Children and Psychotropic Medication: What Role Should Advocacy Counseling Play?

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There are currently millions of children with mental and emotional symptoms who are being treated with psychotropic medication. The authors critique such treatment and suggest that advocacy counseling is a responsible approach to balance the power of both the pharmaceutical companies and the medical model in the mental health arena.

During the last 5 years, there has been a growing emphasis on advocacy in the counseling profession summarized as advocacy counseling by Kiselica and Robinson (2001). During the last 10 years, there has also been an enormous increase in the use of psychotropic medications, but there is still a paucity of research on the effects of these agents on children (Riddle, Labellarte, & Walkup, 1998; Weller, 1999; Werry, 1999; Wozniak, Biederman, Spencer, & Wilens, 1997). The medical model in Western society, with its focus on alleviating symptoms using psychotropic medications, continues to dominate as the paradigm for understanding mental and emotional disorders (Gabbard, 2001) despite increasing evidence of its limitations (Fisher & Greenberg, 1997). In addition, pharmaceutical companies continue to hold a great deal of economic power in a society that overvalues the medical model (Healy, 1997). The convergence of increasing psychotropic medication prescriptions for children, the dominance of the medical model, and the economic power wielded by pharmaceutical companies are all issues that could be appropriately addressed by advocacy counseling.

Advocacy counseling includes social action and social justice approaches to counseling and works to "increase a client's sense of personal power and to foster sociopolitical changes that reflect greater responsiveness to the client's personal needs" (Kiselica & Robinson, 2001, p. 387). In terms of children being prescribed psychotropic medication, advocacy counseling can help counselors to critically examine the shortcomings of the medical model and how counseling interventions can address the same symptoms that the medical model claims to treat. In addition, children and their families face difficult treatment choices when psychotropic medication is recommended and may have limited information with which to make those choices. Advocacy counseling can help these clients and their families increase their sense of personal power as well as address sociopolitical dynamics that may increase the treatment choices available to them. In this article, we outline a brief history of pediatric psychopharmacology, the current prescribing trends and power issues, and then recommend related areas for advocacy counseling practice. Although this article focuses on the medicating of children for mental and emotional disorders, it should be noted that the effectiveness of psychotropic medications for adults is also being questioned in the field (Fisher & Greenberg, 1997).

A BRIEF HISTORY

Werry (1999) noted that the use of drugs to control children's behavior is an old practice. From the use of brandy to soothe infants to other sedating drugs like barbiturates and opiates, children have been administered psychotropic agents as long as such agents have existed; however, research on such practices dates only to the early 20th century. Werry has asserted that research in psychopharmacology for children began with the publication of Bradley's (1937) article on how amphetamines seemed to calm overactive children. In the same period, studies were conducted on the effects of antihistamines on children (Connors, 1972). Outside of these two areas, studies examining how antipsychotic medications affected children with mental retardation were the only primary contributions to child psychopharmacology until very recently (Werry, 1999).

Bradley's work (see Gabbard, 2001) reemerged in the 1960s after psychiatry began moving away from a psychodynamic model toward the biological model dominant today. The decade of the 1960s saw increasing use of double-blind, placebo-controlled trials that have become the norm in evaluating medications. Using these methods, medication effects on learning and academic performance began to be evaluated, but the research focused primarily on stimulant medications that were being used to treat minimal brain dysfunction (MBD). MBD, a label now discarded, was a diagnostic precursor to today's attention-deficit/hyperactivity disorder (ADHD).

Currently, there are more trials occurring on children with a growing number of medications including newer antide-

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pressants (Emslie, Walkup, Pliszka, & Ernst, 1999) and new generation antipsychotics (Findling et al., 2000). Despite this, the debate over the effectiveness of medications versus counseling continues (Fisher & Greenberg, 1997). Adding to the confusion, medications that were being used "off-label" for children 30 years ago continue to be used in this manner because many studies investigating their efficacy with children do not show significant results (Gadow, 1997). In the United States, drugs may be prescribed either *on-label* or *off-label*. On-label means that the drug has specific Federal Drug Administration (FDA) approval for the disorder it is prescribed to treat. Off-label means that the prescribing professional believes, based on clinical experience and case studies, that the drug will help the condition she or he is prescribing it for, but it has not been specifically approved by the FDA for that purpose (Julien, 2001). Referring to off-label use, Werry (1999) wrote,

> Most of what we know in pediatric psychopharmacology is rather like twiddling the knobs on a television set in the absence of any real understanding of radiophysics . . . this may seem rather crude, but it is a truthful reflection of the state of medical knowledge. (p. 12)

The relatively small number of studies we do have that examine the effects of psychotropic medication on children frequently report lower efficacy than is found in similar studies with adults.

There have been other barriers to studying psychotropic medications in children as well. Riddle et al. (1998) have noted that, historically, there has been little support for pharmaceutical companies to test their compounds on children because children (and other vulnerable populations) are routinely being screened out of pharmaceutical drug trials. In addition, because there are differences between adults and children, a pharmaceutical company that tests a drug on children (that has efficacy in adults) risks tarnishing the general reputation of the drug should the study on children show no or less efficacy. Because changes in the law in the late 1990s (discussed below), pediatric psychotropic drug trials beyond stimulant medications are increasing in frequency.

An oft-neglected aspect of the history of pediatric psychopharmacology is the number of parent advocacy groups that have arisen to resist the notion that children's mental or emotional symptoms are solely medical disorders best treated with psychotropic medication. Groups like Parents Against Ritalin (http://www.p-a-r.org/) act as a reference for parents seeking psychosocial treatments for children with ADHD. Although some may regard such groups as unrealistic in their desire that psychotropic medications not be given to children, there has been no systematic study of the issues these groups have raised.

THE PROBLEM

It is estimated that between 7.5 and 14 million children in the United States experience significant mental health problems (Wozniak et al., 1997), many of whom will be treated with psychotropic medications. The estimated range is vague due to the ambiguity of psychiatric diagnoses (Gadow, 1997, 1999) and the general problems with epidemiological research on diagnostic categories (Ingersoll & Previts, 2001). The majority of psychotropic medications lack FDA on-label approval specifically for children but are increasingly being prescribed as part of their treatment (Gadow, 1999; Jensen et al., 1999; Pelham, 1993). Despite the paucity of data, the trends noted in the following section demonstrate that psychotropic medication prescriptions for children are increasing dramatically each year.

TRENDS IN PRESCRIBING

According to the associate director of the Office of Research of the American Psychiatric Association, it is difficult to get exact estimates on psychotropic prescriptions in the United States (T. Tanielian, personal communication, February 8, 1999). This difficulty is compounded when children are concerned because there are no existing national databases to monitor pediatric psychopharmacology practices (Gadow, 1997). There are studies that can help to approximate trends, most of them done by private companies that monitor market share for medications. Psychotropic medications account for approximately 10% of the prescription market, and their proportion is growing substantially each year with more drugs being approved and more people being prescribed these drugs (Ingersoll, 2000). According to the pharmaceutical consulting firm Scott-Levin, psychotropic medications also accounted for slightly more than 10% of the top 200 prescription drugs used in the year 2003 (RxList, 2003).

There is currently a trend toward medicating younger children (ages 4–7; Zito et al., 2000; Zito et al., 2003) despite the fact that there is "no empirical evidence to support psychotropic drug treatment in very young children and that such treatment could have deleterious effects on the developing brain" (Coyle, 2000, p. 1060). In the 5 years spanning 1993 to 1997, Minde (1998) described a threefold increase in methylphenidate prescriptions in Canada in children 5 years and younger as well as a tenfold increase in antidepressant prescriptions for the same group in the U.S. There is also some evidence that younger children are less likely than adults to receive psychological services in addition to medication (Rappley et al., 1999).

In general, there has been a steady increase in the number of visits children make to pediatricians and in the number of psychotropic drug prescriptions these doctors write. The number of visits to primary care physicians and psychiatrists for psychotropic medication has increased, and much of the increase is attributable to children being treated with newer antidepressants as well as the increased use of stimulants to treat children and adolescents with ADHD (Rushton & Whitmire, 2001). Even though stimulants remain the best researched medication for children, there are still comparatively few studies focusing on younger children. Despite this, there is a steady rise in the number of children taking these medications at younger ages (Gadow, 1999; Safer & Krager, 1988) and an unending debate on the appropriateness of this practice, particularly for preschoolers. Prescription rates for children are also increasing for nonstimulant psychotropic medications

including antidepressants, mood stabilizers, and antipsychotics medications (American Academy of Child and Adolescent Psychiatry, 1997; Bostic, Wilens, Spencer, & Biederman, 1997).

POWER ISSUES

Relationships Between the FDA, the DSM, *and Pharmaceutical Companies*

Counselors should be concerned about the vagueness of medication classifications and the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM;* see, for example, the most recent edition, American Psychiatric Association, 2000) diagnoses that classes of medication are used to treat. There is an important relationship between FDA standards, *DSM* diagnoses, and pharmaceutical companies. Basically, to receive on-label approval, a company must demonstrate that a drug has efficacy in at least two pivotal trials. "Pivotal" here means double-blind, placebo-controlled trials. There are no restrictions on how many trials a company may run to achieve the two pivotal trials, thus many studies show no efficacy for a range of drugs. In addition, the drug must show efficacy to treat a certain disorder, thus the system of categorical psychiatry (discrete *DSM* diagnoses) is reinforced despite questions about its validity (Fisher & Greenberg, 1997; Healy, 1997).

In this manner, *DSM* diagnoses are portrayed as akin to allopathic disease processes despite the fact that there are no clear physiological markers to support that assertion (Colbert, 2002). Regardless, drugs are classified in relation to the disease processes they are tested on even if the disease process is ill defined. If it is admitted that gray areas exist in the diagnostic manual or drug classification schemes, companies may have difficulty getting FDA approval. This could translate into difficulties capturing market share and profits. Coyle (2000) also noted that many of the *DSM* diagnostic categories that serve as the basis for pharmacological treatment do not have demonstrated reliability and validity when applied to young children. Critics, like Healy and Doogan (1996), allude to the fact that the latter admissions could be destabilizing in an industry in which it costs $200 million to $600 million to bring a drug to market and in which only one in five is likely to get to that point (Bodenheimer, 2000; Pediatric Pharmacotherapy, 1995).

Pharmaceutical companies can also capture more market share by testing a compound on a *DSM* disorder that it was not initially intended to treat. For example, there are a great number of antidepressants but no real clue as to why their pharmacological effects alter mood. There is a great deal of evidence that many diverse psychotropic compounds function similarly by generally disabling ongoing brain functions and temporarily reducing symptoms (Breggin, 1997; Healy, 1997). Antidepressants seem to be helpful for symptoms in a variety of disorders and currently hold FDA approval for major depressive disorder, posttraumatic stress disorder (PTSD), generalized anxiety disorder (GAD), premenstrual dysphoric disorder (PMDD; which at the time of writing is not even an official diagnosis), obsessive-compulsive disorder (OCD), and enuresis, to name a few. This situation leads one to conclude that the notion of an "antidepressant" is far too limiting a classification for the compounds referred to or that the disorders referred to are less discrete than the *DSM* makes them appear. Regardless, the categories of medications and disorders gain credibility through this reinforcing cycle, a credibility that may be undeserved.

A related issue has to do with the FDA, the pharmaceutical companies, and the consumer. Currently, pharmaceutical companies are allowed to advertise directly to consumers via print and media campaigns for medications. This is called direct-to-consumer advertising. Before the ban on such advertising was lifted in the late 1980s, pharmaceutical companies spent approximately $12 million a year on drug ads, mostly aimed at prescribing professionals. Since allowing direct-to-consumer advertising, companies spent $600 million on ads in 1996 (Borzo, 1997) and $900 million on ads in 1998 (Hollon, 1999). Companies are currently including psychotropic compounds for children in their marketing strategies for those few drugs (like stimulants) that do carry FDA on-label approval.

While supporters of the direct-to-consumer advertising movement note that it can be an excellent way of providing educational information to the consumer (Holmer, 1999), critics note the considerable profit margins correlated with advertising and suggest that, without medical oversight, whatever quality information is available will get lost in the race for profits (Hollon, 1999). Many advertisements for psychotropic medication make a point of stating that the psychological disorder (being targeted in the ad) is a medical illness, thus trying to capitalize on the association with allopathic disease processes like bacterial infections. Direct-to-consumer advertising is correlated with significantly larger profits. In the year 2000, the most advertised drugs saw increases in sales of 32% (Express Scripts, 2001). This trend, for better or worse, will certainly drive pharmaceutical companies to get FDA on-label approval for the as-yet-untapped market of children.

Another concern related to advertising and FDA approval is how pharmaceutical companies research the products that they submit for FDA approval. Bodenheimer (2000) has noted that a new research model has sprung up in the last 10 years. Whereas previously, pharmaceutical companies frequently relied on academic medical centers to run trials, now they are contracting out research services and may even run them in-house. This raises questions about the ethical aspects of a company paying researchers to test products that may potentially bring the company large profits. In addition, Bodenheimer has documented numerous cases in which companies prevented important research findings from being published because they were not favorable regarding the compound being tested. If more and more compounds are going to be tested on children, the ethical dilemmas surrounding such research need to be resolved.

Trends, Costs, and the Law

When Smith, Kline, and French first marketed Thorazine in 1955, they made $75 million; this established the fact that

psychotropic medications were profitable (Healy, 1997). That anticipated profitability extends to psychotropic medications used to treat children. According to IMS Health (2000), the market for stimulant medications to treat ADHD in the 12 months leading to November 2000 was worth $625 million. This makes the pharmaceutical industry a force that requires checks and balances. Some checks and balances come from the law, but others must be exercised through responsible advocacy.

We know that per-prescription costs for drugs typically prescribed for children are increasing more than for any other age category (Express Scripts, 2001). Part of this is likely due to recent legislation requiring drug companies to test new and existing compounds on children. In 1995, the FDA announced that all new drug applications had to contain information on pediatric use. If such information is not included, the sponsor must provide a specific explanation why the drug should not be used with children (on- or off-label; Pediatric Pharmacotherapy, 1995).

In 1997, Congress passed the FDA Modernization Act (Binder, 1999) that increased the number of medication studies focusing on children. Through this act, pharmaceutical companies doing pediatric trials can win a 6-month extension on patent rights for an existing adult drug. This 6-month patent extension brings millions of dollars to pharmaceutical companies (Solov, 2001). This act has led to a steady increase in research on the specific effects of pharmacological compounds (including psychotropic medications) on children. The FDA Modernization Act was renewed with some modifications in 2002. The renewal bill was called the "Better Pharmaceuticals for Children Law" (Dodd, 2001). Although such bills increase the rigor with which drugs must be tested before being prescribed for children, they do not contribute to the debate over whether psychotropic drug interventions are the best choice for children.

THE ETHICS OF COUNSELORS DISCUSSING PSYCHOTROPIC MEDICATION

Before outlining areas of advocacy, we must address the ethical aspects of counselors discussing medication issues with parents, teachers, or prescribing professionals. There are no clear prohibitions against a nonmedical mental health professional talking with clients about psychotropic medications, although this is still a gray area. Littrell and Ashford (1995) explored the issue of psychologists discussing psychotropic medications with clients. They noted the history of court decisions on this topic related to the nursing and pharmacy professions and concluded, "given the precedent established in other professions, it is unlikely that a psychologist's discussion of medication could be construed as practicing medicine without a license" (p. 241). Littrell and Ashford also concluded that there was no basis in case law for assuming that psychologists' sharing information about psychotropic medication is illegal.

There is no literature exploring related ethical issues for counselors, and research in this area is needed. It is important to note that the American Counseling Association's (1995) *Code of Ethics and Standards of Practice* (Section A. 1) states that one primary responsibility of counselors is to promote clients' welfare. This includes being knowledgeable about treatment options, which, in turn, can include supplementing counseling with psychotropic medication prescribed by a physician. Counselors who may discuss psychotropic medications with clients need to closely observe the ethical principles for collaborating with cooperating agencies and professionals (Patterson, 1996). A benefit to discussing psychotropic medications with clients (and/or their caregivers/families) is that good information that empowers them to make informed decisions should contribute to the therapeutic alliance. Certainly a limitation to such conversations is that the client may expect more than the counselor can give. It is important that counselors clarify clients' expectations regarding conversations about psychotropic medication so that clients understand the general scope of the counselor's expertise.

RELATED ADVOCACY ISSUES

The trends and power issues outlined in this article point toward important advocacy issues for counselors. Although counselors are not professionals who prescribe medication, with the proper education, they can consult with clients about medication issues and advocate responsibly in this area (Ingersoll, 2000). The aforementioned trends and power issues constitute what Kiselica and Robinson (2001) called "extrapsychic forces" (p. 387) that may affect the well-being of clients. In the following section, we discuss advocacy issues related to the history of and research on using psychotropic medications with children, research on treatment versus medication, the use of *DSM* diagnoses with children, and power issues including who defines mental or emotional symptoms as "illnesses."

When acting as advocates, counselors all have a responsibility to the truth. The truth may encompass several perspectives and lack a definitive conclusion. When that is the case, an honest advocate shares available knowledge and facilitates decision making in the context of how the available knowledge relates to the life of the client(s) in question. Advocacy is not about embracing extreme examples for the purposes of a particular political agenda (for example an agenda that children should never be prescribed psychotropic medication). Advocacy in this area requires thoughtful, dispassionate evaluation of the information available and how it relates to clients and the context of their life.

Advocacy and Historical Issues

As noted earlier, the history of research on using psychotropic medications with children is limited. Counselors cannot advocate responsibly without knowing the history and research that does exist. Riddle et al. (1998), Gadow (1997), and Werry (1999) all have good summaries of the history of studying psychotropic medication for children. A review of the summaries will temper any unwarranted enthusiasm for medicating children while at the same time highlighting situations in which psychotropic medication has consistently

treated particular symptoms. Implied in advocacy concerning research issues is that counselors know how to evaluate and understand research. In addition, counselors need to recognize the political aspects of publication. In many controlled research trials on psychotropic medication, the medication is not significantly better than a placebo in alleviating target symptoms (Colbert, 2002; Greenhill, 1998; Khan, Leventhal, Khan, & Brown, 2002); however, far fewer of these studies actually see publication because studies with positive results are more likely to be published (Olson et al., 2002). Thus, just because a compound has two trials showing efficacy, advocacy counselors should keep abreast of what other studies have been done in addition to those. This is not a simple task and may require consideration of non-peer-reviewed books like Breggin (1997) or studies like that of Khan et al., who examined studies in the FDA database.

Underlying an understanding of this history, the politics of publishing, and the current research on treating children with psychotropic medications is the question of who decides if a child should be treated with medication. As advocates, counselors can help families through the difficult decision of whether or not to medicate a child as well as provide information on nonmedical treatments (discussed later in this article). This may be perceived as opposition to the dominant medical paradigm simply because it can involve questioning a physician's recommendation that a child be medicated. The advocacy in this instance is not about the compound prescribed as much as whether psychosocial interventions may be equally helpful. Counselors must be sources of educational information and help parents understand information the parents have received about a certain treatment. Finally, counseling organizations need to establish positions based on the current research. For example, even medical professionals are stating that younger children should not be routinely prescribed certain medications (Coyle, 2000; Zito et al., 2000; Zito et al., 2003). Our professional organizations must possess the courage to explore and develop such positions.

Treatment Versus Medication

The most powerful tool we have as advocacy counselors is our knowledge of treatments that work and the conditions under which they are thought to work best. There are many studies that support the efficacy of counseling versus medication for several different disorders. Even in disorders like schizophrenia, historically thought to virtually require medication, there are those who question the methodology as well as the wisdom of assuming that medication is a necessary part of treatment (Hegarty, Baldessarini, Tohen, Waternaux, & Oepen, 1994). Researchers doing newer studies on depression are using brain scan technologies and concluding that in many cases, counseling or psychotherapy may induce changes similar to those associated with medication (Brody et al., 2001; Martin, Martin, Rai, Richardson, & Royall, 2001). The notion that antidepressants are the first line of treatment for depression has been contested by Antonuccio, Danton, DeNelsky, Greenberg, and Gordon (1999). Antonuccio et al. concluded that the effects of antidepressants are smaller than previously thought and that powerful financial and political interests maintain the notion that they are a first line of treatment. Even in ADHD treatment, with all the research that has been done, there is still debate as to when medication is beneficial and when treatment without medication may be called for (Greenhill, 1998).

Again, advocacy for psychosocial treatment rather than medication begins with knowledge of the client, his or her risk factors, and the literature supporting psychosocial treatment. One possibility for advocacy lies in the journals of our profession. What sort of impact would occur if, in a given year, all American Counseling Association journals published around a theme of effective treatments or comparing psychosocial with pharmacological treatments? For that year, the focus could be meta-analyses of various treatments, innovative studies supporting the efficacy of particular psychosocial treatments, or even how certain psychosocial treatments compare with medication.

DSM *Diagnoses: Advocacy Versus Complicity*

Although counselors have successfully lobbied in many states for the right to make *DSM* diagnoses, the question of what such a diagnosis means remains unanswered. Does it mean the client experiences symptoms that may be usefully categorized under a *DSM* diagnosis, but are overdetermined in etiology? Or, does it mean the client is diagnosed with an allopathic disease process best treated with allopathic medicine?

Again, counselors must be familiar with the *DSM* as well as with literature on the validity and reliability of the diagnoses. Perhaps more important is the question of whether such diagnoses represent allopathic diseases or rather useful categories to help us make sense of symptoms. While pharmaceutical companies, in particular, advocate the former, current evidence supports the latter. Even scientists strongly in favor of a biological model of psychiatry will admit that there are no physiological markers that would define mental and emotional disorders as organic in etiology (Andreasen, 2001), thus making such a perspective more a statement of faith than anything. Perhaps most alarming is the practice of pharmaceutical companies advertising medications for mental and emotional symptoms that they label "medical disorders" (e.g., "depression is a serious medical disorder"; Lilly Pharmaceuticals, 1998). Because advocacy also involves the good of the profession (Eriksen, 1999), counselors need to dispute this image of mental and emotional disorders as solely allopathic medical disorders. If such models are allowed to dominate, counselors and other nonmedical mental health professionals may find themselves accused of practicing medicine without a license.

Power Issues

It has been said that the first rule of history is that no one who has power gives it up willingly (S. I. Roberts, personal communication, January 8, 1984). The pharmaceutical industry has a great deal of power to shape public opinion

through its access to resources and its unique relationship to the medical profession. Through advertising, the industry supports many of the journals that publish the results of medication trials. Bodenheimer (2000) has already raised the ethical implications of this uneasy alliance. Counselors and their professional organizations need to monitor this relationship and understand its ramifications for the prescription rates of psychotropic medications, in general, and for children, in particular. Reasonable advocacy recognizes that power is merely a force that can be channeled productively or destructively; however, reasonable advocacy also recognizes that such power must have checks and balances.

CONCLUSION

The issues in this article are far-reaching, multidisciplinary, and may seem too broad to some. The primary question that all the issues have in common is, how can counselors best advocate for clients and their families regarding children and psychotropic medication? Although many of the issues raised pertain to adolescents and adults too, we have focused on children because of the remarkable lack of data supporting the growing trend of medicating children. We noted that the idea that mental and emotional symptoms derive from some as yet undiagnosed allopathic disease process is more a statement of faith than fact. We believe the facts require advocacy counseling to protect the rights of children to receive appropriate treatment. Even though that treatment may involve some form of psychotropic medication, advocacy counseling can help families explore treatment options, evaluate relevant literature, and become empowered to stand up to pharmaceutical companies that have a vested interest in medication being a first line of treatment.

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