

PsychRights[®]
Law Project for
Psychiatric Rights, Inc.

December 2, 2011

Senator Tom Carper
United States Senate
513 Hart Building
Washington, DC 20510

via fax (202) 228-2190

Re: The Financial And Societal Costs Of Medicating
America's Foster Children

Dear Senator Carper:

I wrote you on November 9, 2010, about your request of the General Accountability Office (GAO) to report on the use of psychotropic drugs in foster children and youth, so it was with great interest that I watched yesterday's hearing on The Financial And Societal Costs Of Medicating America's Foster Children in anticipation of the forthcoming GAO Report.

At the hearing, you said the government should be able to stop the practice. The tools to do so are in hand. The Department of Health and Human Services (DHHS), and the Department of Justice should be required to enforce the already enacted restriction on outpatient drug coverage under Medicaid to those that are for a medically accepted indication.

The DHHS representative, Bryan Samuels, testified that DHHS has no authority to do anything but give the states guidance. This is not true. As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

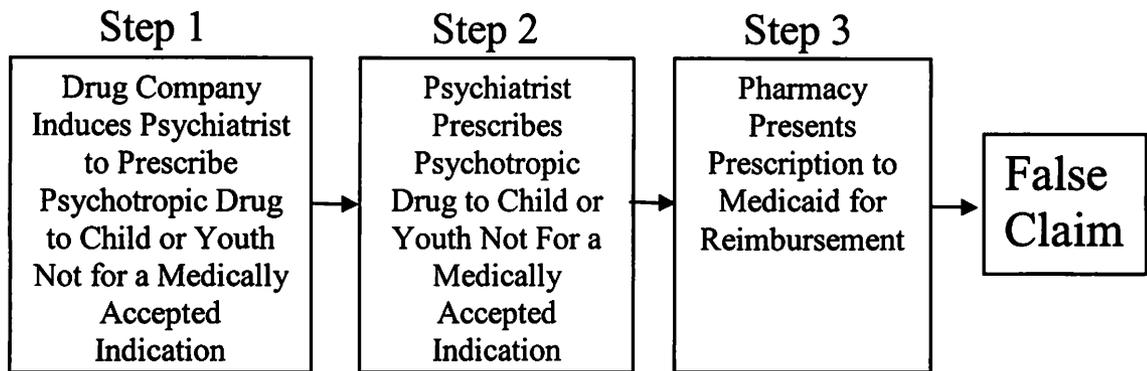
Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

The Department of Justice agrees only prescriptions for a medically accepted indication are legally reimbursable under Medicaid and has extracted billions of dollars in settlements with drug companies under the False Claims Act for inducing doctors to write prescriptions that are not for a medically accepted indication.¹

However, such recoveries from drug companies are completely ineffective because the doctors continue to prescribe these uncovered drugs in the drug company inspired fraudulent scheme that can be depicted as follows:

¹ I supplied all but the first of the following documents with my letter of last year: September 24, 2010, United States' Statement of Interest in *U.S. ex rel Polansky v. Pfizer, Inc.*, Case 1:04-cv-00704-ERK-ALC, USDC EDNY; September 2, 2009, Department of Justice News Release regarding settlement agreement in *United States of America ex rel Stefan Kruszewski et al., v. Pfizer, Inc.*, Case No. 07-CV-4106, USDC EDPA; Settlement Agreement in *United States ex rel Wetta v. Atrazenaca*, USDC EDPA, Case No. 04-3479, United States Complaint in Intervention and Settlement Agreement and Release in *United States ex rel Gobble v. Forest Laboratories*, USDC Mass, Case No. 03-10395-NMG. I can supply the Statement of Interest in *Polanski* at your request, but didn't want to make this fax too long.

Fraudulent Scheme



In the related context of the psychiatric drugging of the elderly in nursing homes, last May, the Inspector General of DHHS acknowledged that going after the drug companies is insufficient:

The drug companies have paid billions to resolve these civil and criminal liabilities under federal health and safety laws. But money can't make up for years of corporate campaigns that market drugs with questionable benefits and potentially deadly side effects. . . .

Doctors should base prescribing decisions on their best medical judgments, weighing scientific evidence and an especially careful analysis when they are prescribing drugs for off-label use.²

The doctors engaging in the horrific prescribing practices described in yesterday's hearing are clearly betraying the trust placed in them by our system as described by the Inspector General.

However, the current non-enforcement by the Centers for Medicare and Medicaid Services (CMS) of Congress's restriction of drug coverage to medically accepted indications is encouraging such doctors to continue to prescribe these drugs inappropriately. In his Report, the Inspector General notes that CMS takes the position that it does not have the statutory authority to refuse to pay for drugs that are not covered under the statute. Mr. Samuels essentially testified to the same thing. This does not appear to be true and I think is cause for inquiry by Congress.

Because of CMS's failure to follow Congress's limitation of outpatient drug coverage to those for a medically accepted indication, the Law Project for Psychiatric Rights (PsychRights[®]) launched a False Claims Act initiative to bring lawsuits against psychiatrists, their agencies, and pharmacies for their participation in the Fraudulent Scheme described above.

Thus far, there have been two cases unsealed in Alaska, one in Illinois and one in Wisconsin. Ironically, just today, the 9th circuit denied rehearing of its non-precedential ruling affirming dismissal of the Alaska cases on the grounds that because the government knows all about the fraud and isn't doing anything, private *qui tam* enforcement is not allowed. In other words, the 9th Circuit essentially said, "If the government doesn't care about the fraud, why

² May 9, 2011, Statement accompanying May, 2011, Inspector General Report, "Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents."

should we?" In July of this year, the Illinois case was dismissed because *the Department of Justice said the psychiatrist didn't have enough money to make it worthwhile*. The Wisconsin case is just getting started. We expect more cases to be filed, including in the 9th Circuit, since its ruling is explicitly not precedent.

The goal of PsychRights' Medicaid Fraud Initiative is to stop the doctors from prescribing psychotropic drugs to children and youth that are not for a medically accepted indication by making them realize they face financial ruin by continuing the practice.³

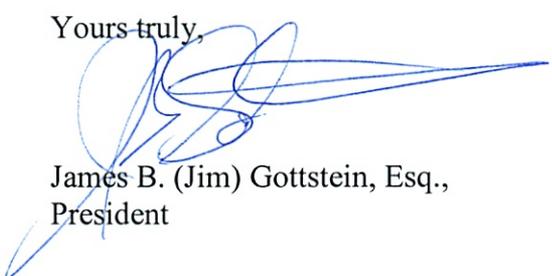
PsychRights should not have to take this extraordinary step; the government should stop paying for the drugs Congress decreed are not covered. Also, these False Claims Act cases are blunt instruments having the potential of financially ruining any psychiatrist who is sued. Instead, PsychRights believes the government should take the following three steps:

1. Announce that outpatient drug prescriptions that are not for medically accepted indications are not covered under Medicaid, and will no longer be reimbursed; except
2. Where abrupt withdrawal from drugs that are not for medically accepted indications can cause serious problems, allow reimbursement for responsible tapering; and
3. Grant amnesty from False Claims Act liability for all past prescriptions that are not for medically accepted indications.⁴

At the hearing, you assured Ke'onte that his testimony was going to help many other foster children avoid being inappropriately given psychotropic drugs. This can be done if DHSS/CMS were to implement's Medicaid's statutory restriction of outpatient drug prescriptions to those that are for medically accepted indications. It is urgent this step be taken immediately to prevent the many tragedies that are occurring on a daily basis.

I will be pleased to work with you, your subcommittee, and staff on this very important issue if you so desire.

Yours truly,



James B. (Jim) Gottstein, Esq.,
President

cc: Sen. Mark Begich (202) 224 - 2354

³ Detailed information on PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth is available on our website, <http://PsychRights.org>. In a nutshell, each uncovered prescription carries a minimum False Claims Act penalty of \$5,500.

⁴ I don't think it would be constitutional to eliminate *relators'* rights under pending False Claims Act cases, but the Wisconsin one is the only pending one I know about.