

A quarterly newsletter designed to address legal and risk related issues that child and adolescent psychiatrists encounter.

INSIDE THIS ISSUE

Reducing the Risks Involved
in Prescribing Mood
Stabilizers Off-Label to
Bipolar Children

Page 2

Culture Corner:
Haitians

Page 6

Case Closed – Claims and
Risk Management Insights

Page 9

Private Practice, Group
Practice or Independent
Contractor?

Page 10

Upcoming Speaking Events

Page 15

In Session with Allied World is published in support of the American Professional Agency's child and adolescent psychiatrist insurance program, exclusively for members of the American Academy of Child & Adolescent Psychiatry.

Dear Friends,

We are pleased to present the second issue of *"In Session with Allied World for AACAP."* The newsletter highlights the extensive healthcare know-how possessed by Allied World's claims and risk management teams — and the broad range of services offered by the American Professional Agency, Inc. (APA, Inc.) — to provide a valuable source of information for child and adolescent psychiatrists.

APA, Inc. has focused on serving the professional liability insurance needs of child and adolescent psychiatrists as the AACAP-endorsed insurance program since 2000. With 120,000 healthcare policyholders nationwide, APA, Inc. ranks as one of the largest malpractice providers in the country. Although we are a large agency, our success stems from our ability to provide individual attention and underwriting expertise to our professional liability insurance policyholders. We are a family run business, are experts regarding the liability challenges child and adolescent psychiatrists face and work diligently to provide insurance solutions that are comprehensive and responsive.

Richard Imbert is the company's President and has been with APA, Inc. for fifty years. He is a certified insurance counselor and licensed insurance agent who is recognized as a leading expert in mental health malpractice insurance.

Peter Imbert is the company's Executive Vice President and has been with APA, Inc. for over twenty years. He has over thirty years of experience in the insurance industry, has extensive professional liability experience and was instrumental in the development of the AACAP Malpractice Program.

By combining Allied World's financial strength, claims handling and risk management services, with our agency's experience in underwriting and working closely with child and adolescent psychiatrists, we have created an exemplary professional liability product available exclusively to AACAP members. Our professional and business liability program for child and adolescent psychiatrists is open to individual and group practitioners, and provides broad coverage with limits of up to \$2 million/\$6 million. The program is offered in both claims-made and occurrence forms.

It has been our privilege to work with many of you. Our approach has been, and will always be, to provide superior coverage, written by a highly rated, financially secure carrier, in order to protect your assets from vulnerability and to provide exemplary service. We look forward to continuing to serve as your insurance resource. If you have any questions, or would like to discuss the newsletter or the endorsed program further, please contact either of us at (800) 421-6694.



Richard Imbert
President
American Professional Agency, Inc.



Peter Imbert
Executive Vice President
American Professional Agency, Inc.

Reducing the Risks Involved in Prescribing Mood Stabilizers Off-Label to Bipolar Children



By **Robert L. Boston**, Morrison Mahoney, LLP

It is estimated that bipolar disorder may affect close to one million children and adolescents in the United States.¹ Because of limited testing of pediatric medications, the Food and Drug Administration (FDA) has approved only a handful of medications for the treatment of children and adolescents with bipolar disorder. Lithium is the only mood stabilizer currently approved by the FDA for treatment of this population.² Clinicians who wish to prescribe a different mood stabilizer must therefore do so off-label. This practice involves risks to both the patient and the clinician, but those risks can be significantly reduced by establishing prudent practice guidelines and safeguards in obtaining informed consent, record keeping, tracking evidence-based support and in patient monitoring.

When a drug is developed, the manufacturer must first obtain FDA approval before the drug can be released to the market. Approval is based on the FDA's evaluation of the safety and efficacy of the drug for the proposed use or uses. However, once approval has been granted, a clinician is free to prescribe that medication "off-label" for uses and in doses beyond those which were approved by the FDA.³ Off-label use is widespread and accounts for approximately 20% of all prescriptions in the United States and an even greater percentage of pediatric prescriptions.⁴ This practice is not prohibited or regulated by the FDA.⁵ There is nothing illegal or improper about off-label use so long as the clinician uses sound professional judgment in choosing a medication.⁶

The Supreme Court of the United States has noted that off-label use is "accepted and necessary" and that this practice is generally recognized by the courts of several states as well as the FDA.⁷

The efficacy and safety of mood stabilizers in treating bipolar children and adolescents has not been thoroughly researched in randomized controlled studies.⁸ Clinicians must rely on clinical reports, personal experience, or extrapolations from adult studies involving mood stabilizers to arrive at treatment decisions for bipolar children.⁹ Unless a clinician prescribes lithium to a child over the age of ten, any decision to treat pediatric bipolar disorder with a mood stabilizer will involve off-label use. Several antiepileptic or anticonvulsant drugs — such as valproic acid (Depakote) — are commonly used to stabilize moods.¹⁰ Because Depakote was developed to treat seizures, it has been well-studied in treating that disorder even in a pediatric population.¹¹ Some non-randomized controlled trials have found that Depakote is effective in treating bipolar disorder in children.¹² Nevertheless, when a clinician decides to prescribe a medication such as Depakote off-label, particularly to a child, he or she risks exposure to legal liability in the event of an adverse outcome by the patient. This is particularly true given the recent FDA warnings regarding increased risk of suicidality in patients taking antiepileptics and anticonvulsants.

On January 31, 2008, the FDA issued an alert to health care providers about the increased risk of suicidal thoughts and behaviors in patients taking antiepileptic and anticonvulsant drugs to treat epilepsy, bipolar disorder, migraine headaches and other conditions.¹³ Depakote and other medications commonly used to treat pediatric bipolar disorder are included in this class of medications. The FDA's analysis of suicidality reports from placebo-controlled studies showed that patients taking these medications had about twice the risk of suicidal thoughts and behaviors (0.43%), compared with patients receiving placebo (0.22%).¹⁴

On December 16, 2008, the FDA issued a notice to the manufacturers of antiepileptic drugs to add a warning on their label regarding the increased risks of suicidality. The warning would not be a "Black Box" warning but would be included in the "Warnings" and "Information for Patients" sections of the label. In addition, the FDA required that manufacturers submit a Risk Evaluation and Mitigation Strategy, including a Medication Guide for

patients.¹⁵ The Medication Guide would be handed out to patients, their families and their caregivers to identify the risks of suicidal thoughts and behaviors discovered in the FDA studies. The use of off-label mood stabilizers to treat pediatric bipolar disorder must be considered carefully in the context of these FDA warnings to avoid potential legal exposure.

Liability

There are two ways in which a clinician can be found liable for prescribing a medication off-label. First, the decision to prescribe a particular medication at a particular dose could be negligent – in other words, a plaintiff could allege that the actual prescription deviated from the accepted standard of care in the community. While this standard varies state to state, it is typically accepted that a clinician must practice with the degree of care, knowledge and skill ordinarily possessed by clinicians in similar situations.¹⁶

Second, even if the prescription itself is appropriate, the clinician could be liable if he or she failed to obtain the patient's informed consent prior to prescribing the medication. The doctrine of informed consent is based on the belief that patients have an interest in determining the direction of their medical treatment.¹⁷ To facilitate that interest, courts have generally recognized that a clinician can be held liable for failing to divulge details and information sufficient to allow the patient to make an informed decision regarding a recommended course of treatment.¹⁸ In the context of treating pediatric patients, this responsibility extends to informing the parents or guardians. While this principle may be applied differently in every jurisdiction, it is clear that a clinician is required to make a sufficient disclosure of the risks, benefits and alternatives of the recommended treatment. It is not difficult to see how

clinicians who prescribe mood stabilizers off-label to bipolar children can be vulnerable to liability under either of these legal theories, particularly under the doctrine of informed consent.

Clinicians are particularly vulnerable because the failure to treat bipolar disorder carries a similar risk of suicidality as off-label treatment with a mood stabilizer.

Therefore, clinicians who prescribe mood stabilizers for bipolar children are advised to implement certain safeguards and practice guidelines to reduce their risk of being sued if the patient has a bad reaction to the medication or attempts suicide. Such clinicians are particularly vulnerable because the failure to treat bipolar disorder carries a similar risk of suicidality as off-label treatment with a mood stabilizer. Clinicians can reduce their potential exposure by implementing policies that address the following areas: informed consent, record keeping, evidence-based support and patient monitoring.

Informed Consent

Engaging in a thorough and open discussion with a patient and his or her parents or guardian is essential in avoiding potential liability under either a theory of negligence or an informed consent claim. Though acquiring a patient's informed consent is essential in avoiding a claim under that theory of liability, the details provided in discussions with patients are also helpful in supporting the appropriateness of the underlying prescription.

Thank you for your input on the first issue of "*In Session with Allied World for AACAP*." We welcome your continued feedback and suggestions on future topics germane to your practice. If you would like to see a particular topic addressed, we would love to hear from you. In addition, we are seeking contributions to future newsletters and development of educational resources. Please contact Kristen Lambert at (857) 288-6036 or kristen.lambert@awacservices.com.

Though off-label use is not negligence per se, it could be considered evidence of negligence in a court of law.¹⁹ Therefore, any recommendation to use a medication off-label should be disclosed up front. Depending on the age of the patient, it may make sense to have separate discussions with the patient and the parents or guardian. Teenagers may be more willing to pay attention and ask questions one-on-one with a clinician when their parents or guardians are not present. As such, segregating such discussions could be beneficial. Likewise, parents or guardians may have concerns or fears that they would prefer raising without their child present. Segregating these discussions can be particularly useful regarding the increased risks of suicidality that these medications carry. As will be discussed below, the details of any discussion aimed at obtaining a patient's informed consent should be thoroughly documented.

When discussing the risks, benefits and alternatives of prescribing an off-label mood stabilizer to treat a bipolar child, it is essential that a clinician explain and document why one of the FDA-approved pediatric bipolar medications is not being used. Perhaps lithium or an approved antipsychotic was ineffective or caused unacceptable side effects. Whatever the reason, a clinician must discuss these details and document the particular reasons why an approved medication is not being used or is being discontinued in favor of an off-label mood stabilizer.²⁰

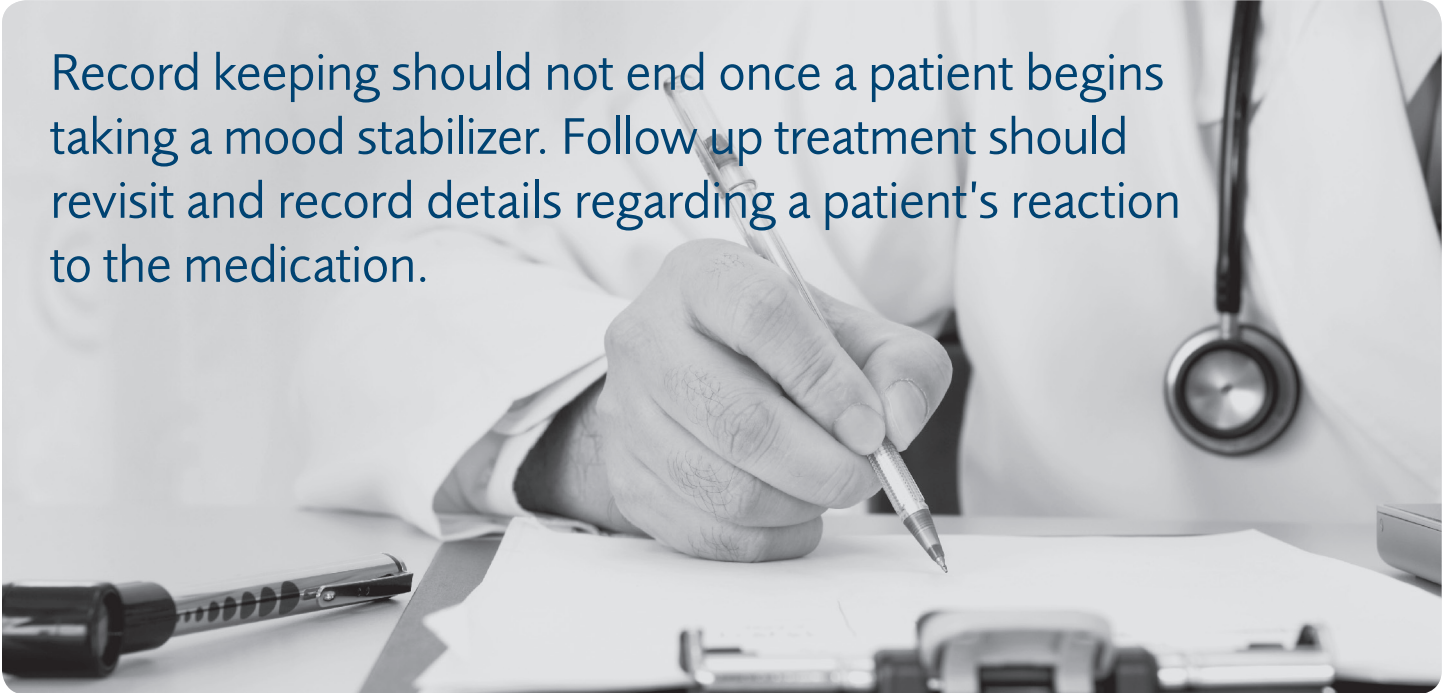
Allied World's Experienced Claims

Team: As the largest insurer for mental health providers, Allied World's analysts understand the intricacies of psychiatric claims, including the unique challenges associated with patient complexities, patient rights and various state regulations. Possessing both the legal and clinical backgrounds that are critical for handling psychiatric claims, each team member has experience handling claims specific to child and adolescent psychiatrists.

The clinician should discuss his or her rationale for suggesting a particular mood stabilizer including reference to evidence-based support for the recommendation. The fact that the mood stabilizer is not FDA-approved should also be discussed and documented.²¹ One should explain that there has not been a great deal of research into the use of mood stabilizers in pediatric bipolar patients and the ethical reasons why such research is limited. It is often difficult to know precisely what the risks and alternatives of these off-label therapies might be, and a clinician should be candid with the patient regarding these limitations. The risks of these medications for an approved use should be disclosed as well as any of the risks that may be known regarding use in the adult population. Throughout the informed consent discussion, the patient and his or her parents or guardian should be afforded ample opportunity to ask questions.

A clinician should clearly note the FDA warnings regarding increased suicidality found in patients taking anti-convulsants and antiepileptics. It is worth mentioning that the increased risk of suicide was higher in epileptics than patients taking these medications for bipolar disorder.²² When recommending treatment, the clinician should be sure to inquire into a patient's risk factors for suicide including any history of depression, prior attempts, or a family history of suicide. Not only is such a discussion helpful in guaranteeing that informed consent is obtained, it might reveal issues that could create vulnerability under a claim for negligence if the history is positive. The patient and family should be instructed to call the clinician immediately if any signs of suicidality or change in mood is displayed after treatment has begun. If available, the manufacturer's Medication Guide should be provided to the patient, although it is likely that this information will be provided by the pharmacy at the time the prescription is filled. Nevertheless, having the clinician also provide this information could add an additional level of protection for the patient and the clinician.

As discussed in the Patient Monitoring section (on page 6), patient follow up regarding the effect of a mood stabilizer should be carefully tracked and documented. If changes in mood or suicidality are revealed, a clinician should revisit the issue and engage in another discussion regarding risks and alternatives. Because the underlying disease carries a risk of suicide, a clinician must balance the risk of continuing treatment with a mood stabilizer with alternate forms of treatment and these issues should be openly discussed and documented.



Record keeping should not end once a patient begins taking a mood stabilizer. Follow up treatment should revisit and record details regarding a patient's reaction to the medication.

Record Keeping

Documentation and obtaining a patient's informed consent should go hand in hand. The essential details of the informed consent discussion set forth above should be thoroughly documented. This should include not only the information provided by the clinician but the questions asked by the patient or parents/guardians. If no questions are asked, one should note that an opportunity to ask questions was afforded to the patient or parents/guardians. Finally, one should clearly document that the patient's informed consent, and that of his or her parents or guardian, was obtained. This should not be done in a conclusory way but with detail that evidences understanding about the choice being made.

In light of the FDA warnings regarding suicidality, a clinician should devote time discussing and documenting a basic history regarding the patient's mood and any suicidality in the past. If the patient has any risk factors for suicide, or has attempted suicide in the past, it should be documented. Record keeping should not end once a patient begins taking a mood stabilizer. Follow up treatment should be revisited and details regarding a patient's reaction to the medication should be recorded. Details regarding changes in mood, increased depression or suicidality should also be recorded.

Evidence-Based Support

Patients who assert a malpractice claim based on off-label use will need to prove, usually through expert testimony, that the particular off-label use was not medically appropriate or accepted in the community. For that reason, a clinician defending such a claim would benefit from maintaining a file in the office, but apart from patient charts, with documents and evidence which support the appropriateness of the particular off-label use. This file could contain clinical reviews, medical literature and any other anecdotal evidence which might support the clinician's decision to prescribe a particular medication off-label.²³ However, maintenance of such a file is only as valuable as the materials it contains. Therefore it is prudent to periodically review and update such a file to ensure that its contents are current and accurate.

It is not recommended that a patient be provided with materials from a clinician's evidence-based file, but the details of this information should be discussed in the context of obtaining informed consent. If a clinician has treated bipolar children with mood stabilizers in the past, he or she may consider tracking such use and maintaining details of past treatment in the evidence-based file. It is widely recognized that more testing is needed regarding the efficacy and safety of mood

stabilizers in treating pediatric bipolar disorder.²⁴ The Best Pharmaceuticals for Children Act (BPCA) has created an opportunity to advance research in this area.²⁵

Patient Monitoring

Once a clinician has recommended off-label use of a mood stabilizer in treating pediatric bipolar disorder and has engaged in and thoroughly documented a discussion aimed at obtaining the patient's informed consent, the patient should be carefully monitored regarding his or her reaction to that medication. This follow up should include questions regarding whether the patient has exhibited any suicidality or change in mood. These discussions should be carefully documented. Monitoring bipolar children who are taking mood stabilizers is helpful in ensuring a particular patient's safety, but it can also afford assistance in defending a claim for negligent prescription of a mood stabilizer in future patients.

Conclusion

Because there is limited research regarding the use of mood stabilizers in treating bipolar children, any clinician who chooses to engage in this type of off-label use runs the risk of legal action in the event of an adverse outcome. Protecting oneself from these risks can be reduced by instituting policies and procedures aimed at ensuring that a patient and his or her parents or guardians provide an informed consent to such treatment and that details regarding these discussions are carefully documented. Maintaining a file of evidence-based support for treating bipolar children with mood stabilizers could prove invaluable in the event of a lawsuit under a negligence or informed consent theory. Finally, children taking mood stabilizers should be carefully monitored to track the effect of treatment including any potential increase in suicidality. Implementing these recommendations into one's practice can help protect patients from the risks of off-label use of mood stabilizers in treating pediatric bipolar disorder and in protecting clinicians from potential legal action.



About the Author

Robert L. Boston is a Senior Associate at the law firm of Morrison Mahoney LLP in Boston, Massachusetts. His practice is focused on defending healthcare providers, including mental health clinicians. Mr. Boston has participated in

medical malpractice jury trials and has argued before the Commonwealth Court of Pennsylvania and the Massachusetts Court of Appeals. He is a member of the American Bar Association and the Massachusetts Bar Association and sits on the Health Law Section Council of the MBA. Prior to joining Morrison Mahoney, Mr. Boston was an associate in the Philadelphia firm of Marshall, Dennehey, Warner, Coleman & Goggin. He is admitted to the bars of Pennsylvania and the Commonwealth of Massachusetts. Mr. Boston earned his law degree from Boston University School of Law and a B.A. in Russian Studies from Washington & Lee University.

Culture Corner



By Kristen M. Lambert, Vice President, Healthcare Risk Management and **Marjorie J. Thompson, Esq.**, Vice President, Professional Lines Claims

Psychiatrists often encounter patients and family members from diverse cultures and backgrounds. Although there are many differences and variations within a culture, we will feature different cultural groups which may be of interest to you in your daily practice as well as some relevant legal issues which

you may encounter. Not everyone from the same culture shares the same beliefs and it is important not to stereotype. However, learning whether a patient considers himself typical or different from others in his cultural group is important as there are many factors which influence how an individual views his own culture/beliefs. You may never encounter some of the featured cultures in your practice; however, we hope you find the information interesting nevertheless. In this newsletter, we feature Haitians.

Haitians

It has been about a year and a half since the devastating earthquake hit Haiti. The destruction was and continues to be widespread with many deaths and families displaced. Family relationships are very important within the Haitian culture.^{26, 27} One can only imagine the impact a disaster of this magnitude can have — either on a person who directly experienced it or on a person who lost or had family members displaced as a result. Cultural sensitivity and research on the Haitian culture is important when providing mental health treatment.²⁸

Major Language/Dialects: There are two official languages of Haiti: Creole and French. French is the official language but the majority of Haitians only speak Creole. However, most Haitians living in the United States for a number of years usually become proficient in English.

Education: Many Haitians are well educated and successful. Nonetheless, the literacy rate in Haiti remains among the lowest in the Western Hemisphere. Consideration should be given to whether the patient is able to read and write in French, Creole or English. For those patients who are struggling, various modes of communicating should be considered, including oral versus written, use of interpreters and visual aides.

Nonverbal Communication: Haitians usually are affectionate, polite and shy. If a person does not understand, he will typically nod in agreement rather than exposing limitations. Eye contact is avoided, especially with those in positions of authority. Interpreters are often mistrusted and preference is to use family members.

Tone of Voice: The Haitian culture is rich, expressive; often loud with the use hand gestures for emphasis.

Consents: In general, Haitians are trusting of physicians, believing they are the experts. To obtain consent, it is important to discuss the treatment and the need for consent. However, thorough documentation is also important. This culture is private in general with a tendency to reveal only what is necessary. Haitians may not appreciate a provider talking about their condition with a family member or friend unless they have given permission to do so. They may be upset if this is done but may not show it outwardly; however, the relationship may be permanently severed.

Religion: Roman Catholicism is the dominant religion in Haiti. While other Christian and non-Christian religions are also practiced by Haitians, voodoo, a traditional religion partially derived from West African beliefs, is widely popular and practiced in tandem with other religions, such as Christianity. Many voodoo priests are accomplished herbalists who may be called upon to treat a variety of illnesses. Acknowledgement of voodoo as part of the belief system of some Haitians is important for physicians treating Haitians as some Haitian patients may opt for the protections and remedies offered by a voodoo priest (houngan or bokor) over traditional medicine. This results in a cultural distrust of modern medicine and tendency by Haitian patients to refrain from taking prescribed medication.

Concept of Health: Illness has a range of explanations based on cultural, religious and social beliefs. Illness is divided into several categories including: *maladi Bondye* (God's disease or of natural origin); *maladi peyi* (country of common, short-term ailments); *maladi moun fe mal* (magic spells sent by someone who is trying to harm you, perhaps because of jealousy or human greed); of supernatural origin, *maladi lwa* (disease of family spirits); and *maladi Satan* (Satan's or sent sickness). Diseases of supernatural origin are considered very serious and attributed to spirits' (*lwa*) anger which happens when the body that the *lwa* inhabits deceives it. Therefore, there is a general tendency to attribute health problems to magic spells and treatments may be two-pronged, modern medicine coupled with the advice of a voodoo priest. This multi-layered approach to health may result in the patient rejecting modern medicine altogether and opting for the non-traditional treatments offered by a voodoo priest. Treating physicians should, therefore, assess whether their patient will be reluctant to take medication and consider alternative therapies.

Mental Illness: Mental illness is not well accepted and it is often believed to have supernatural causes. There is a cultural stigma of shame that may be associated with mental illness. Most Haitians are reluctant to seek mental help and will generally do so outside of their community in order to ensure privacy. As an alternative, Haitians may rely upon spiritual and religious strength to cope with their problems. People with mental illness may be seen as victims of powerful forces beyond their control, which may cause them to be ostracized by family and friends. Thus, it is important to be aware of the cultural differences that you may experience when treating Haitian patients.

- **Depression:** The stigma associated with mental illness is so strong that Haitians will not readily admit to depression and will not seek treatment. It is important to be aware of the belief in voodoo within the Haitian culture which deals with depression as possession by malevolent spirits or as punishment for not honoring good protective spirits. Depression can be also viewed as a hex put on by a jealous person. It is important to be sensitive about the root cause of the problem. Described symptoms may be expressed in terms of headaches, back pain, or non-specific bodily pain.
- **Psychosis:** If a person has suffered from repeated psychotic episodes and his functioning is impaired, his or her judgment and cognitive ability may never be trusted again. This may be considered a loss within the family. For those who have access to biomedical

psychiatric care, schizophrenia is generally treated with antipsychotic medications. It is important to look at the form and also the theme of the context of the behavior exhibited by the person. It goes without saying that it is important to distinguish spiritual practices and beliefs from psychiatric problems.

Children within the family unit: Education in the Haitian culture is extremely important and children are encouraged to perform well in school. Highly protective, Haitian parents also require their children to be respectful and to care for their elders.

Other Therapeutic Considerations - *Restaveks*: A *restavek* (or *restavec*, from the French *reste avec*, “one who stays with”) is commonly a female child who is sent by her parents to live with a more affluent family as a domestic servant in exchange for food, shelter and, possibly, an education. The *restavek* may be treated well and given the opportunity to thrive or may be verbally and physically mistreated, including beatings and sexual abuse. A former *restavek* may have conflicting feelings about her biological parents (who gave her away for, presumably, her own good) and her adoptive family which may have provided for basic needs but not more. In treating Haitians it is, therefore, important to consider whether there is any history of a *restavek* situation and, if so, the potential impact on the patient. A physician treating a former *restavek* should do more research into this practice, which continues to this day in Haiti.



About Our Co-Author

Marjorie Thompson was born in Haiti and lived there with her family until age nine. Marjorie’s responsibilities as Vice President, Claims include oversight of all coverage litigation brought by or against Allied World. Prior to joining Allied World in 2003, Marjorie was a Complex Claims Director in the Commercial Directors & Officers Claims Unit of National Union. She also worked as an associate at LeBoeuf, Lamb, Greene & MacRae and as an attorney with the United States Department of Justice (DOJ), Civil and Criminal Divisions. While with the DOJ, Marjorie worked in Haiti for two years. She has been a panel member at various conferences and symposiums, including those sponsored by the American Bar Association (ABA), the Professional Liability Underwriting Society (PLUS) and the Practising Law Institute (PLI). Marjorie received her law degree from Georgetown University Law Center in 1992 and her undergraduate degree from Wellesley College in 1988. Marjorie has family still living in Haiti and returns to visit.

Case Closed – Claims and Risk Management Insights



By Susan Lynch and Robert Patria, Allied World Senior Claims Analysts

We recently resolved a challenging malpractice claim that illustrates some of the issues and considerations which impact the decision to take a case through trial. Although this article may be germane to psychiatrists treating adult patients as it is a case which involves an adult, the information may be important in the event that you are ever involved in a lawsuit.

This case involved a 72-year-old female with a long history of depression. In early 2009, the patient's symptoms were exacerbated due to an impending foreclosure on her home. Complaining of difficulty sleeping, the patient took a non-lethal (but more than prescribed) dose of Ativan. After being taken to a local hospital, the patient was transferred and admitted to a geriatric psychiatric unit. Our insured psychiatrist served as the medical director of this unit and managed the patient's care during her hospitalization. The patient received medical management and individual and group psychotherapy sessions. After providing treatment over the course of nine days, our insured psychiatrist determined that it was safe to discharge the patient. The patient was released to a family member, who had agreed to stay with her. The next morning, the family member found the patient deceased, having committed suicide.

The patient's family filed suit against the psychiatrist alleging that the psychiatrist inappropriately discharged the patient without sufficiently assessing her suicidal risk. The family retained a geriatric psychiatry expert who testified that the patient had not improved during her hospitalization and that she should not have been discharged. This expert testified that the fact that the patient committed suicide in less than 24 hours from discharge proved that her suicide was foreseeable and preventable. Throughout the litigation, Allied World's claim analysts partnered with defense counsel, to defend our insured psychiatrist. Allied World evaluated the facts of the case and assessed the risk of proceeding to trial while simultaneously — and with the insured psychiatrist's consent — exploring settlement options. The components of this case were optimal for a strong defense, including:

- The defense team consulted with a renowned forensic psychiatrist who supported all aspects of the insured psychiatrist's care
- The insured psychiatrist made a compelling witness on his own behalf, and
- The insured's thorough documentation in the medical chart supported his rationale for treatment and discharge.

Ultimately, and with the agreement of both defense counsel and the insured psychiatrist, Allied World made the decision to proceed to trial. Our claims staff closely monitored the week-long trial to assess whether the defense was proceeding as anticipated. As there is no such thing as a surefire case, careful monitoring permits us to evaluate and respond quickly, should unexpected developments in trial suggest the need to explore settlement. The trial progressed as expected and, ultimately, the jury returned with a unanimous defense verdict.

In suicide cases such as this, grieving families often search for someone to blame. While this death is a tragedy for the patient and her family, placing responsibility on the psychiatrist in this case was misdirected. We were able to defend against the plaintiff's allegations by working as a team. Allied World's experienced claims handlers, in tandem with highly regarded, expert defense counsel, worked closely with the insured psychiatrist to bring this case to a successful resolution resulting in a defense verdict. By taking the time to provide quality patient care supported by thorough documentation of the care and treatment decisions, this case was successfully defended against the plaintiff's claims.

Private Practice, Group Practice or Independent Contractor?



By Kristen M. Lambert

Whether you are a new physician who has just completed residency or an experienced provider considering an employment change, there are a number of practice arrangement options to consider. Should you:

- join an existing group practice as an employee, partner or shareholder?
- join a group practice as an independent contractor?
- start your own practice?

Weighing these decisions can be difficult. Each option has unique legal and risk issues which may arise before, during, or after your decision is made. Therefore, it is important to consider each option to the extent possible, before you begin any affiliation.

Among the issues that need to be considered and agreed upon are:

- Contracts with provisions that set forth employment status, compensation, and benefits
- Exclusivity and non-compete provisions
- Arrangements for on-call coverage
- Professional liability insurance coverage, funding, nose and tail coverage
- Ownership of the medical records
- Consensus on office policies and procedures such as medical records and documentation
- Supervision of midlevel practitioners, trainees, and office staff

Given that there are numerous issues to consider, it would be prudent to engage the services of an attorney who specializes in dealing with physicians on business arrangements and contracts. Specifically, it would be in your best interest to hire an attorney who is skilled in setting up physician practice groups and physician contract negotiation. Hanging a sign with your name above the door without assistance from an attorney could prove to be very costly.

Forming a Partnership/Practice

Forming a new group practice is not unlike entering into a marriage: when or if things sour, you are contractually bound to the other person(s) and typically you cannot just walk away if conditions do not work out. Entering into the relationship with your eyes wide open and being prepared is the best scenario for all involved. This does not mean that you can plan for anything and everything that could go wrong, but addressing as many issues as possible ahead of time is important in the event that you decide to part ways. For example, you will need to determine:

- If you are forming a partnership, limited liability company, a D/B/A, or a corporation
- The percentage of distribution of profits (i.e., the percentage share for each physician) as well as liabilities
- The number and type of office staff (and who is responsible for supervising them)
- Whether you will have an office compliance system (and who will be responsible for it)

Office Policies: Office policies should be agreed upon and established before the first patient is seen. They should set forth standard practices such as telephone procedures, documentation, patient confidentiality, release of medical records, etc. and can be used both as a training tool for staff and as a way to ensure consistency among physicians and staff. Should you or your practice ever be sued for malpractice, these established office policies may become important in the defense of your case. A plaintiff's attorney will often use office policies, or lack thereof, as a way to show either that your office did not comply with its own policies or that the practice was a fly-by-night operation if the group had a lack of policies or deficient policies. Plaintiff's counsel could attempt to draw an inference that your practice must have been negligent in the patient's care and treatment because you did not adhere to your own policies (or that you did not have policies).

Leadership/Supervisory Role: If you have office staff, employ other physicians, mental health providers, midlevel practitioners such as psychiatric nurse clinical specialists, or nurse practitioners, it is important to determine who is responsible for supervising these staff members. Most states have specific regulations setting the scope of practice and the appropriate level of supervision of midlevel practitioners. These should be adhered to in collaborative practice agreements. In the event that a claim is asserted, often the plaintiff's attorney will add the head of the group, the corporate entity or any partner/shareholder/officer within the group, particularly in a catastrophic injury case. Often the plaintiff's counsel will want the maximum insurance available on a case, especially if there is a catastrophic injury. As such, determining who is supervising whom is critical in the event that suit is filed.

Vicarious Liability: Supervisory relationships are those when the psychiatrist is hierarchically responsible for the overall care of the patient. The legal doctrine of vicarious responsibility (or vicarious liability) is known as respondeat superior. Respondeat superior is the proposition that an employer should be held vicariously liable for the torts of its employee or servant which were committed within the scope of his or her employment.²⁹ It will often hinge upon whether an employee-employer relationship existed. A corporation or an individual employing a physician may be held liable for the malpractice of the physician despite the fact that the corporate entity may not control the precise treatment decisions. The entity may not be able to avoid liability for that physician's malpractice.³⁰

As you know, in a clinic setting, often the psychiatrist is providing medication management and other mental health professionals may provide the psychotherapy. The psychiatrist may not see the patient for more than 15 minutes once per month while the patient is seeing other providers more often. As such, it is important to determine who you are supervising. The liability risks in this type of clinic setting may depend upon the relationship with the psychiatrist's clinical collaborators.³¹ This is in contrast to a hospital setting where the attending psychiatrist is ultimately responsible for the care provided by a resident.

Negligent Supervision: Another claim which can be brought against a supervisor is a claim of negligent supervision.³² If there is a bad outcome which occurs

as a result of negligent supervision, the supervisor may be held accountable for his or her own actions, or lack thereof, in allegedly failing to provide the supervisee with proper guidance, instruction, direction or control.³³ (See also the APA guideline for supervision, consultative or collaborative relationships with non-physician clinicians.)³⁴ Therefore, whenever a practice employs non-physician clinicians or other psychiatrists, it is important to determine supervisory roles.

In the event of a lawsuit, a plaintiff's attorney may bring you into a case where you had no direct involvement. A lack of knowledge of the acts of your employees is not a defense.³⁵ It is important that the medical and non-medical staff who work for you or within the practice are trained and supervised. At the end of the day, you cannot blame your office assistant for violating HIPAA as you are his or her supervisor. Thus, it is important to stay current with what is happening within your practice.

Office Compliance System: When forming a new practice or partnership, you should also establish an internal monitoring and auditing system. The Office of the Inspector General of the Department of Health and Human Services has set forth a Compliance Program - Guidance for Individual and Small Group Physician Practices.³⁶ This provides seven components upon which a physician practice can create a voluntary compliance program and includes:

- A process for conducting internal monitoring and auditing
- Implementation of compliance and practice standards
- Designation of a compliance officer or contact within the office
- Conducting training and education
- A system for responding and developing corrective actions for issues that occur
- A process to develop open lines of communication
- A process to enforce disciplinary standards through industry guidelines

Joining an Existing Partnership

Among the issues to consider when joining an existing partnership, either as an employee or as an independent contractor, is your employment agreement/contract. Bargaining power may be limited when joining an existing partnership because contracts are typically

drafted to protect the partnership, not the employee or independent contractor. As such, you should review all contracts with your attorney. The best time to negotiate is *before* you join.

If you join the group as an independent contractor, you will probably not have bargaining power within the group. However, you may have more flexibility than if you join as an employee.

Employment Agreements

Typically, an employment agreement will set forth working hours, compensation and duties. Employment agreements may also include competitive activities, a liquidated damages provision, exclusive services, physician-earned fees and honoraria, malpractice insurance coverage, patient confidentiality, medical group confidentiality, and compliance with the Federal Stark law. In general, important issues within the contract may include:

- **Compensation:** May be based solely on salary or include productivity or quality measures. Again, it is important to have an attorney review your contract/employment agreement prior to signing.
- **Exclusivity Provisions:** Whether joining a practice, starting a group practice or signing on as an independent contractor, the employment contract should indicate whether you can moonlight or engage in other employment and/or receive income unrelated to the practice. Often if you are joining a group, the practice will look at the hours you are expected to work and whether the group will meet its financial goals. These considerations will often be a factor in determining whether moonlighting is an option.

Insurance Coverage

It is important to determine if you have an individual policy only or if the group itself is insured. If it is an incorporated group, many times only the psychiatrist has an individual policy, not the group. As previously

stated, in the event of a lawsuit, plaintiffs' attorneys typically file suit against the individual physician or physicians involved in the care of the patient as well as the group. By adding multiple defendants, plaintiff's attorneys can maximize the insurance policies which could potentially be involved. It is important to determine whether the group itself has separate coverage. This will likely impact the policy limits involved and may determine whether your personal assets are at risk.

If you decide to open your own practice and set up an LLC or D/B/A, or if you join an existing group practice, you should inquire about additional coverage for the practice — as well as insuring yourself personally — as

It is important to determine whether the group itself has separate insurance coverage. This will likely impact the policy limits involved and may determine whether your personal assets are at risk.

issues may arise in the event of a lawsuit. For example, let's assume that you are a physician employed by a group practice and the group is incorporated. A patient commits suicide and his family files suit against you and the group. The limits on your personal policy are \$1 million. However, the group does not have its own policy (i.e., it is not separately insured). If the group were insured then there would

potentially be additional monies available to cover any potential settlement or verdict. Thus, it is crucial to inquire into additional coverage for your group practice.

If joining an existing practice or setting up a group practice, it is also important to determine whether you will have insurance tail coverage after you leave the group for acts while with the group. Equally important is to know in advance who will be responsible for paying for coverage.

Record Retention

Before joining an existing practice or forming a new practice, you will need to determine who will own and maintain your patients' medical records. Additionally, you will need to know if the records are electronic (EMR) or in written form, or a combination of the two. You should also determine if you will be allowed to take your patients' records with you if you should ever leave the practice.

Important Issues to Consider in EMR Systems: If you plan to have an EMR system and your practice is part of a larger healthcare entity, is the EMR system in your office the same system as that entity or is it separate and apart from the entity's system? This may be important when and if a patient becomes hospitalized. If there is inadequate access to documentation, there may likely be a gap in the continuity of care. In other words, do providers in the healthcare entity have access to the same information as the psychiatrist in his office and vice versa? If they do not have access to the same information, then it may become problematic in the overall care of the patient.

Important Issues to Consider When Dealing with Separate EMR systems: Do you have access to all or only a portion your patient's records from that entity and do other providers have access? Is there a back-up system in case there is an electronic record failure? If there is no back-up system, then records may be permanently lost and this not only may be problematic in the care and treatment of the patient at the present time but also down the road — either when the patient has ceased treatment or in the event that the patient/family files suit.

How are the electronic medical records retained? Each state has its own regulations on the length of time records should be retained, whether written or electronic. Check with your specific state on how long you are required to keep patients' medical records. For more information, see "How Long Do You Keep Records?"

Important Issues to Consider in Written Documentation: As you are providing psychiatric care, it is important that your office has proper policies in place to maintain medical records which are compliant with the law and regulations within your state. Psychiatric records are often highly confidential and sensitive in nature. As such, whether beginning anew or joining an existing partnership, you should be aware of how records are maintained. For example, if your office stores records in a box in the basement of a building which becomes flooded, the stored records could be destroyed. A spoliation issue may arise in the event that you are sued. Thus, having a safe, secure storage area may protect you down the road.

How Long Do You Keep Records? The National Association of Medical Record Administrators recommends that medical records be retained for ten years. However, how long you are obligated to keep patients' medical records varies on a state-by-state basis. For example, Missouri indicates that records are to be kept a minimum of seven years from the date the patient was last seen.³⁷ In contrast, Massachusetts indicates that records may be destroyed twenty years after the discharge or the final treatment.³⁸ Therefore, it is important to check with your particular state on regulations that set forth how long you and/or your practice must retain medical records. Considering that psychiatric patients may often stop treatment for a period of time and then re-engage, maintaining records indefinitely beyond your states' statutory time frame would be prudent. In the event of a lawsuit, past records may be helpful in the overall defense of a malpractice action.

Conclusion

Joining an existing physician group or forming a new practice can be a difficult decision. We have touched upon a number of scenarios which could be encountered when weighing your options. However, there are numerous factors that come in to play in these situations. Therefore, consulting and working with an experienced attorney when considering these options is critical.

In Session with Allied World for AACAP is provided, free of charge, as a benefit for participants of the AACAP-endorsed Psychiatrist Malpractice Insurance program.

Offered exclusively through the American Professional Agency, Inc.

End Notes

Reducing the Risks Involved in Prescribing Mood Stabilizers Off-Label to Bipolar Children

¹ According to research by the Juvenile Bipolar Research Foundation.

² Karen Dineen Wagner, M.D., Ph.D., "The Challenges of Treating Youths With Bipolar Disorder," *Psychiatric Times*, June 2, 2010, Vol. 27, No. 6. The article points out that the FDA has approved treating children with bipolar I disorder with three atypical antipsychotics: aripiprazole, quetiapine and risperidone for ages 10-17; as well as olanzapine for ages 13-17; and the mood stabilizer, lithium, for ages 12-17. The FDA has not approved any medications for the treatment of bipolar disorder in patients under 10 years of age.

³ Mitchell Oates, "Facilitating Informed Medical Treatment Through Production and Disclosure of Research Into Off-Label Uses of Pharmaceuticals," October 2005, 80 *N.Y.U. L. Rev.* 1272.

⁴ American Academy of Pediatrics, Committee on Drugs; "Uses of Drugs Not Described in the Package Insert (Off Label Uses)," *Pediatrics*, 2002; 110; 181-183.

⁵ Muriel R. Gillick, M.D., "Controlling Off-Label Medication Use," *Annals of Internal Medicine*, March 3, 2009, Vol. 150, No. 344-347.

⁶ American Academy of Pediatrics, Committee on Drugs; "Uses of Drugs Not Described in the Package Insert (Off Label Uses)," *Pediatrics*, 2002; 110; 181-183.

⁷ *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001), citing to Beck & Azari, "FDA, Off Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 *Food & Drug L.J.* 71, 76-77 (1998).

⁸ Neal D. Ryan, M.D., Vinod S. Bhatara, M.D. and James M. Perel, Ph.D., "Mood Stabilizers in Children and Adolescents," *Journal of the American Academy of Child & Adolescent Psychiatry*, Vol. 38, No. 5, pp. 529-536.

⁹⁻¹¹ *Ibid.*

¹² Cincinnati Children's Hospital Medical Center performed an extensive study of mood stabilizers in treating pediatric bipolar disorder. In a press release on October 26, 2007, the hospital revealed that both Depakote and lithium were found to be effective in the pediatric bipolar population. Robert A. Kowatch, M.D. was quoted as stating that the study "proves that these agents definitely work, which may give clinicians and families peace of mind."

¹³ The FDA Release covered the following antiepileptic drugs: Carbamazepine, Felbamate, Gabapentin, Lamotrigine, Levetiracetam, Oxcarbazepine, Pregabalin, Tiagabine, Topiramate, Valproate and Zonisamide, along with the generic forms of these drugs.

¹⁴ See FDA News Release, "FDA Alerts Health Care Providers to Risk of Suicidal Thoughts and Behavior with Antiepileptic Medications," January 31, 2008.

¹⁵ See FDA News Release, "FDA Requires Warnings about Risk of Suicidal Thoughts and Behavior for Antiepileptic Medications," December 16, 2008.

¹⁶ Judith G. Edersheim, J.D., M.D., "Off-Label Prescribing," *Psychiatric Times*, April 14, 2009, Vol. 26, No. 4.

¹⁷ *Harnish v. Children's Hospital Medical Center*, 387 Mass. 152, 154 (1982)(cases cited in this case demonstrate wide support for this principle in a variety of jurisdictions, although the specific application of the doctrine may vary state to state).

¹⁸ *Harnish v. Children's Hospital Medical Center*, 387 Mass. 152, 154 (1982).

¹⁹ Edersheim, "Off-Label Prescribing."

²⁰⁻²¹ *Ibid.*

²² Gardiner Harriss and Benedict Carey, "F.D.A. Finds Increase in Suicide Symptoms for Patients Using Seizure Medications," *New York Times*, February 1, 2008.

²³ Edersheim, "Off-Label Prescribing."

²⁴ Ryan, Bhatara and Perel, "Mood Stabilizers in Children and Adolescents."

²⁵ Mitchell Oates, "Facilitating Informed Medical Treatment Through Production and Disclosure of Research Into Off-Label Uses of Pharmaceuticals," October 2005, 80 *N.Y.U. L. Rev.* 1272. Citing, the Best Pharmaceuticals for Children Act, Pub.L.No. 107-109, 115 Stat. 1408 (2002) (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.).

Culture Corner

²⁶ WHO/PAHO. (2010). *Culture and Mental Health in Haiti: A Literature Review*. Geneva: WHO (and cited references within).

²⁷ <http://www.everyculture.com/multi/Du-Ha/Haitian-Americans.html>. *Countries and their Cultures. Haitian Americans*.

²⁸ <http://pn.psychiatryonline.org/content/45/5/4.1.full>. Levin, Aaron. *No Short-Term Solutions for Haitians' MH Issues*. *Psychiatric News* (March 5, 2010). Vol. 45, No. 5, P. 4. American Psychiatric Association.

Private Practice, Group Practice or Independent Contractor?

²⁹ *Dias v. Brigham Medical Associates, Inc.*, 438 Mass. 317 (2002).

³⁰ *Ibid.*

³¹ Appelbaum, Paul, S., Gutheil, Thomas, G. *Clinical Handbook of Psychiatry & the Law*. 4th Ed. (2007).

³²⁻³³ *Ibid.*

³⁴ Guidelines for Psychiatrists in Consultative, Supervisory or Collaborative Relationships with Nonphysician Clinicians, American Psychiatric Association, 2009.

³⁵ Applebaum and Gutheil.

³⁶ Federal Register, Vol. 65, No. 194, October 5, 2000. <http://www.nachc.org/client/documents/health-center-information/health-center-growth/CorporatCompliance.pdf>.

³⁷ Missouri Revised Statutes, Chapter 334, Section 334.097(2).

³⁸ Massachusetts General Law, Chapter 111, Section 70.

Upcoming Speaking Events

Kristen Lambert will be speaking at the following event:

**ASHRM Annual
Conference**

**October
19**

10:00 – 11:00 a.m.

Phoenix, AZ

Co-Presenting with Kelley Woodfin, R.N., B. S. DFASHRM, CPHRM and Dawn Cushman, Esq.

Topic: "Legal and Risk Considerations: Managing Age-Related Psychiatric Behaviors in LTC Residents"

If you have a topic of interest, **please contact Kristen Lambert at (857) 288-6036.**

Editors

Susan R. Chmielecki, APRN, CPHRM, DFASHRM, JD

Senior Vice President

Global Risk Management and Loss Control Lead

Kristen M. Lambert, JD, MSW, LICSW

Vice President, Healthcare Risk Management



In Session with Allied World for AACAP is a quarterly newsletter which is a service provided to AACAP members by Allied World Assurance Company (U.S.), Inc. Each author is solely responsible for the statements of fact and opinions expressed in their respective articles. Information contained in the articles should not be construed as legal or clinical advice. The newsletter and the articles contained therein may not be reproduced either in whole or in part without express, written permission from Allied World Assurance Company Holdings, AG.

© All rights reserved. Allied World Assurance Company Holdings, AG. July 2011.

In Session with Allied World for AACAP

Allied World
Assurance Company
9 Farm Springs Road
Farmington, CT 06032

Please send all general
email inquiries to:
riskmanagement@awac.com

For more information, visit us on
the web at www.awac.com



American Professional Agency, Inc.

In Session with Allied World for AACAP is published in support of the American Professional Agency's child and adolescent psychiatrist insurance program, exclusively for members of the American Academy of Child & Adolescent Psychiatry.



AACAP Sponsored Medical Malpractice Insurance Program

NEWLY ENHANCED COVERAGE FEATURES*

- Fire Damage Legal Liability included
- Medical Payments Coverage included
- Information Privacy Coverage (HIPAA) included
- Licensing Board Coverage with no aggregate
- Personal Injury and Advertising Injury
- Insured's consent is required for any settlement recommended by the Insurer; Policy provides for arbitration by your peers to resolve any "consent to settle issues"
- 10% Discount for New Insureds who are claims-free in the last six months
- Lower rates for practitioners whose patient base is more than 50% Child and Adolescent
- Interest Free Quarterly Payments/Credit Card Payments are available
- No Surcharge for Claims

*Above coverage features are subject to individual state approval.

AMERICAN ACADEMY OF
CHILD & ADOLESCENT
PSYCHIATRY



American Professional Agency, Inc.
www.americanprofessional.com
(800) 421-6694