set up to advocate for patients with a particular medical condition. The public may erroneously perceive such organizations to always be independent of commercial interests (Herxheimer, 2003). However, even casual scrutiny shows that many of these organizations are typically heavily underwritten by the pharmaceutical industry and are designed, at least in part, to promote drug treatments (Koerner, 2002; Public Citizen, 2002; Templeton, 2002). A good example is the National Alliance for the Mentally Ill (NAMI). NAMI received at least $11.7 million from 1996 to mid-1999 in drug company support (Silverstein, 1999). The leading donor to NAMI during that time was Eli Lilly, the maker of Prozac, donating an estimated $2.87 million. The company even loaned NAMI a Lilly executive who worked out of NAMI headquarters. Another example would be the nonprofit organization called Children and Adults With Attention Deficit/Hyperactivity Disorder (CHADD). CHADD apparently received more than $500,000 in support during 2002 from various pharmaceutical companies, including Novartis, the makers of Ritalin, a common treatment for attention deficit disorder (O'Meara, 2003).

A Psychology Manifesto

Along with prescription privileges, psychology likely will experience increasing financial ties to the drug industry. The evidence overwhelmingly suggests that such financial connections create conflicts of interest that are a threat to the integrity of our science. The AMA, the American Nurses Association, the American College of Physicians, the American Academy of Pediatrics, the Accreditation Council on Continuing Medical Education (ACCME), and the American Psychiatric Association have recognized this threat and developed policies or guidelines designed to address conflicts of interest with regard to the pharmaceutical industry. An independent group of physicians has established a Web site (www.nofreelunch.org) to assist physicians who wish to free themselves of links to the industry. To their credit, even the Pharmaceutical Research and Manufacturers Association has developed a marketing code designed to regulate themselves. The ACCME, which sets and administers standards for CME providers, has recently drafted updated guidelines that, in addition to requiring disclosure, actually propose barring individuals who have a conflict with a commercial interest from planning or conducting educational sessions, unless the conflict can be resolved (Accreditation Council on Continuing Medical Education, 2002). The ACCME proposal has drawn the implied threat from the industry of litigation on First Amendment grounds (Relman, 2003). All of these codes have strengths and weaknesses that are not within the scope of this article. Now is the time to create guidelines that apply specifically to organized psychology prior to the development of any serious industry conflicts of interest. Former APA president Phil Zimbardo initiated, and the Board of Directors has established, a Board Task Force to address issues raised by external funding of psychological activities. Pharmaceutical funding is an obvious challenge the task force will have to address. In the end, a vote of the APA council or membership may be necessary to ratify recommendations of the task force.

One of the most important promises made by organized psychology in the pursuit of prescription privileges is that it will approach pharmacotherapy from the perspective of the scientist-practitioner (DeLeon & Wiggins, 1996; Levant & Sammons, 2003). To back up this promise, we propose a high standard of scientific integrity and a clear boundary between science and advertising. We propose the adoption of the following guidelines (summarized in Table 1) by professional psychology organizations and psychology training programs across the United States (Antonuccio & Danton, 2002, 2003). We sincerely hope that both proponents and opponents of psychology prescription privileges can come together in support of these aspirational guidelines. This represents a subset of the many conflict of interest issues that could be addressed. This is an evolving document, and we welcome input from all interested par-

Table 1
Recommended Guidelines for Professional Psychology Organizations and Psychology Training Programs

Issue	Safeguard
Conflicts of interest	Disclosure of all financial conflicts for public presentations, publications, computer mailing lists, interactions with human subjects, policymaking meetings, and journal reviewers should be required. Divestiture or exclusion due to financial conflicts may be appropriate under some circumstances.
Journal advertising	Drug industry advertising should be prohibited in scientific journals, but may be permitted in house publications.
Continuing education	Continuing education credits should generally be prohibited for training sponsored by drug companies but may be permitted if an independent opposing "counterdetailing" perspective is also presented.
Training programs	Contact between drug company representatives and students should be prohibited.
Gifts	All gifts, even nominal gifts, should be discouraged. Nominal gifts might be permissible if there is a direct patient benefit.
Clinical consultation	Drug company contact with patients or patient data should be prohibited. Clinical practice guidelines should be developed independently of commercial interests.
Research	Researchers should test and report double-blind status. There should be no placebo washout exclusion. Patient-rated measures should be required. Researchers should document concurrent treatments. Internet-accessible databases should be constructed. Independent data access should be guaranteed for all participating researchers. A writing contribution should be required for authorship.

ties about any of these or related ideas. Though we expect there will be debate about the scope, quantity, and quality of these recommendations, we also hope this proposal strikes a balance and achieves something fair, reasonable, and practical.

Although these guidelines specifically target financial conflicts with the drug industry, they could be generalized to address any commercial conflict of interest. The guidelines proposed here offer one way to approach this problem, though they are certainly not the only possible solution. It is hoped that others will modify and improve on them while addressing the related legal issues.

Conflicts of Interest

Full public disclosure of all financial conflicts of interest should be required in any psychology-sponsored presentation (including all publicity and handouts), publication, computer mailing list, interaction with a human research subject (as recommended by the Association of American Medical Colleges), or policymaking public meeting (similar to AMA requirement). All journal reviewers should also be required to disclose such conflicts and should be excluded from the peer review of any article that evaluates products related to any stated financial conflicts. There may be other situations in which disclosure would not be sufficient and exclusion or divestiture might be more appropriate (e.g., a financial conflict of interest involving an APA officer).

Advantages. Full disclosure would enhance the creditability of the information provided and allow consumers of any information on any topic the opportunity to consider the source. Another advantage of such a strategy would be that it could apply universally to any financial conflict of interest, not just drug industry conflicts. The policy could enhance the credibility of the peer-review process.

Disadvantages. Some will certainly see this as unwieldy. It would take up extra journal space to publish the information. Additional training will be required to educate psychologists about when and where such disclosures are required.

Practicality. This is already being done at the top journals. Authors need only fill out a single-page form. This policy can and should be extended to reviewers as well. It is likely that requiring disclosure of conflicts of interest for participation on computer mailing lists or public meetings would be seen as too intrusive, yet the same single-page disclosure form could easily be used for this purpose. The information could be displayed on a publicly accessible Web page and serve as one disclosure source for all purposes.

Journal Advertising

No pharmaceutical company advertising should be permitted in scientific psychology journals because of the inherent conflict of interest. Drug company advertising could be permitted in the house organ (e.g., the *APA Monitor*).

Advantages. Such a policy would free editors from the concern that publishing or not publishing certain articles will impact advertising revenue. It would enhance the credibility of APA journals as independent unbiased arbiters of the studies they publish. One could even envision a future in which consumers of information about psychotropic medications would choose a psychology journal when they want access to the highest quality studies.

Disadvantages. This practice would be costly in terms of lost potential advertising revenue. In some cases, it may be difficult to specify when and where such prohibitions would apply. Some may argue that such a policy would represent an inappropriate restraint of trade.

Practicality. This policy could be implemented easily now, but once journals start accepting pharmaceutical advertising, it will likely be very difficult to step backward. Legal counsel would probably have to sort out the restraint of trade issues.

Continuing Education

No continuing education credit should be permitted for presentations sponsored by pharmaceutical companies because the primary goal of these presentations is advertising and not education (Relman, 2003). Continuing education credit might be acceptable for such a presentation if equal time is given to an independent opposing presentation on the same topic at the same venue.

Advantages. We believe this is an essential prohibition that will help prevent the kind of advertising masquerading as education seen at some conventions. When drug-company-sponsored educational talks are given, there will be an opportunity for an alternative perspective. This could actually increase the supply of scientific debate at conferences and foster a lively exchange of ideas.

Disadvantages. Some will argue that there is educational value in drug-company-sponsored presentations. Removing continuing education credit will reduce the incentive and opportunity to take advantage of this sort of education. It may put psychologists at a disadvantage in earning continuing education units.

Practicality. Even though the APA may choose to adopt such a policy, there would be nothing to require state psychology boards to adopt a similar policy or to stop APA's competitors (e.g., state organizations or the American Psychological Society) from offering credits. The hope would be that state boards across the country would see the value of such a policy and begin to adopt it on a widespread basis. The APA could create a special fund for 50% of all drug company money coming into the organization designated for "counterdetailing" presentations to compete with any drug-company-sponsored presentations.

Training Programs

No involvement, contact, or financial support of any kind (e.g., no free lunches, course credits, or text purchasing programs) by pharmaceutical companies or their representatives or paid consultants in any undergraduate, graduate, or internship training programs in psychology.

Advantages. Students need access to data, not advertising. Students are often poor and potentially exploitable by companies seeking to influence them with gifts of

significant monetary value. This policy would help raise the awareness and prevent financial conflicts of interest in the developing professional.

Disadvantages. This would be difficult to track and enforce. This policy would prevent some financially strapped students from taking advantage of this source of funding.

Practicality. The National Collegiate Athletic Association has developed a policy for amateur athletes to shield them from corporate influences that seems to work reasonably well. A similar policy for psychology students would help protect them from inappropriate influences while educating them about the importance of professional boundaries.

Gifts

As much as possible, practitioners need access to unbiased scientific data, not advertising, and patients need to know that their health care providers are unbiased sources of health information. All gifts, even nominal gifts (e.g., pens and post-it notes) should be actively discouraged because of the inherent conflict of interest. No gifts for any psychologist valued at more than a nominal amount (e.g., $25) from any pharmaceutical company or its representative should be permitted. Even gifts of nominal value should generally be of direct benefit to patients (e.g., a patient assessment packet rather than theatre tickets).

Advantages. Psychologists will be viewed as more independent from the drug industry than other prescribers. This may influence consumers to seek psychology prescribers and to see them as a primary source of information about medications.

Disadvantages. Gifts may be almost impossible to define, track, or sanction. Many professionals view gifts as inconsequential perks associated with prescribing and will consider such a prohibition unwieldy, unnecessary, and disappointing.

Practicality. Although this policy could certainly be implemented at APA-sponsored functions, this is perhaps the most idealistic and most challenging of all the proposed guidelines to implement. Although we would like to see no gifts of any kind permitted as has been proposed by some (e.g., Dana & Loewenstein, 2003), we fear that such a strict guideline would be impossible to monitor and even harder to enforce. There would be nothing to stop such activities outside of the APA. Also, it would beg the question about what sort of punishment, if any, would be appropriate for someone who takes a gift. A specific guideline could be written into the APA ethical code, but this would take time and it would be challenging to reach agreement. The most practical strategy initially may be to try to shape a culture within psychology in which all gifts are discouraged, similar to that promoted by the American Medical Student Association (2002)

Clinical Consultation

Pharmaceutical companies and their representatives should be excluded from involvement in clinical activities, including treatment planning, consultation, or the provision of patient information in clinical venues. Organized psychology should not offer, under any circumstances, industry access to psychology identifying or prescribing data. Relatedly, clinical practice guidelines should be developed by scientist-practitioners who do not have industry financial ties.

Advantages. This policy will ensure that people who are not properly trained and are not part of the treatment team will have no access to patient data or input into treatment decisions.

Disadvantages. Sometimes a company representative may have some information that would be helpful to the treatment of a particular patient.

Practicality. This would be fairly simple to implement but perhaps somewhat more difficult to monitor.

Research Safeguards

At a minimum, reports of all drug treatment RCTs should conform to the CONSORT guidelines (Moher et al., 2001). The following requirements are designed to complement those standards.

1. All studies claiming double-blind status should test and report whether the blind was penetrated to pass peer review for a psychology journal (Piasecki, Antonuccio, Steinagel, & Kohlenberg, 2002). This could be done by asking research subjects and clinicians early in the study to attempt to identify the actual treatment condition while analyzing the impact of accurate identification on outcome.

Advantages. Psychology journals would offer a more stringent methodological standard than other journals. As a result, our journals could become a more respected source of information on true drug efficacy. Additionally, the prevalence and influence of blind penetration would become known.

Disadvantages. It would require extra effort on the part of researchers who would be expected to ask subjects and clinician raters to guess the actual treatment condition.

Practicality. This could very easily be accomplished without modifying existing designs or adding significant cost. A simple blindness assessment and protection checklist has even been established to help facilitate this process (Even, Siobud-Dorocant & Dardennes, 2000). A few studies are starting to report assessment of blind integrity in mainstream journals.

2. No patients should be excluded from any study on the basis of improvement during placebo washout (see Antonuccio et al., 2002). In clinical practice, there is no placebo washout, and these patients would likely get antidepressants. It is important to understand what happens to them when they do.

Advantages. The placebo washout procedures very likely penalize the placebo condition in placebo-controlled studies. We are suggesting that patients could still participate in the placebo washout and participate in the study even if they improve. This would permit separate analyses with and without "placebo responders" and help solve the mystery about how placebo washout procedures actually affect the outcome of these studies.

Disadvantages. This would require extra subjects, extra analyses, and extra time. It might be argued that including patients in an antidepressant study when they are no longer depressed after the washout procedure does not make sense or is unethical. It is clear such patients did meet criteria at the beginning of the study and are at least at risk for relapse. These patients still stand to benefit from the study.

Practicality. Placebo washout responders could be included in the study or the placebo washout procedure could simply be eliminated entirely. Researchers might balk at the extra cost of including washout responders. The FDA would have to be consulted about the acceptability of any changes in washout procedures.

3. All studies should include patient-rated self-report measures in addition to clinician-rated measures (Antonuccio et al., 2002).

Advantages. This policy will reduce the possibility of clinician bias affecting estimates of treatment effects. From our perspective, it would fulfill an ethical obligation to give patients an opportunity to directly self-report their outcome experiences.

Disadvantages. Patients are not always the best sources of information about their conditions. This guideline would also result in a slight increase in assessment costs.

Practicality. This could be implemented fairly easily because patient self-report measures are often used even though they may not be reported. Data from both clinicians and patients could provide a database that will allow researchers the opportunity to compare and contrast these sources of data.

4. Use of any concurrent medication or concurrent treatment of any kind should be well specified in the analysis and abstract of all RCTs.

Advantages. Consumers will be informed about the possible contribution of concurrent treatments.

Disadvantages. Minimal.

Practicality. This guideline could be implemented fairly easily just by reporting data that will likely have already been collected.

5. All raw data for any study published in a psychology journal should be made available on a publicly accessible Web site, allowing for independent review of the data and data analysis (Bekelman et al., 2003; Klein et al., 2002). The data would be stripped of any patient identifying information. Perhaps APA could also support proposals for an international registry of all initiated clinical trials by requiring prior registration in the Current Controlled Trials Meta-Register to qualify for publication (Dickersin & Rennie, 2003).

Advantages. Although psychologists already agree to share their data with other researchers as a condition of publication at some journals, this policy would permit independent verification of prior data analyses by anyone, including members of the public, who often contribute to the data as volunteer human subjects and deserve access. This could also reduce publication bias because researchers without vested interests could have access to all of the data. This could also give reviewers the same kind of direct access to data that the FDA scientists now enjoy, improving the quality of peer review.

Disadvantages. Issues of confidentiality would have to be addressed. Extra effort would have to be made to ensure that no identifying information inadvertently became public. Professional rivals might use this as an opportunity to try to discredit each other's research. Drug companies could afford to hire specialists to try to discredit data that might be damaging to their products. However, consumers and scientists could benefit in the long run from the extra scrutiny.

Practicality. This would be difficult to implement. Some scientists would be reluctant to make their data accessible out of concern that others might steal their ideas. The potential benefits would seem to outweigh the potential risks, especially because most top journals already require access to data if requested.

6. All authors should offer signed assurance that they had independent access to all data and contributed to the writing of any manuscript for any study published in a psychology journal. Research contracts between psychologists and industry should be made available during the journal review process and specifically exclude industry control of publication or data ownership (Schulman et al., 2002) for articles to be published in a psychology journal.

Advantages. This policy would reduce (but not eliminate) the risk of unfavorable outcome data being placed in a file drawer, a practice that may violate the Belmont principle of beneficence. It would help ensure that the public will benefit from research involving human subjects.

Disadvantages. Researcher autonomy would be difficult to independently verify. Many drug companies may decline to include psychologists in conducting their research if other professionals are willing to sign a contract without such limitation.

Practicality. Assuring independent data access could be as easy as having authors sign a declaration of some sort. This is already being done at some top medical journals. More difficult would be requiring the submission of a copy of a research contract, something many might be reluctant to do. An agreement among university administrators for a standardized contract would probably have to be developed at a national level for this to work.

Conclusions

It is entirely reasonable for a business such as the pharmaceutical industry to market its products as effectively as possible. However, business and science make strange bedfellows and address fundamentally different goals. A primary goal of business is to influence sales and turn a profit. A primary goal of science is to produce objective data. It is not difficult to see how these primary goals could come into conflict. A profession such as psychology, priding itself on the highest standards of scientific methodology in the study of human behavior, has an obligation to separate science and industry influence if it wishes to maintain its credibility with the public. In other words, psychology has to be

willing to publish data that are in the public interest, even if they conflict with the corporate interests. The infrastructure must be set up now to create a meaningful boundary between the drug industry and psychological science, before such safeguards become impractical. For organizations already dependent on pharmaceutical largesse, it may be difficult to retroactively build in such safeguards. For the APA, there may still be time to debate these issues and develop standards that sustain a clear boundary between marketing and science. Perhaps other professional organizations will some day be able to look to the APA for a model of effective guidelines. Some will view the proposed guidelines here as too draconian in nature, whereas others will conclude they do not go far enough. In any case, our hope is to help provide an impetus for addressing these important issues.

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