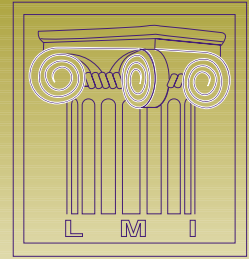


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R E P O R T E R



The Review of Medical Information Management For Litigation

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ATTENTION-DEFICIT/HYPERACTIVITY DISORDER AND PHARMACOTHERAPY

Medical Information Management Considerations in Emerging Litigation

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Introduction

Throughout its history, psychiatry has been fraught with adversity over the diagnosis of mental disorders. Unlike the situation for many medical disorders, diagnostic terminology employed by the psychiatric profession continues to evolve, as does the criteria employed to effectively diagnose mental conditions. Interventions for psychiatric disorders have been equally controversial, with medical management proponents on the right of the treatment spectrum, behaviorists at the left, and advocates of numerous combination therapies at various points in between.

Such differences have generated conflict not only within the medical ranks but also throughout the larger American public. The practice of child psychiatry is a good case in point, and given the perceived vulnerability of children and adolescents in today's society, makes this discipline susceptible to litigation. Within this subspecialty, the diagnosis and treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) is emerging as an especially formidable medical legal issue.

ADHD is often believed to be only a disturbance of school age children; however, this condition can be equally disabling for adults. Labeling a child or adult with the ADHD diagnosis can have significant social, occupational, and academic consequences. For example, a child's placement and progression in specialized school programs represents operationalization of ADHD terminology.

ADHD and Current Litigation

Litigation surrounding the diagnosis of ADHD and its treatment with psychostimulant and other medications is both diverse and possibly on the increase. At the time of the writing of this article, ADHD litigation has taken the form of a variety of mass torts and individual actions:

- ❖ At least three class actions (California, New Jersey, and Texas) have been filed against Novartis Pharmaceuticals, the American Psychiatric Association, and the group, Children and Adults with Attention-Deficit/Hyperactivity Disorder. These suits allege a con-

spiracy exists surrounding the invention and promotion of ADHD as a medical disorder and the marketing of Novartis' drug, Ritalin, as the drug of choice for its management.^{1 2} Such mass ADHD litigation has been described as the "next class-action battleground."³

- ❖ A British class action involving 34 parents and 35 children was filed against doctors who prescribed psychostimulants and allegedly failed to properly advise patients/families as to the potential side effects of these drugs or inform them of alternative treatments.⁴
- ❖ Last year in *Hall v. Novartis Pharmaceuticals Corp., et al*, one Ohio family sued Ritalin manufacturers following the death of their 11-year-old daughter from severe cardiac tachycardia,

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which they in part attributed to inadequate warnings regarding the preparation's side effects.⁵

- ❖ A lawsuit was filed by the family of a Texas boy who allegedly died following an allergic reaction to a generic form of Ritalin.⁶
- ❖ Siblings of a 19-year-old male filed a lawsuit against drug manufacturers and other parties in a case where the youth killed his parents with an ax during a state of rage, purportedly the result of his consumption of Ritalin and other psychotropic agents.⁷
- ❖ A North Dakota man was ruled not criminally responsible for the murder of his infant daughter because he was determined to have been in a rare delusional state produced by his intake of Adderall, which he took to enhance his college study skills.⁸ The family subsequently filed a civil lawsuit against the manufacturer, British-based Shire Pharmaceuticals. Shire responded that in ten million Adderall prescriptions, only fourteen cases of "very mild" psychosis had been reported.⁹
- ❖ Two New York parents were directed by the court to administer Ritalin to their seven-year-old son to control his behavior in school, despite their contention he suffered from medication side effects of loss of appetite and sleep.¹⁰
- ❖ Some attorneys have identified an increase in discrimination lawsuits filed on behalf of adults undergoing treatment for ADHD, who contend they need special accommodation to function on the job or in school.¹¹

This diversity of cases may be indicative that ADHD-based litigation is still evolving. As additional verdicts are rendered in ADHD lawsuits, a more cohesive "theme" may emerge, and for purposes of this paper, clarify the role of medical information management in formulation of defense strategy.

Additional Legal Issues

Concern also has arisen over the recreational use (or rather misuse) of some of the medications currently in use for treatment of ADHD. A Massachusetts study indicated that almost thirteen

percent of surveyed high school students reported they had abused Ritalin at some time, such as crushing and snorting the pills to obtain a "high." Oftentimes, psychostimulant medication which has been legitimately prescribed to an individual for treatment of ADHD ends up in the illicit drug market stream through either sale or theft of the prescription product.¹²

Ongoing dispute exists over the possibility that prescribed use of some ADHD medications may result in the patient becoming more prone to addictive disorders in adulthood. There presently is no answer to this question. Research studies have supported positions arguing both sides of this debate.¹³ However, a 1999 study released by the National Institute of Health noted that boys who underwent treatment for ADHD with psychostimulants were less prone to abuse drugs and alcohol in later life.¹⁴

Another growing trend has been the prescription of ADHD medication to preschool children, although the safety of this practice has not been established. For instance, Novartis Pharmaceuticals clearly specifies in the *Physicians' Desk Reference* that Ritalin should not be prescribed to children under age six because its safety and efficacy have not been determined for this population.¹⁵ Nonetheless, off-label prescription practices are not uncommon. Most strikingly, in a study of ambulatory care prescription patterns for the years 1991, 1993, and 1995 in one health maintenance organization (HMO) and two state Medicaid programs, investigators discovered that the prevalence of methylphenidate administration to preschool patients had actually increased, sometimes by as much as three (3) fold.¹⁶ Accordingly, an editorial in the *Journal of the American Medical Association* called for much more extensive study of the effects of such prescription practice in preschoolers, given the rapid developmental changes taking place in the brain during early childhood years.¹⁷

Rendering a Diagnosis

Unfortunately, at this time there are no universally accepted diagnostic or laboratory tests which can definitively identify a case of ADHD. Instead, the diagnosis of this disorder is established via observational and subjective assessments of a number of facets of the patient's day-to-day functioning. This can make diagnosing ADHD contentious. Combined behavioral, school, occupational, and social impressions rendered by such nonmedical parties as parents, teachers, and employers may play a more pivotal role in diagnosing ADHD than a physician's stand-alone evaluation. Indeed, published protocols for diagnosing ADHD may actually discourage rendering a diagnosis solely on the basis of a physician's office assessment.^{18 19}

Although the subject of some of the present controversy in ADHD and psychostimulant litigation, criteria published by the American Psychiatric Association in its *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*



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(*DSM-IV-TR*TM) are the benchmarks by which the ADHD diagnosis is made.²⁰ See Figure I. The *DSM* has experienced significant revisions over the years as psychiatry has gained deeper insights into the nature of mental disorders. Accordingly, the medical legal reviewer should maintain a library of older versions of the *DSM* to support analysis of plaintiff medical records, some of which may date from several years past.

Patient Characteristics

According to the American Psychiatric Association, approximately 3-7% of school age children suffer from ADHD. It occurs two to nine times more frequently in males than females. Causation is unclear, but a genetic element is suspected.

Typically, ADHD is diagnosed in the early school years when a child experiences difficulty adjusting to the constraints and expectations of the academic environment. Problematic behavior which *might* indicate early signs of ADHD may be noted by parents in their preschool children; however, diagnosis at this age is difficult because of problems distinguishing normal preschool exuberance from true ADHD. Although ADHD may run its course by late adolescence, some individuals may continue to manifest this disorder into adulthood. In these cases, occupational, collegiate, and social performance may be impacted.²¹

Treatment

Although much remains unknown about the etiology of ADHD, it is believed that dopamine imbalances in the brain play an important role. Use of positron emission tomography (PET) in one newly-released study indicated that oral Ritalin amplified dopamine release, leading to researcher speculation that this biochemical adjustment would account for the improvement of ADHD symptoms experienced in Ritalin therapy.²²

The highly publicized 1999 Multimodal Treatment Study of Children with Attention-Deficit/Hyperactivity Disorder (MTA) study confirmed that carefully structured medication management of ADHD was superior to behavioral treatment alone. In fact, combined medication and behavioral therapy was found not to produce significantly greater benefits for core ADHD symptom relief than drug therapy alone.^{23 24}

“First-line” medications for treatment of ADHD are the psychostimulants, such as methylphenidate (Ritalin), dextroamphetamine (Dexedrine), and amphetamine salt mixtures (Adderall). Psychostimulants are reported to be effective in 70-80% of childhood ADHD cases.²⁵ According to one 1999 article, methylphenidate is prescribed for over ninety percent of children in the United States with diagnosed ADHD.²⁶

The impact of psychostimulant medication in the management of ADHD symptoms can be dramatic. Advocates of drug therapy for ADHD note that almost immediately

Figure I

Diagnostic Criteria for Attention-Deficit/Hyperactivity Disorder

A. Either (1) or (2):

1. Six (or more) of the following symptoms of **inattention** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

Inattention

- (a) often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities
- (b) often has difficulty sustaining attention in tasks or play activities
- (c) often does not seem to listen when spoken to directly
- (d) often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace (not due to oppositional behavior or failure to understand instructions)
- (e) often has difficulty organizing tasks and activities
- (f) often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
- (g) often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)
- (h) is often easily distracted by extraneous stimuli
- (i) is often forgetful in daily activities

2. Six (or more) of the following symptoms of **hyperactivity-impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

Hyperactivity

- (a) often fidgets with hands or feet or squirms in seat
- (b) often leaves seat in classroom or in other situations in which remaining seated is expected
- (c) often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness)
- (d) often has difficulty playing or engaging in leisure activities quietly
- (e) is often “on the go” or often acts as if “driven by a motor”
- (f) often talks excessively

Impulsivity

- (g) often blurts out answers before questions have been completed
- (h) often has difficulty awaiting turn
- (i) often interrupts or intrudes on others (e.g., butts into conversations or games)

- B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
- C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).
- D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.
- E. The symptoms do not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder and are not accounted for by another mental disorder (e.g., Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).

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after administration, impulsive behavior decreases and attention span increases. This allows the ADHD patient to better concentrate and function more effectively in school or on the job.²⁷ Critics contend that such functional improvements can be also observed in non-ADHD subjects who receive psychostimulants.²⁸

“Second-line” medications may be prescribed in cases that are unresponsive to first-line drugs, or in which these agents have produced problematic side effects. Examples of second-line medications are the non-tricyclic antidepressants, such as bupropion (Wellbutrin); the antihypertensive, clonidine (Catapres); the tricyclic antidepressants, imipramine (Tofranil) and desipramine (Norpramine); and the stimulant, pemoline (Cylert).²⁹ These agents are also indicated in ADHD cases which present with associated psychiatric comorbidity. For example, many adults with ADHD also suffer from depression. One recent study found a 42% ADHD symptom reduction in adults treated with bupropion.³⁰

The use of psychotropic medications has soared in the treatment of childhood psychiatric disorders. The United Nations Narcotics Control Board reported that 8.5 tons of ADHD medication were distributed globally in 1994, with the United States consuming 90% of this amount.³¹ It is estimated that over five million children in the U.S. are prescribed Ritalin alone.³² In England, Ritalin prescriptions increased for children from 3,500 in 1993 to 126,000 in 1998, to 131,000 in 1999.^{33 34} A Canadian study of psychostimulant prescription practices revealed that such compounds were also more highly prescribed in adult patient populations than indicated by earlier studies.³⁵

Adverse Medical Effects

Pharmacotherapy involving the psychostimulants has become especially contentious because of possible side effects of these agents in the ADHD patient. In the case of methylphenidate, adverse reactions include, but are not limited to:

- ❖ **Neurologic:** Nervousness, insomnia, dizziness, headache, dyskinesia (impaired movement of voluntary muscles), drowsiness.
- ❖ **Cardiovascular:** Palpitations, blood pressure and/or pulse changes, angina (chest pain), tachycardia, arrhythmia.
- ❖ **Gastrointestinal:** Anorexia, nausea, weight loss, abdominal pain.
- ❖ **Hypersensitivity:** Skin rash, urticaria (itching skin wheals), fever, arthralgia (joint pain), dermatitis, etc.
- ❖ **Psychiatric:** (Rare) Tourette’s syndrome, toxic psychosis.
- ❖ **Other:** Although reported as potentially problematic, a definitive causal relationship to methylphenidate use

has not been established for abnormal liver function, cerebral arteritis, leukopenia, anemia, transient depressed mood, and hair loss.³⁶

Record Acquisition and Mass Torts

Attorney Connie Matteo, of Porzio, Bromberg & Newman in Morristown, New Jersey, has been monitoring the status of large scale psychostimulant litigation and recently co-authored an analysis of the future of methylphenidate class actions.³⁷ In an interview with *The M.I.M. Reporter*, Matteo notes that it is somewhat early to predict the direction that medical information management would take in the defense of the mass tort. However, she envisions at least two scenarios.

If mass litigation for methylphenidate remains predicated on the conspiracy concept, Matteo indicates that certain facets of medical information management, such as medical record retrieval and review for individual plaintiffs, would probably not be a central focus in the case. On the other hand, if allegations of medical injury overshadow the conspiracy theory in driving mass litigation involving these pharmaceutical agents, Matteo states that medical information management requirements would be more encompassing. In this situation, a thorough acquisition and review of medical, occupational, school, and other records for each claimant would be a necessity.³⁸

Record Acquisition and Individual Cases

In contrast to the aforementioned mass tort/class action situation, medical information management requirements for single cases involving prescription of psychostimulants for ADHD are much clearer at this time. Medical allegations for these individual cases can be more clearly defined and accordingly, record acquisition, review, and analysis can be structured with greater precision.

Joseph Thomas, a partner at Cincinnati’s Ulmer and Berne, comments that in personal injury cases involving the administration of psychotropic medications, all inclusive retrieval of medical records can be crucial for a full investigation. For example, according to the *DSM-IV-TR*, to render a diagnosis of ADHD, some hyperactive or inattention symptoms will manifest in the child before age seven (7). Accordingly, medical discovery in an ADHD case could require complete retrieval of medical and school records as far back in time as they are available.^{39 40}

Record Review and Analysis

The evolving status of ADHD and psychostimulant litigation can pose challenges when defense attorneys engage in strategic planning for cost-effective medical information management. The following overview will outline the record review activity from a generalist perspective; in actual application with an individual case, record review can be more specifically targeted.

- **Informed Consent:** In confronting allegations of insufficient patient education regarding the availability of alternative therapies for ADHD or the possible side effects of psychostimulant medications, one should search medical records to locate documentation establishing that such instruction actually took place. In some cases, an actual informed consent sheet may be located in physician or hospital records. More likely however, physician and nursing progress notes will need to be reviewed to precisely identify what information was communicated verbally to patients/families. These notes may also describe standardized, printed materials that were dispensed, such as drug inserts or information sheets developed by the individual prescriber or dispensing pharmacy.
- **Product Identification:** Early in the discovery process, defense attorneys should confirm product identification. Physician prescription, pharmacy, hospital medication administration, and other treatment records must be reviewed to ascertain if the preparation named in the lawsuit was in fact administered to the plaintiff, or if it was in reality a generic or other agent manufactured by a different pharmaceutical company. Examination of insurance billing records can prove invaluable in uncovering all dispensing sources for a plaintiff's medications.
- **Neurological Records:** The *PDR* notes that there is some clinical evidence that Ritalin may lower a patient's seizure threshold.⁴¹ If this contention arises in an ADHD treatment lawsuit, all physician neurologic assessments should be evaluated to determine the actual time of appearance of convulsions and tests administered in their subsequent evaluation.

Observation of patients for tic disorders (involuntary, repetitive movements usually involving the face or shoulders) is recommended during the administration of methylphenidate. One review of recent research reports notes that methylphenidate does not cause or worsen existing tics.⁴² However, if such allegations arise during litigation, physician and hospital records should be assessed for the date of appearance and/or worsening of tic disorders. Likewise, because rare reports of Tourette's syndrome have been associated with Ritalin therapy,⁴³ similar discovery techniques for this condition should be executed.

Insomnia and nervousness are more frequently observed, but are usually less severe, side effects observed in children receiving psychostimulant therapy for ADHD. Evaluating the etiology of these symptoms can be difficult, as they can be associated with a medley of disorders exclusive of medication intake. Record analysis should determine date(s) of onset for these symptoms, suspected causation, and outcomes of any treatment.

- **Psychiatric Records:** Records of evaluation and treatment at psychiatric facilities should be reviewed to ascertain the presence of mental disorder co-morbidity, and the misapplication of psychostimulant therapy. For example, Ritalin's manufacturer does not advocate the agent for treatment of certain pre-existing depressive states. Likewise, Ritalin is not advised for use in children diagnosed with psychotic disorders, because thought disorder symptomatology might increase.⁴⁴

In litigation alleging the induction of a psychotic state arising from Ritalin or other ADHD medication therapy, review of psychiatric records is especially important to identify the presence of delusions, hallucinations, disorganized thoughts and behavior, and "negative symptoms," such as flat emotional affect, which may have been diagnosed before the initiation of ADHD treatment. A review of pharmacy records which reveals prescription of major tranquilizers, i.e. Haldol, Clozaril, Thorazine, etc., prior to the initiation of ADHD therapy is a strong indicator of a diagnosed pre-existing psychotic state.

Ritalin and other psychostimulants should be cautiously prescribed in patients with known histories of drug or alcohol abuse. Accordingly, plaintiff records from any substance abuse rehabilitation facilities and drug/alcohol counselors should be reviewed to identify any misuse of prescribed medication.

- **Cardiovascular Records:** The date of appearance and progression of any cardiovascular disorders should be noted during a review of physician and hospital records. Items of special importance in psychostimulant litigation are repeated headaches, dizziness, blood pressure abnormalities, angina (chest pain), tachycardia, and heart arrhythmias. In addition to documentation in progress notes,

Medical Malpractice Publishes Pressure Ulcer Article

Does your insurance company or law firm represent defendants confronted by nursing home litigation? The February 2001 edition of *Medical Malpractice Law & Strategy*, Leader Publications, a division of the New York Law Publishing Company, featured LMI's article describing the medical information management aspects of these cases. If you missed out on reading this issue, please contact James Fell at 440-484-2000 to receive a free copy of this article, or send LMI a message via contactlmi@litigation-mgmt.com.

the reviewer should consider findings contained in electrocardiograms (EKG) reports, graphic records of pulse and blood pressure measurements, and any special cardiac examinations.

- **Diagnostic Tests:** The American Psychiatric Association states that there are presently no laboratory tests for the diagnosis of ADHD.⁴⁵ However, the medical record may contain reports of electroencephalogram (EEG) evaluation designed to rule out other neurological disorders. Blood cell studies should be evaluated for abnormalities, as the *PDR* description for Ritalin advises their monitoring in prolonged drug therapy.⁴⁶

Neurological changes induced by lead, mercury, solvent, and other toxic exposures can seriously impact a child's mental development and behavior. Any toxicology studies, such as blood lead levels, should be closely examined.

- **School Records:** Review of school records will uncover details regarding concerns over academic, cognitive, social, and behavioral functioning. Documentation from a number of professionals—teachers, special education personnel, psychologists, various therapists, school nurse—should be perused to establish dates of diagnosis, initiation of psychostimulant therapy, compliance with therapy, parents' support of therapy, etc. Academic records will include notes from interdisciplinary team meetings in which the child's disorder was discussed, as well as a written blueprint for educational and behavior management, such as an Individualized Educational Plan (IEP).

Batteries of tests will be administered to the child with ADHD. Individual studies may include IQ tests (Wechsler Intelligence Scale for Children, Stanford-Binet, Kaufman Assessment Battery for Children, and Woodcock Johnson Psychoeducational Battery Tests of Cognitive Ability) and achievement tests (Woodcock Johnson Psychoeducational Battery: Tests of Achievement, Peabody Individual Achievement Test, Wide Range Achievement Test, Key Math, and Wechsler Individual Achievement Test). Group tests, i.e. the Iowa Tests of Basic Skills, although commonly administered, are not adequate in themselves for formal ADHD assessment.

Behavioral rating scales may be included in school records, or in those of an outside psychologist. Recommended tests include the ADHD-IV Rating Scale, which separates inattention and hyperactive/impulsive factors; the Child Attention Profile, which separates overactive and inattention factors; and the Conners Parent & Teacher Rating Scale, consisting of multiple scales that assess conduct, learning, impulsivity/hyperactivity, psychosomatic issues, and anxiety dimensions.⁴⁷ While results from these tests should be noted by the medical legal reviewer, actual interpretation is best referred to a child psychologist skilled in this field.

- **Growth Charts:** The significance of growth decreases possibly associated with methylphenidate and ADHD are unclear, and may be related to the anorexic side effect of psychostimulant use.⁴⁸ Because growth suppression allegations may be incorporated into ADHD litigation, growth charts located in pediatric records should be reviewed. If these are not available, pediatric progress notes will contain height/weight documentation for many office visits. This information can be graphically plotted to ascertain the relevance of any growth reductions, when compared to actual periods of drug intake and drug "vacations."
- **Speech Therapy:** Up to 50% of children with ADHD may evidence speech disturbances. Evaluation of childhood speech problems should differentiate between conditions arising from ADHD and those of other childhood disorders, such as autism, tics, or Tourette's disorder.⁴⁹ Speech therapy may be administered in the school setting, in which case these records should be acquired for review when requesting other academic records. However, the plaintiff may have undergone speech therapy by an independent practitioner or in conjunction with a hospital or medical clinic. To locate documents in these cases, insurance billing records should be reviewed as this can be a treatment covered in part by third-party payers.
- **Learning Centers:** Educational records from learning centers are often overlooked as informational resources regarding a plaintiff's ADHD and performance disturbances. Various types of behavioral and learning evaluations may be administered in these programs. Because the expense of these adjunct academic services is typically borne by the family, information regarding the use of such services may be difficult to discover because of the lack of an insurance paper trail. However, close review of school, psychologist, and other records may reveal sufficient data to inquire about such services during deposition.
- **Independent Psychologist:** Children and adults with ADHD may be evaluated and treated by psychologists outside the school or work environment. Insurance billing records and referral notations in other medical records will assist in discovery of records for these providers.
- **Employment:** Review of an adult claimant's military, employment, Workers' Compensation, and Social Security records should be undertaken to identify the extent of any ADHD disability and treatments. Documentation may exist wherein the worker officially requested special accommodation for his ADHD disorder.

Employers increasingly utilize the services of occupational psychologists to evaluate the capabilities of job applicants or to subsequently assess performance difficulties following hire. Most companies do not retain the services of a full-time occupational

psychologist, but instead will contract for such assistance on an hourly basis. Records from these practitioners may or may not be a component of the typical employment record; however, the consulting occupational psychologist should maintain such files in his/her office. Accordingly, these documents must be acquired separately from other employment records.

Summary

Although it is still relatively premature to accurately forecast the scope of emerging ADHD and psychostimulant litigation, certain elements of these cases are already clear. The difficulties inherent in arriving at definitive diagnoses for ADHD, coupled with the emotionality associated with diagnostic labeling and treatment, will have the potential to stimulate litigation. Medical information management requirements will be somewhat limited in psychostimulant litigation constructed on theories of organizational collusion and corporate documentation. On the other hand, medical information management will play an extremely important role for those actions in which actual or perceived medical injuries are designated as the primary focus.

- 1 A Donohue. Criticism of Ritalin use induces lawsuits, federal investigations. *The Fresno Bee*. December 25, 2000:A1.
- 2 MP Gallagher. Ritalin under attack in class actions. *The National Law Journal*. October 23, 2000:A4.
- 3 E. Tobin. Tobacco antagonist zeroes in on Ritalin. *Reuters News*. September 15, 2000.
- 4 J West. Legal battle launched for Prozac children. *The Scotsman*. April 3, 2000:4.
- 5 Andrews Publications. Lawsuit claims Ritalin caused child's death. *Andrews Diet Drugs Litigation Reporter*. 2000;3(7):12.
- 6 MJ Layton, L Washburn. Hyperactive kids: victims of a plot? *The Record (Bergen County, NJ)*. October 1, 2000:A1.
- 7 Associated Press. Suits filed over 1998 killings of Huntsville couple. March 15, 2000.
- 8 Associated Press. Judge says father lacked criminal responsibility in baby shooting. October 7, 1999.
- 9 S Boseley. Family sues drug firm over baby killing. *The Guardian (London)*. September 23, 2000:11.
- 10 C Shepherd. Campaigning for an insanity plea. *The Augusta Chronicle*. September 24, 2000:F2.
- 11 M Boorstein. Adults face kids' learning problems. *Associated Press Online*. March 1, 1999.
- 12 P Wen. 'As easy to get as candy' a new Mass. study finds wide teen abuse of Ritalin. *The Boston Globe*. October 29, 2000:A1.
- 13 A Donohue. Ritalin under growing attack 'quick fix' concerns over drug. *Sacramento Bee*. December 23, 2000:A1.
- 14 National Institutes of Health news release. Boys treated with Ritalin, other stimulants significantly less likely to abuse drugs later. August 2, 1999.
- 15 Medical Economics Company. *Physicians' Desk Reference*. Montvale, NJ, 2001:2206.
- 16 JM Zito, DJ Safer, S dosReis, JF Gardner, M Boles, F Lynch. Trends in the prescribing of psychotropic medications to preschoolers. *JAMA*. 2000;283(8):1025-30.
- 17 JT Coyle. Psychotropic drug use in very young children. *JAMA*. 2000;283(8):1059-60.
- 18 PDR 2001: 2206.
- 19 American Academy of Pediatrics, Committee on Quality Improvement, Subcommittee on Attention-Deficit/Hyperactivity Disorder. Clinical practice guideline: Diagnosis and evaluation of the child with Attention-Deficit/Hyperactivity Disorder. *Pediatrics*. 2000;105(5).
- 20 American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*. Washington, DC: American Psychiatric Association, 2000: 85-93.
- 21 APA. *DSM-IV-TR*. 89-92.
- 22 National Institute on Drug Abuse press release. NIDA research expands understanding of treatment for ADHD. January 16, 2001.
- 23 MTA Cooperative Group. A 14-month randomized clinical trial of treatment strategies for Attention-Deficit/Hyperactivity Disorder. *Arch Gen Psychiatry*. 1999;56:1073-86.
- 24 MTA Cooperative Group. Moderators and mediators of treatment response for children with Attention-Deficit/Hyperactivity Disorder. *Arch Gen Psychiatry*. 1999;56:1088-1096.
- 25 Institute for Clinical Systems Improvement. Diagnosis and management of attention deficit hyperactivity disorder in primary care. Bloomington, MN; 2000:28-29.
- 26 HC Kimko, JT Cross, DR Abernethy. Pharmacokinetics and clinical effectiveness of methylphenidate. *Clin Pharmacokinet*. 1999;37(6):457.
- 27 Medication effectively treats ADHD; decision to use it controversial. *Today's School Psychologist*. 2001;4(6).
- 28 WB Carey. What the Multimodal Treatment Study of children with Attention-Deficit/Hyperactivity Disorder did and did not say about the use of methylphenidate for attention deficits. *Pediatrics*. 2000;105(4 Pt 1):863.
- 29 ICSI: 32-33.
- 30 TE Wilens, TJ Spencer, J Biederman, K Girard, R Doyle, J Prince, D Poliser, R Solhkhah, S Comeau, MC Monuteaux, A Parekh. A controlled clinical trial of bupropion for attention deficit hyperactivity disorder in adults. *Am J Psychiatry*. 2001;158:282-8.
- 31 C Wittmeier. More reasons not to drug kids. *Alberta Report*. 1999;26(39):29.
- 32 Andrews Publications. Class action claims deceit to boost Ritalin profits. *Andrews Diet Drugs Litigation Reporter*. 2000;3(10):13.
- 33 A Browne. The battle for children's minds. *The Observer News*. April 9, 2000:19.
- 34 S Beck. Are too many children needlessly drugged? *The Times (London)*. June 20, 2000.
- 35 C Beck, P Silverstone, K Glor, J Dunn. Psychostimulant prescriptions by psychiatrists higher than expected: A self-report survey. *Canadian Journal of Psychiatry*. 1999;44.
- 36 PDR. 2207.
- 37 DJ Campbell, CA Matteo, JG Calella. The conspiracy theory: Plaintiffs' latest weapon in the battle for class certification. *Mealey's Emerging Drugs & Devices*. 2000;5(21).
- 38 Connie Matteo. Telephone interview. January 25, 2001.
- 39 Joseph Thomas. Telephone interview. January 22, 2001.
- 40 APA. *DSM-IV-TR*. 85.
- 41 PDR. 2206.
- 42 TD Challman, JJ Lipsky. Methylphenidate: Its pharmacology and uses. *Mayo Clin Proc*. 2000;75:715.
- 43 PDR. 2207.
- 44 PDR. 2206.
- 45 APA. *DSM-IV-TR*. 81.
- 46 PDR. 2206.
- 47 ICSI. Dx & management of ADHD: 21-2, 42.
- 48 Challman, Lipsky. 715.
- 49 ICSI. Dx & management of ADHD: 46.

BOOK REVIEW

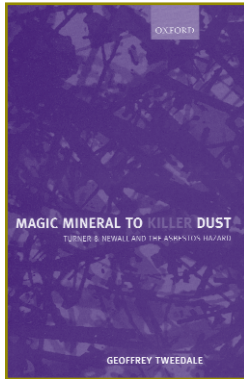
G TWEEDALE. *Magic Mineral to Killer Dust: Turner & Newall and the Asbestos Hazard.*
NEW YORK: OXFORD UNIVERSITY PRESS, 2000. HARDCOVER, 313 PAGES.

In 1995, Chase Manhattan Bank sued the British asbestos company, Turner & Newall, to recover costs associated with removal of asbestos-containing products from its New York office building. During the discovery phase of this litigation, Turner & Newall was required to release approximately one million documents, which were subsequently micro-filmed and made public by Chase Manhattan. This archive proved to be a valuable resource for historian Geoffrey Tweedale, who sifted through these and other materials to author a chronology of British social policy for asbestos-related diseases and how it impacted one of the world's major asbestos products manufacturers. The remainder of this review will present some highlights of his analysis.

The rise of asbestos medicine in Britain occurred in phases. Although originally marketed as a "magic mineral," allegorically depicted in advertisements as a Greek goddess, "Lady Asbestos" was noted over one hundred years ago to negatively impact the health of exposed workers. Even though the connection was not well understood prior to the 1920's, some British physicians coined the term "asbestos poisoning" in an attempt to define medical conditions they observed in asbestos workers but could not fully comprehend.

Dr. William Cooke first coined the term "asbestosis" to describe the lung pathology he observed in a 1927 autopsy on an asbestos worker. The rising numbers of deaths from asbestosis soon alarmed the British government; con-

sequently, in 1931 Asbestos Industry Regulations were implemented to control dust exposures in a limited number of specified asbestos occupations. Concurrently, the Medical Arrangements Scheme was put in place to provide medical monitoring and compensation for certain restricted categories of asbestos workers.



British asbestos policy functioned essentially unchanged until 1970—with disastrous effects according to Tweedale. For forty years, the British approach to the asbestos problem emphasized medical monitoring of workers with asbestosis, rather than addressing the actual etiology of the problem. In part, this policy was a victim of its times. During the Depression of the 1930's people were preoccupied with maintaining employment. Subsequently, Britain's rearmament for World War II placed a focus on national security needs. To a great degree the medical and epidemiological aspects of asbestos exposure and asbestos-related diseases remained poorly understood.

Until the 1940's, instances of lung cancer among British asbestos workers were so uncommon that some medical authorities disputed the association. As an increasing number of these cases arose, research documenting the asbestos-lung cancer connection was published, beginning in the early 1950's. Up to this point, British asbestos policy had been driven by the 1930's asbestosis paradigm. The author notes that this narrow perspective had an unfortunate outcome in that it provided the foundation for programs of medical evaluation and compensation for workers with

other, more life threatening asbestos-related diseases. In some cases, financial compensation for asbestos-related lung cancer victims was denied because it did not fall under the 1930's Medical Arrangements Scheme. It was to take thirty years for the British government to recognize asbestos-related lung cancer as a compensable disability.

In the meantime, the third and most severe asbestos-related disease appeared among British workers. It was some time before British physicians understood the disease process and etiology of mesothelioma, and understandably so. For example, while asbestosis demonstrates a dose-response relationship, mesothelioma has more of an "all or none" type of response. The actual exposure insult can be relatively brief. In addition, mesothelioma is characterized by a long lag period, that can be as long as forty or more years between the date of offending exposure and onset of disease. Rising numbers of mesothelioma cases delivered a deathblow to the British asbestos industry. Once perceived as a "magic mineral," Lady Asbestos had become a "killer dust."

Despite the implementation of strong occupational control measures coupled with the movement away from use of asbestos-containing products, the medical fallout from asbestos exposure is expected to continue well into this millennium. Tweedale predicts a continued rise in British mesothelioma mortality with a peak in the year 2020 at 2,700-3,300 deaths. Citing a British government estimate, Tweedale forecasts annual mortality of 5,000 to 10,000 for all asbestos-related diseases combined. Indeed, the asbestos crisis is far from over.

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