

Running Head: Drug Promotion & Prescribing Trends

Peter J. O'Donnell, M.A., NCC, NBCDCH, BCIAC, CSP

Drug Promotion & Prescribing Trends

Northcentral University

November 2007

Prescription use is increasing for individuals of all ages. Nearly half of all Americans take at least one prescription medication (USDH&HS, 2004). The most frequently dispensed prescription in 2005 was Prozac, and Lexapro was second (RxList, 2007). Between: 1988-1994 and 1999-2000, adults using antidepressants tripled, with ten percent of women and four percent of men taking antidepressants, of these adults approximately three times as many were whites as compared to African Americans or Hispanics (USDH&HS, 2004). For children and adolescents antidepressants are prescribed equally to both boys and girls (USDH&HS, 2004). For children and adolescents in both inpatient and outpatient settings, there is a significant occurrence of medication use (primarily SSRIs and newer antidepressants), including polypharmacy, which is outpacing the research on medication efficacy, safety, short and long term consequences including mortality, quality of life, etc. (Dean et al., 2006).

Governmental programs are the predominant payers for behavioral health care in the United States, accounting for two thirds of funding (The American Hospital Association [AHA], 2007). Spending on prescription drugs is the fastest growing component of the health care budget (Rosenthal et al., 2002). Despite prescription prices being less expensive in Canada, as compared to the United States, there has been a significant increase in expenditure for psychotropic medication in Canada (Dewa & Goering, 2001). In Canada between 1992 and 1998 there was a 216 percent increase in psychotropic expenditures attributable with 61% on antidepressants, 33% on antipsychotics and less than 7% on anxiolytics (Dewa & Goering, 2001). The increased cost was primarily due to the higher prices of the newer agents. Therefore even when governmental lower pricing exists this does not fully protect the healthcare system from increased expenditures. This is a global trend with psychotropic prescribing trends for children rising

significantly in seven out of nine countries from 2000 to 2002 with the United Kingdom showing the greatest increase (68%) (Wong, Murray, Camilleri-Novak & Stephens, 2004).

Nowhere has prescribing increased than with the general practitioner or family physician. Glenmullen (2001) indicated that pharmaceutical companies intentionally established psychotropic initial dosages at higher levels in order to by pass the need for psychiatric providers to titrate the dosage upward. The pharmaceutical companies could market directly to the primary care physician. Primary care physicians (PCP) may be the default providers for most mental health treatment. Geddes, Butler & Hatcher (2002) indicate that there was no reliable direct evidence that any one type of treatment (drug or non-drug) is superior to another in improving the symptoms of depression. If psychotherapy can be prescribed as an equally if not superior treatment with no side effects and with decreased relapse rates, then why is it not recommended or prescribed more (Glenmullen, 2001; Antonuccio, Burns & Danton, 2002)?

Mortimer, Shepard, Rymer & Burrow (2005) studied primary care prescribing and treatment with antipsychotic medications in the United Kingdom. The audit revealed that prescribing was not rare and several issues such as lack of adherence to guidelines, poor diagnosis, documentation issues, polypharmacy, use for non approved or contraindicated conditions, and significant motoric side effects where observed. It was felt that prescribing of psychotropic medications was for social and personal problems rather than for medical illness. Patients were placed on irrational combinations of medications at inappropriate dosages for extended periods of time without a clear basis for their prescription. Therefore physicians where providing a medical solution where there was none indicated. An excessive reliance on psychopharmacological treatments was observed.

In understanding the decision making of PCPs Prosser, Almond & Walley (2003) explored what influences primary care physicians' decisions for prescribing. Prescribing new medications was not simply related to their examination but was determined to be to the mode of exposure to pharmaceutical information as well as social influences. The pharmaceutical representative wields much influence. Patients also request medications. The PCP did not actively seek information but were mostly reactive and passive recipients of new drug information. Dobson (2003) found that PCPs report that 92% saw pharmaceutical representatives and 70% regarded them as expedient means of obtaining drug information and considered the information to be accurate.

Influences on the decision making process have been found in a variety of specialties and the pressure and influence comes from many directions. There is social and psychological pressure for physicians to prescribe the newest, latest and often most expensive medication, even when there may be appropriate and effective and cheaper alternatives. Additional pressure comes from pharmaceutical companies' free gifts, free continuing education, trips to conferences, meals, and payment for various services. Miller (2007) reports that in 2004 pharmaceutical companies spent an average of \$10,000 per practicing American physician on these various amenities. Drug representatives give the average physician \$21,000 in free drug samples. The drug representative strategies exceeded \$23.7 billion in 2004. This represents a two fold increase in a period of just over five years.

Pharmaceutical companies direct to consumer advertising has significantly expanded since the federal Food and Drug Administration (FDA) issued guidelines in 1997. The pharmaceutical companies have targeted five therapeutic classes of drugs to directly advertise to consumers. This

advertising amounted to \$2.5 billion between 1996 and 2000, but this only accounts for fifteen percent of the money that is spent on drug promotion (Rosenthal, 2002). In 2001 \$19 billion was spent in advertising alone (Antonuccio, Burns & Danton, 2002). Marketing strategies beyond what has already been mentioned also consists of paying professionals to speak at meetings or presentations, funding research projects (with the industry underwriting @70% of all clinical trials in the U.S.A.), pulling studies that do not support their agenda prior to publication, paying journalist to cover their products, preparing information for presentations and media releases, funding advocacy and public interest groups (Antonuccio, Burns & Danton, 2002).

The pharmaceutical industry is one of America's most profitable industries and a third of pharmaceutical sales occur within the United States. Its influence on the American economy is obvious, but its influence on the political system may be less obvious. The pharmaceutical industry has one of the largest lobbying and campaign contribution systems. Given the immensity of their monetary influence their influence trickles throughout various venues from federal regulatory agencies, professional organizations, professional publications, researchers, academic institutions, consumer advocacy agencies (Antonuccio, Burns & Danton, 2002; Kirsch et al., 2002; Moncreiff, 2004; Healy, 2005).

Smith (2005) reports that the influence of the pharmaceutical industry has risen significantly such that Britain's House of Commons Health Committee had recommended fundamental changes to impact the realignment of relationships between pharmaceutical industry, government, regulators, physicians, health services and patients. The committee's report indicated, "We need an industry which is led by the values of its scientists not those of its marketing force." Interest in examining the industry derived from the activities of the industry as

well as the increasing medicalisation of societal issues and problems. The pervasive influence on every aspect of health care creates conflict of interest that is self serving rather than in the public's interest. Given that the industry funds the clinical trials upon which clinicians' base their evidence for treatment and that the evidence upon which decisions are made is biased. The flow of information is tainted. Professional evidenced based practices are not based on accurate comprehensive information and the experts may be less than objective as relationships and influences with pharmaceutical companies are pervasive. Additionally the industries influence on educating physicians and the public only serves to further the interest of the industry. Smith (2005) reports, "The consequences of all these relationships, says the committee, are bad decisions on the regulation and prescription of drugs, over-reliance on drugs rather than on other interventions (such as dietary change, exercise, or counseling), and the 'medicalisation' of life's problems, including baldness, shyness, unhappiness, grief and sexual difficulties."The committee recommended a variety of suggestions to provide more transparency to the conflicts and difficulties that are developing. Some of the suggestions include more independent oversight of clinical trails, stricter controls on marketing practices and recommendations that professional and patient organizations should make public any relationships with the industry.

With the advent of psychologists prescribing the ethical issues that physicians face will be a new challenge (Behnke, 2004; Reist & VandeCreek, 2004). The scientist practitioner model of psychologists should help train clinicians to more objectively review the data. The manipulation of data by the pharmaceutical companies has been documented although not made publically aware (Antonuccio, Burns & Danton, 2002; Kirsch et al., 2002; Moncreiff, 2004; Healy, 2005). Analysis of confidence intervals, p values, sample size, measuring instruments, what questions are asked, attrition rates, lack of standard deviations being reported, drug placebo differences,

use of active placebos, drug wash outs and exclusion of non-responders, lack of balancing placebo designs are some of the inherent problems that have not been thoroughly reported or examined. By not doing trials with a large number of participants the statistical power of the study will result in not finding the problem as statistically significant at the 0.05 level and erroneously concluding that the problem is not real and consequently overestimating the effect of the drug (Healy, 2005). The more the drug is used with the general population the greater the number of difficulties present (such as suicidal ideation, sexual side effects, etc.) indicating that indeed the problem is real. The efficacy of antidepressants and the significant side effects have been overshadowed by this and the public hoodwinked. Teasing out placebo effects is problematic, because if individuals will show improvement with contact from a profession is it the interaction or the medication? If most problems naturally improve in a month, then is it the natural progression of the process or is it attributable to the drug? Unfortunately it has only been through legal actions that more comprehensive data has been revealed in order to be more accurately assessed to obtain the whole truth [such as Paxil® Pediatric Settlement Web site: Hoorman et al. v. SmithKline Beecham Corp., (2007)] (Dörken, 1990; Glenmullen, 2001; Breggin, 2003/2004; Moncreiff, 2004; Healy, 2005; PsychRights.org, 2007; Public Citizen, 2007).

Increased prescriptions and the expansion of psychopharmacological treatment have occurred simultaneously as many factors have converged. Individuals seek a quick solution not requiring effort or self examination, the consumer mentality has extended to medical treatment and medications. Along with this psychiatry has moved away from its roots and has sought the validation of their profession by exploring increasingly neuroanatomical and psychopharmacological explanations rather than embracing a biopsychosocial integrative

perspective. Psychiatric treatment is increasingly more biologically explained and treatment reduced to prescribing. This trend has served to move away from counseling or psychotherapeutic interventions. Inpatient hospital units in this region have stopped employing psychologists and many have reduced ancillary services such as recreational therapy. The fertile ground of the confluence of the pharmaceutical industry with vague diagnostic and treatment regimens of psychiatry has extended into social problems. This reductionist and simplistic view of complex social and societal problems elude the superficial and profit focused. Off label uses continue to increase and are applied to a variety of issues such as characterological dysfunction, substance abuse, shyness, grief, etc. A drug company may not be able to claim that their medication is useful for problems for which it was not approved, but they can hire experts to make claims and recommendations that they cannot. Recently there was an attempt to make excessive video game playing a mental disorder. Pharmaceutical companies can bypass claims and oversight by federal regulators by funding education and patient advocacy groups perpetuating myths or biased claims such as “chemical imbalances”.

With the advent of increased pharmacological interventions come increased issues. These issues include polypharmacy and drug interaction. Drug related adverse effects are one of the leading causes of death (Moncreiff, 2004). Increasingly significant effects are revealed after a medication has been on the market for some time. The cardiotoxic effects of some of the older antipsychotics such as mellaril (droperidol & thioridazine) which is now removed from the market only after many years of being used. What about the long term consequences of the newer antipsychotics impacting metabolic and cardiac functioning? Other medications can quickly come to mind such as Vioxx® (rofecoxib) a Cox-2 inhibitor. Now cold medicines are

contraindicated for use with children. Is America finally examining the science and seeking to protect the public?

Glenmullen (2001) sees a historical pattern repeating itself that he describes as the 10-20-30 year pattern. The initial advent of a drug is marketed aggressively, wondrous claims are made, and many champion its cause, use spreads all within the first ten years. Then problems begin to appear. Its use is defended and due to no systematized means of monitoring long term consequences of drugs, slowly data trickles in by twenty years. At twenty years enough data has been accumulated that concerns are being voiced. It usually takes another ten years before professional organizations; regulatory boards engage fully to take action to curtail the prescribing of the drug. At this point the patent is expired and the pharmaceutical company has made significant revenue and come forth with a newer improved version of the miracle elixir. Hence the cycle continues.

References

- American Hospital Association. (2007, February). Research and trends: TrendWatch: Community hospitals: Addressing behavioral health care needs. Retrieved September 20, 2007, from <http://www.aha.org/aha/trendwatch/2007/twfeb2007behavhealth.pdf>
- Antonuccio, D., Burns, D., Danton, W. (2002, July). Antidepressants: A triumph of marketing over science? *Prevention & Treatment* 5(1).
- Behnke, S. (2004). Introduction to the special section. *Ethics & Behavior. Special Issue: Ethics and behavior*, 14(2), 103-104. Retrieved September 8, 2007, from PsycINFO database.
- Breggin, P. R. (2003/2004). Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis. *International Journal of Risk & Safety in Medicine*, (16), 31-49.
- Cole, S. O. (2002). Pros & cons: Prescription privileges for psychologists and its forensic impact. *The Forensic Examiner*, 11(7-8), 34-41. Retrieved September 8, 2007, from PsycINFO database.
- Comer, R. J. (2004). *Abnormal psychology* (5th ed.). New York, NY: Worth Publishers.
- Dean, A. J., McDermott, B. M., & Marshall, R. T., (2006). Psychotropic medication utilization in a child and adolescent mental health service, *Journal of child and adolescent psychopharmacology*, (16), 3, 273-285.

- Dewa, C. S. & Goering, P. (2001). Lessons learned from trends in psychotropic drug expenditure in a Canadian province. *Psychiatric Services, 52*(9), 1245-1247.
- Dobson, R. (2003). Pharmaceutical industry is main influence in GP prescribing. *British Medical Journal, 326*(7384), 301.
- Dörken, H. (1990). Malpractice claims experience of psychologists: Policy issues, cost comparison with psychiatrists, and prescription privilege implications. *Professional Psychology: Research and Practice, 21*(2) 150-152.
- Geddes, J., Butler, R. & Hatches, S. (2002). Depressive disorders. *Clinical evidence: Mental health, BMJ, 11*, 114-137.
- Glenmullen, J. (2001). *Prozac Backlash: Overcoming the dangers of Prozac, Zoloft, Paxil and other antidepressants with safe, effective alternatives*. New York, NY: Simon and Schuster.
- Healy, D. (2005, October). Psychopharmacology in turmoil: An ethical or scientific crisis? *Alliance for Human Research Protection*. Retrieved November 11, 2007, from <http://www.ahrp.org/COI/HealyColumbia1005/index.php>
- Kirsch, I., Moore, T., Scoboria, A., Nicholls, S. (2002). The emperor's new drugs: An analysis of antidepressant medication data submitted to the U.S. Food and Drug Administration. *Prevention & Treatment, 5*(23).
- Kirsch, I., Scoboria, A., & Moore, T. J. (2002, July). Antidepressants and placebos: Secrets, revelations, and unanswered questions. *Prevention & Treatment, 5*(1).

Miller, J. D. (2007). Study affirming pharma's influence on physicians. *Journal of the National Cancer Institute*, 99(15), 1148-1150.

Moncreiff, J. (2004). Healthy skepticism: Countering misleading drug promotion: Is psychiatry for sale? *Healthy Skepticism International News*, 22, 1-3. Retrieved November 11, 2007, from <http://www.healthyskepticism.org/news/issue.php?id=1>

Moore, B. A., & McGrath, R. E. (2007). How prescriptive authority for psychologists would help service members in Iraq. *Professional Psychology: Research and Practice Professional Psychology*, 38(2), 191-195. Retrieved September 8, 2007, from PsycARTICLES database.

Mortimer, A. M., Shepherd, C. J., Rymer, M. & Burrow, A. (2005). Primary care use of antipsychotic drugs: An audit and intervention study. *Annals of General Psychiatry*, 4(18), 1-8.

National Institute of Mental Health. (2006). *The numbers count: Mental disorders in America*. Retrieved September 9, 2007, from <http://www.nimh.nih.gov/publicat/numbers.cfm#Intro>.

Paxil® Pediatric Settlement Web site: Hoorman et al. v. SmithKline Beecham Corp. (2007). Retrieved October 13, 2007 from <http://www.paxilpediatricsettlement.com>

Posser, H., Almond, S. & Walley, T. (2003). Clinical research: Influence on GPs' decision to prescribe new drugs- the importance of who says what. *Family Practice*, 20(1), 61-68.

Preston, J. & Johnson, J. (2007). *Clinical psychopharmacology made ridiculously simple* (5th ed.). Miami, FL: MedMaster.

PsychRights.org (2007). Law Project for Psychiatric Rights. Retrieved November 11, 2007, from <http://psychrights.org/index.htm>

Public Citizen. (2007). Paxil Payback. Retrieved October 13, 2007, from <http://www.paxilpayback.org>

Reist, D., & VandeCreek, L. (2004). The pharmaceutical industry's use of gifts and education events to influence prescription practices: ethical dilemmas and implications for psychologists. *Professional Psychology: Research and Practice*, 35(4), 329-335.

Rosenthal, M. B., Berndt, E. R., Donohue, J. M., Frank, R. G. & Epstein, A. M. (2002). Promotion of prescription drugs to consumers. *New England Journal of Medicine*, 346(7), 498-505.

Rx List. (2007). *Top 300 prescriptions for 2005: By number of US prescriptions dispensed*. Retrieved September 9, 2007, from <http://www.rxlist.com/script/main/art.asp?articlekey=79509>

Smith, R. (2005). Curbing the influence of the drug industry: A British view. *Public Library of Science Medicine*, 2(9), e241. Retrieved November 11, 2007, from <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020241>

The National Working Group on Evidence Based Healthcare. (2007). Rebalancing evidence-based healthcare: The central role of patients and consumers. Retrieved November 11, 2007, from <http://www.evidencebasedhealthcare.org/>

United States Department of Health and Human Services. (1999). Mental Health: A Report of the Surgeon General—Executive Summary. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health. Retrieved November 10, 2007, from <http://www.surgeongeneral.gov/library/mentalhealth/home.html>

United States Department of Health and Human Services. (2001). Mental Health: Culture, Race, and Ethnicity, A Supplement to Mental Health: A Report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health. Retrieved November 10, 2007, from <http://www.surgeongeneral.gov/library/reports.htm>

United States Department of Health and Human Services, Center for Disease Control and Prevention, National Center for Health Statistics. (2004). *Almost Half of Americans Use at Least One Prescription Drug Annual Report on Nation's Health Shows*. Retrieved September 20, 2007, from <http://www.cdc.gov/nchs/pressroom/04news/hus04.htm>.

Wong, I. C. K., Murray, M. L., Camilleri-Novak, D. & Stephens, P. (2004). Increased prescribing trends of paediatric psychotropic medication. *Archive of Disease in Childhood*, 89, 1131-1132.