

# PsychRights®

Law Project for  
Psychiatric Rights, Inc.

December 1, 2011

Senator Mark Begich  
United States Senate  
111 Russell Senate Office Building  
Washington, DC 20510

via Fax (202) 224 - 2354

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

Dear Senator Begich: *Mark*

I would like to arrange a time to speak with you about the following at your earliest convenience.

As you know, I have been raising the alarm about the psychiatric drugging of children and youth on Medicaid for quite some time. In connection with that I have come to realize that most of it is not legally reimbursable. Further investigation has revealed that the Department of Health and Human Services (DHSS), and more particularly, the Centers for Medicare and Medicaid Services (CMS), is failing to enforce Congress's restriction of Medicaid drug coverage to medically accepted indications.

At this morning's hearing of the Subcommittee on Federal Financial Management on "The Financial And Societal Costs Of Medicating America's Foster Children," there was what I would describe as hand-wringing over how to deal with the problem. However, if CMS would enforce Congress's restriction of coverage for outpatient drugs to those that are for a medically accepted indication, the problem would be almost completely solved.

The DHSS representative, Bryan Samuels, testified that it has no authority to do anything but give the states guidance. This is not true. In 42 USC 1396R-8(k)(3), 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 provides:

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.

As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

Senator Mark Begich

December 1, 2011

Page 2

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 that prescriptions not for a medically accepted indication are not 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 for psychotropic drugs to children and youth that are not for a medically accepted indication.<sup>1</sup>

Such recoveries from drug companies are completely ineffective because the doctors continue to prescribe these uncovered drugs. In the related context of the psychiatric drugging of the elderly in nursing homes, last May, the Inspector General of DHSS acknowledged this:

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.<sup>2</sup>

However, even if certain doctors continue to prescribe these drugs when they are not medically indicated, Medicaid should not continue to pay for them. In his Report, the Inspector General notes that CMS takes the position that it doesn't have the statutory authority to refuse to pay for drugs that Congress directed not be covered. This borders on the absurd.

There is more, which I would like to go over with you at your earliest convenience.

Yours truly,



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

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<sup>1</sup> I can supply the following documents for this, but didn't want to make this fax too long: 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.

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