

PsychRights[®]

Law Project for Psychiatric Rights, Inc.

May 5, 2009

Senator Charles E. Grassley
135 Hart Senate Office Building
Washington, DC 20510-1501

Re: Pediatric Psychopharmacology Representing Medicaid
Fraud

Dear Senator Grassley:

I. Summary

In the early 1990's, the drug companies began targeting children and youth for psychiatric drugs beyond the use of stimulants on children diagnosed with Attention Deficit Hyperactivity Disorder (ADHD). As a result, claims to Medicaid for psychiatric drugs prescribed to children and youth has skyrocketed. In 2006, the care and treatment for children diagnosed with mental disorders rose to approximately \$9 Billion. In no small part because of your courageous work, the fraudulent activities of drug companies in promoting off-label pediatric use of psychiatric drugs in children and youth has begun to be exposed. It is hard to come up with an adjective that adequately conveys the horror this is inflicting on America's children and youth. Suffice it to say that when the country wakes up to the carnage this has caused, it will be recognized as the largest iatrogenic (doctor caused) public health disaster in history.

The scope of harm and complete lack of morality can be analogized to our current economic debacle caused by unrestrained Wall Street greed. It is much worse, here, however, because children's and youth's future, health, and even lives, have been sacrificed and continue to be sacrificed on the altar of corporate profits.

We must try to end this horror as soon as possible and I am writing to suggest a means to do so.

While it is not illegal for doctors to prescribe drugs for off-label use, through work in a piece of litigation we are conducting, *Law Project for Psychiatric Rights v. State of Alaska et al.*,¹ we have discovered that it is illegal for the vast bulk of these prescriptions to be reimbursed by Medicaid. Thus, we are asking for your assistance in stopping these illegal reimbursements. Also, because most current child psychiatrists no longer know how to help children and youth without resort to the drugs, we are suggesting that the savings be used to fund approaches that have been proven to be safe and effective.

II. Background

The Law Project for Psychiatric Rights (PsychRights[®]) is a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock around the country. Children and youth are almost always forced to take these drugs because they are not the ones making the decisions and are generally not allowed to

¹ Case No. 3AN 08-10115 CI, Superior Court, Third Judicial District, State of Alaska.

decline them. Starting in December of 2004, due to the unprecedented increase in the use of these extremely harmful psychiatric drugs in children and youth, PsychRights attempted to get the State of Alaska to rectify the situation. After almost four years of unresponsiveness, last Fall PsychRights filed *Law Project for Psychiatric Rights v. State of Alaska, et al.*,² seeking declaratory and injunctive relief that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until:

1. evidence-based psychosocial interventions have been exhausted,
2. rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
3. the person or entity authorizing administration of the drug(s) is fully informed, and
4. close monitoring of, and appropriate means of responding to, treatment emergent effects are in place,

and that all children and youth currently receiving such drugs be evaluated and brought into compliance with the above.³

In working on the case, the question arose whether it is illegal to submit claims to Medicaid for the vast bulk of pediatric prescriptions because they are for "off-label" uses, i.e., uses that are not approved by the FDA. PsychRights then conducted an investigation and has determined that the vast majority of psychiatric prescriptions paid for by Medicaid constitutes Medicaid Fraud.

III. Analysis

In 42 USC 1396R-8(k)(3), as relevant here, Congress prohibited reimbursement under Medicaid for any outpatient drugs "used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) then defines "medically accepted indication" as follows:

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC 1396R-8(g)(1)(B)(i), in turn, designates the compendia as:

- (I) American Hospital Formulary Service Drug Information;
- (II) United States Pharmacopeia-Drug Information (or its successor publications); and
- (III) the DRUGDEX Information System.

² Case No. 3AN 08-10115 CI, Superior Court, Third Judicial District, State of Alaska.

³ A copy of the Complaint and latest Amendment are enclosed herewith as Attachment A.

Thus, Congress has established the "universe" of outpatient drugs for which it is permissible to seek Medicaid Reimbursement to indications approved by the FDA or supported by one or more of the designated compendia. This is confirmed by *U.S. ex rel. Franklin v. Parke-Davis*.

[U]nless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.⁴

IV. Pervasive Prohibited Pediatric Psychopharmacology Payments

A tremendous percentage of psychotropic prescriptions to children and youth paid by Medicaid do not qualify for reimbursement. For example, no anti-convulsants masquerading as "mood stabilizers," such as Depakote or Tegretol, have been approved for pediatric psychiatric use or supported by any of the compendia. However, these drugs, especially Depakote, are routinely paid for by Medicaid without any apparent consideration that the practice has been prohibited by Congress.

With respect to the second generation neuroleptics, no pediatric use of Seroquel, Zyprexa or Geodon is approved by the FDA or supported by any of the designated compendia. Risperdal is approved for very narrow uses, as is Abilify, but even when prescribed for these indications, they are almost always prescribed concurrently with another drug(s), which is not FDA approved or supported by any of the designated compendia. In 2007, through a state Freedom of Information Act Request, PsychRights was able to find out that Medicaid was paying approximately \$123,000 per month for anticonvulsants prescribed to children and youth and \$288,000 per month on second generation neuroleptics for a total averaging approximately \$411,000 per month in improper Medicaid payments in Alaska alone.⁵ Extrapolating this to the entire country, there is over \$2 Billion in Medicaid payments for psychiatric drugs to children and youth that Congress has explicitly prohibited. In truth, this is the smallest amount because typically two or more of these drugs are administered concurrently, in what is called poly pharmacy, none of which has been approved by the FDA for pediatric use or supported by any of the designated compendia.

V. There is Good Reason for Prohibiting These Drugs

The evidence is overwhelming that the current practice of prescribing these drugs to children and youth is largely ineffective, even counterproductive, and extremely harmful to children. Rather than recite this overwhelming evidence here, I draw your attention to the [CriticalThinkRx Curriculum](http://psychrights.org/States/Alaska/Kids/Under18ABPMPReportsrcd071109.pdf)⁶ and [references](http://psychrights.org/Research/Digest/CriticalThinkRxCites/AllModulesCompletePresentation.pdf),⁷ consisting of a comprehensive review of the scientific evidence regarding the use of psychiatric drugs on children and youth. The CriticalThinkRx Curriculum was funded by a grant from the Attorneys General Consumer and Prescriber Grant Program, out of the multi-state settlement of consumer fraud regarding the marketing of Neurontin.⁸

⁴ 147 F.Supp. 2d 39, 44-5 (D.Mass. 2001)

⁵ See, <http://psychrights.org/States/Alaska/Kids/Under18ABPMPReportsrcd071109.pdf>.

⁶ <http://psychrights.org/Research/Digest/CriticalThinkRxCites/AllModulesCompletePresentation.pdf>

⁷ <http://psychrights.org/Research/Digest/CriticalThinkRxCites/Complete-Curriculum-References.pdf>

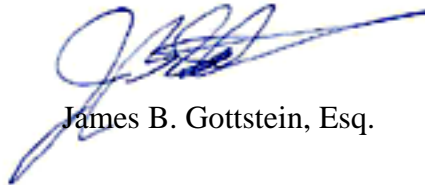
⁸ David Cohen, PhD, is principle investigator of the CriticalThinkRx Curriculum and Stefan P. Kruszewski, M.D, its consulting psychiatrist.

VI. Tried and True Methods Should be Supported Instead

Frankly, the United States has lost its collective mind in the way it has subjected so many children and youth to these drugs. It is insane to believe that all of these children have mental illnesses. They need safe, secure, and loving environments, proper discipline, educational and recreational opportunities, socialization, etc. Children in foster care have been taken into custody because they did not live in safe environments. They "act out" as a result of both the situations they were in before the state took custody and they also "act out" as a result of their treatment in foster care. They are not mentally ill; they need assistance in coping with their problems. Module 8 of the CriticalThinkRx Curriculum sets forth proven psychosocial approaches that help children and youth become successes. PsychRights believes that rather than drugs, these children and youth should have access to such programs and the savings from stopping Medicaid payments for uncovered psychotropic drugs should go to such programs.

Thank you for your attention to this matter. We will, of course, be pleased to answer any questions you might have and assist in any way that we can.

Yours truly,

A handwritten signature in blue ink, appearing to read 'J. B. Gottstein', with a long horizontal flourish extending to the right.

James B. Gottstein, Esq.

Cc: Kathleen Sebelius, Secretary of Health & Human Services
Kerry Weems, Acting Administrator, CMS
Joyce Branda, Esq. Director, Dept. of Justice Commercial Litigation Branch (Frauds)
David Cohen, PhD
Stefan P. Kruszewski, M.D.