IN THE SUPREME COURT FOR THE STATE OF ALASKA

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Appellant, vs. STATE OF ALASKA, et al., Appellees.	)	Supreme Court No. S-13558 Superior Court No. 3AN 08-10115CI

APPEAL FROM THE SUPERIOR COURT
THIRD JUDICIAL DISTRICT AT ANCHORAGE
THE HONORABLE JACK W. SMITH, PRESIDING

APPELLANT'S EXCERPT OF RECORD
VOLUME 3 OF 3

James B. Gottstein (7811100)
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, Alaska
(907) 274-7686

Attorney for Appellant
Law Project for Psychiatric Rights

Filed in the Supreme Court of the State of Alaska, this 23rd day of November, 2009

Marilyn May, Clerk

By: _____
Deputy Clerk

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A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - **David Cohen, Ph.D.**
- **Research Coordinator:**
  - **Inge Sengelmann, M.S.W.**
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

CriticalThinkRx was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®

Module 1

Why a Critical Skills Curriculum on Psychotropic Medications?

Part A

Curriculum Rationale, Funding and Contents

Curriculum Rationale

Physicians write prescriptions, but other professionals often influence who gets prescribed and why

Training for these professionals is mostly haphazard and often influenced by the pharmaceutical industry

6

Curriculum Objectives

Help practitioners in mental health and child welfare sharpen *critical thinking skills* to deal with complex and evolving issues about psychotropic medication

7

Critical thinking

✓involves assessing beliefs, arguments and claims to arrive at well-reasoned judgments

✓uses standards such as clarity, accuracy, relevance, and completeness

8

Critical thinking

✓asks "who benefits?"

✓is sensitive to the influence of vested interests on information

✓emphasizes the ethical implications of treatment decisions

9

CriticalThinkRx

A prescription for critical thinking about psychotropic medications

10

Curriculum funding

- Received from the *Attorneys General Consumer & Prescriber Education Grant Program* (CPGP)
- CPGP is overseen by the Attorney General offices of Florida, New York, Ohio, Oregon, Texas and Vermont (plus two rotating states)

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Funding source of CPGP

2003: Attorneys General of 50 states charged Warner Lambert, a subsidiary of Pfizer, Inc., with conducting an unlawful marketing campaign promoting the off-label uses of the anticonvulsant drug Neurontin

12

Neurontin settlements

2004: The company settled for $430 million

—$21 million was earmarked for research and education aimed at health professionals

13

CPGP awards grants

2006: CPGP funded 28 applications in 19 states

- *CriticalThinkRx*, funded at Florida International University, is the only project targeting non-medically trained professionals in child welfare and mental health

14

CPGP aims to improve prescribing practices by educating health professionals about

- ✓the drug development and approval process
- ✓pharmaceutical industry marketing
- ✓knowledge and skills to evaluate drug information critically

15

CPGP requires that

- ✓the curriculum be maintained in the public domain, freely accessible by anyone
- ✓the investigators and their consultants forego funding from the pharmaceutical industry for the duration of their grants

16

Selection of content

Systematic literature searches were conducted in 2006-2007 on databases in medicine, pharmacology, public health, social work, counseling, and psychology

- Materials were selected based on relevance and accuracy

17

Mainstream views

Researchers agree that clinical practice has far outpaced the empirical evidence, yet…

- Mainstream mental health practice subscribes to a "medical" model supporting medication of children with little evidence of safety or efficacy

18

Content bias

CriticalThinkRx offers alternative views based on empirical evidence to stimulate critical thinking and a more balanced evaluation based on ethical codes of practice

19

Content orientation

CriticalThinkRx emphasizes the ethical dictate: **"First, do no harm"**

CriticalThinkRx tries to close gaps between research and practice to maximize opportunities to help clients and avoid harm

20

Curriculum design

Modules designed by experienced researcher/clinician with input from independent consultants in counseling, psychology, psychiatry, social work, and law

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Principal Investigator

David Cohen, Ph.D., L.C.S.W.

- Professor of Social Work, Florida International University, Miami, and a private practitioner
- Author of numerous publications on psychiatric drugs, medicalization, and law and psychiatry
- His latest books are *Your Drug May Be Your Problem* (2nd rev. ed, 2007) and *Critical New Perspectives on ADHD* (2006)

22

Research Coordinator

Inge Sengelmann, M.S.W.

- M.S.W. with a background in journalism and corporate communication
- Clinician focused on holistic approaches to the treatment of trauma-related mood and behavioral problems

23

Consultant: Counseling

R. Elliott Ingersoll, Ph.D.

- Professor of Counseling, College of Education and Human Services, Cleveland State University
- A licensed psychologist and clinical counselor in Ohio, he has authored books, book chapters, and articles on psychopharmacology, spiritual approaches to counseling, and Integral theory in mental health
- Author, *Psychopharmacology for Helping Professionals: An Integral Exploration* (2006)

24

Consultant: Social Work

Kia J. Bentley, Ph.D., L.C.S.W.

- Professor, Director of the Ph.D. Program, and Associate Dean for Strategic Initiatives in Social Work at Virginia Commonwealth University, where she has taught since 1989
- Author, *The Social Worker & Psychotropic Medication* (3rd ed., 2006) (with Joseph Walsh)
- Editor, *Psychiatric Medication Issues for Social Workers, Counselors and Psychologists* (2003)

25

Consultant: Psychology

- Professor, Department of Psychiatry, University of Nevada School of Medicine
- Fellow, American Psychological Association; Diplomate, clinical psychology, American Board of Professional Psychology
- His articles on the comparative effects of psychotherapy and pharmacotherapy have received extensive national coverage and are models of careful scholarship
- Has received many prestigious awards for his outstanding contributions to clinical science and research

David O. Antonuccio, Ph.D.

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Consultant: Psychiatry

Stefan P. Kruszewski, M.D.

- Harvard Medical School graduate and board-certified in adolescent psychiatry
- Pensylvannia-based clinician and scientist working with U.S. and international judicial, legislative, and regulatory bodies
- His publications appear in *American Journal of Psychiatry* and *BMJ*

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Consultant: Law

Robert E. Rosen, J.D., Ph.D.

- Professor of Law, University of Miami, Coral Gables, FL
- Has taught courses in children and the law, professional responsibility, and sociology and the law
- Has served as member of Miami-Dade's Community-Based Care Alliance, and is a reviewer for Foster Care Review
- Holds a J.D. from Harvard Law School, and a Ph.D. in sociology from the University of California at Berkeley
- Former fellow, Harvard's Program in Ethics and the Professions

Use of drug names

Most prescription drugs have a generic and a brand name (e.g., fluoxetine/Prozac)

In this course, charts show both names, but discussions use brand names because they are more familiar to laypersons

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A recent tragic case raises questions about the use of psychiatric medications in young children

31

Case 1: Rebecca Riley

(April 11, 2002 - Dec.13, 2006)

What went wrong?

Concerns raised before death of 4-year-old girl

Teachers, a social worker, a nurse and a therapist had noticed something wasn't right about Rebecca Riley. A

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CBS NEWS

60 MINUTES

What Killed Rebecca Riley?

Katie Couric Reports On The Diagnosis Of Bipolar Disorder In Kids

Sept. 30, 2007

Girl's death stirs debate over psychiatric meds

Parents of 4-year-old accused of intentionally overmedicating daughter

AP Associated Press

Updated: 3:11 p.m. ET March 23, 2007

HULL, Mass. - In the final months of Rebecca Riley's life, a school nurse said the little girl was so weak she was like a "floppy doll."

The preschool principal had to help Rebecca off the bus because the 4-year-old was shaking so badly.

And a pharmacist complained that Rebecca's mother kept coming up with excuses for why her daughter needed more and more medication.

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Some salient facts

In 2002, then again in 2005-2006, Massachusetts' DSS investigated complaints that the three Riley children might be sexually or physically abused and neglected by their parents

DSS ruled complaints unfounded

34

By 2006, all three Riley children were diagnosed with Bipolar I Disorder and prescribed psychotropic drug cocktails by same child psychiatrist from Tufts Medical Center

- Parents were also diagnosed and mother received Paxil
- As discussed in next modules, diagnosing children with Bipolar Disorder I is a questionable and controversial practice

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Rebecca, the youngest child, was first medicated at age 2

- By age 4, she was taking Seroquel (antipsychotic), Depakote (anticonvulsant), and clonidine (antihypertensive)
- She also took 2 over-the-counter cold medicines

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Dec. 13, 2006: Rebecca Riley is found dead on her parents' bedroom floor

- Autopsy later indicated cause of death as **"intoxication due to the combined effects"** of clonidine, Depakote, and two cough medications
- *"The amount of clonidine alone in Rebecca's system was fatal."*

(Commonwealth of Massachusetts, Feb. 5, 2007)

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Parents indicted …

Michael Riley, 34, and Carolyn Riley, 32, indicted in 2007 for the 1st degree murder of their daughter Rebecca (charge later reduced to 2nd degree murder)

- Parents charged with giving her "excessive amounts" of clonidine
- Child's doctor told mother Rebecca "was already on a high dose of clonidine" and a higher dose could kill the child

(Commonwealth of Massachusetts, Feb. 5, 2007)

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Case leads to resignations…

GOODBYE TO DSS CHIEF

Agency has been under fire
since parents accused of killing Hull girl

By KEN MAGUIRE
Associated Press

BOSTON - The embattled head of the state's child welfare system is resigning five months after his agency was criticized for its action - or lack of action - in the death of a 4-year-old girl in Hull.

Lewis "Harry" Spence

Lewis "Harry" Spence, commissioner of the Department of Social Services since 2001, has been under fire for the agency's handling of the Hull case in which the parents of the dead girl are charged with killing her with an overdose of prescription drugs.

He also has been criticized for the department's handling of another high-profile child-abuse case involving a comatose child from Westfield.

Gov. Deval Patrick plans to replace Spence with Angelo McClain, a former DSS worker who now works for ValueOptions, a New Jersey-based health care company, according to a person with direct knowledge of the decision.

Patrick planned to announced Spence's departure today along with other changes in top positions, a source told The Associated Press.

Spence did not return calls to his cell phone seeking comment.

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… puts careers on the line

February, 2007

Psychiatrist to suspend practice; denies wrongdoing

The Boston Globe

By Liz Kowalczyk, Globe Staff | February 8, 2007

Dr. Kayoko Kifuji, the psychiatrist who treated Rebecca Riley in the months before the Hull girl died from an overdose of prescription drugs, agreed yesterday to immediately stop treating patients while the state investigates her role in the case.

April, 2008

HOME / NEWS / LOCAL

Doctor is sued in death of girl, 4

The Boston Globe

Her psychiatrist treated her with powerful drugs

By Shelley Murphy
Globe Staff / April 4, 2008

Email | Print | Single Page | Text size

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CBS EVENING NEWS

March 10, 2007

(CBS) Rebecca Riley's death shocked the Boston community. Did her parents deliberately give her overdoses of psychiatric drugs as prosecutors suggest? Or are her doctors to blame — as defense lawyers argue — for prescribing powerful medications when she was just 2 years

41

Girl's pill numbers disputed: The prescriptions Carolyn Riley gave 4-year-old were very close to allowed amount, defense says

By JULIE JETTE
The Patriot Ledger

The Patriot Ledger

March 10, 2007

42

Case shines light on therapists' roles…

An LCSW made 12 home visits in summer 2006, working with Rebecca and her 6-year-old sister

- Therapist was "initially concerned" about the medication regimen, since she "did not observe any behavior consistent with the diagnoses"

(Commonwealth of Massachusetts, Feb. 5, 2007)

43

… and on school personnel

In her pre-school, Rebecca was observed to be very lethargic and have "a tremor in her hand"

Mother was observed to be "lethargic" and "fall asleep during interviews"

44

Case stirs heated debate among doctors over bipolar diagnoses

The Boston Globe

Backlash on bipolar diagnoses in children
MGH psychiatrist's work stirs debate

By Scott Allen, Globe Staff | June 17, 2007

45

Leads one doctor to hold another "morally culpable"

LAWRENCE DILLER
Misguided standards of care
The Boston Globe

By Lawrence Diller | June 19, 2007

"… I felt compelled to name Joseph Biederman, head of the Massachusetts General Hospital's Pediatric Psychopharmacology clinic, as morally culpable in providing the 'science' that allowed Rebecca to die."

-- *Lawrence Diller, M.D.*

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FDA "black box" warnings on Depakote ignored?

FDA-approved Depakote black box warning label :

"HEPATOTOXICITY: HEPATIC FAILURE RESULTING IN FATALITIES HAS OCCURRED IN PATIENTS RECEIVING VALPROIC ACID AND ITS DERIVATIVES. EXPERIENCE HAS INDICATED THAT CHILDREN UNDER THE AGE OF TWO YEARS ARE AT A CONSIDERABLY INCREASED RISK OF DEVELOPING FATAL HEPATOTOXICITY....

"PANCREATITIS: CASES OF LIFE-THREATENING PANCREATITIS HAVE BEEN REPORTED IN BOTH CHILDREN AND ADULTS RECEIVING VALPROATE. SOME OF THE CASES HAVE BEEN DESCRIBED AS HEMORRHAGIC WITH A RAPID PROGRESSION FROM INITIAL SYMPTOMS TO DEATH."

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Case 2:
"Susan," 10 years old

Parents divorced 5 years ago, custody awarded to mother

Father seeking shared custody—only sees Susan a few times a year

Susan presented behavior problems since the age of 3

48

Loss and instabililty

Susan's life filled with losses of friends, pets, homes, adopted-away brother

Since age 5, Susan moved 10 times, attended 7 schools, was assessed by 20 physicians and therapists

49

Multiple diagnoses

Diagnosed with ADHD, OCD, bipolar disorder

Lives in a residential treatment center

Her file describes many behavioral outbursts, attributed to "bipolar disorder"

50

Since age 5, Susan has taken:

- ✓5 antipsychotics
- ✓4 anticonvulsants
- ✓3 stimulants
- ✓3 antidepressants
- ✓2 benzodiazepines
- ✓2 other sedatives (incl. antihypertensive)
- ✓lithium

51

Susan now takes:

- ✓2 anticonvulsants
- ✓1 antipsychotic
- ✓1 stimulant, and
- ✓1 antihypertensive

No evaluations of medication…

A psychologist and a social worker conducted separate assessments of Susan's situation for the Court

Neither commented on Susan's drug treatment or suggested any connections between the medications and her behavioral outbursts

53

No one expressed any concern about giving 5 psychiatric drugs (including 4 central nervous system depressants) to a 10-year-old

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55

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- What are the client's symptoms or observed behaviors of concern, who has observed them?
- Has the client experienced any recent or chronic life events or stressors that may contribute to the problems?

57

- Could any of client's problems be caused by current medication?

- Does the client's psychiatric diagnosis truly reflect the client's problems? Is the diagnosis useful to plan for interventions with this client?
- What interventions have been tried to address client's problems? By whom, and with what results?
- Are alternative interventions available to address client's problems? Why have they not yet been tried?

59

- Why is medication being prescribed for this client? What other medication has been prescribed currently or in the past?
- How long before we see improvements? How will the improvements be measured?
- How long will the patient be on the medication? How will a decision to stop be made?

60

- If client is a minor, is the medication designed to benefit the child, or the child's caregivers?

61

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- Why is this particular medication prescribed for this client?
- How long has it been on the market? Is it FDA-approved for use in children? Are there any FDA "black box" warnings about this medication?
- What is the recommended dosage? How often will the medication be taken? Who will administer it?

63

- Have any studies been evaluated by professionals working with this child?
- How much scientific support is there for its helpfulness with other children with similar conditions?
- How much scientific evidence exists to support safety and efficacy of this drug in children, alone or in combination with other psychotropic medications?

64

- Has this medication been shown to induce tolerance and/or dependence? What withdrawal effects may be expected when it is discontinued?

65

- Do any laboratory tests need to be done before, during, after use of this medication?
- Are there other medications or foods the child should avoid while on this medication?
- What are all the potential positive and adverse effects of this medication?

66

- How will the effects of the medication be monitored? By whom? Where will they be documented? What should be done if a problem develops?
- How will the use of medication impact other interventions being provided?

67

- How much does this medication cost and who is paying for it?
- Are there cheaper, generic versions of this medication?

68

69

- What is the experience of the physician prescribing the medication?
- Would you consider the physician's prescribing habits as cautious and conservative?
- Does this physician have any financial relationships with pharmaceutical companies? Have these been disclosed to patients?

70

- Have all the risks and benefits of this medication, and those of alternate interventions, been evaluated and discussed by the physician with the client or the client's family?
- Is there an adequate monitoring schedule and follow-up?

71

- Do I or my client/client's family have the opportunity to speak regularly with the physician and other healthcare providers about the medication's effects? Should my feedback be expressed in writing?

72

- Has a comprehensive assessment (e.g., biopsychosocial, holistic, integral) been conducted? Does it offer plausible reasons for the client's problems?
- Are there other explanations for the child's behavior?

74

- If necessary, do I have access to supervision to help me think through the medication issues?
- How knowledgeable is my supervisor about psychotropic medications?

75

- Am I familiar with all the risks and benefits of this medication, as well as those of alternate interventions? Have I discussed them with the client/client's family?
- Do I know how the client/client's family feel about the use of medication?

76

- What is my role and has it been clearly delineated with all other providers?
- Has the client/client's family been provided with all the information necessary to provide informed consent? Do they understand their choices?

77

- Do I feel confident that I can recognize the effects, adverse or otherwise, of this medication on my client? How should I record my observations?
- Will I be able to educate my client about these effects so he/she can raise concerns with the prescribing physician?

78

- What alternative services/interventions does this family need or want?
- Can I provide these or help them obtain access?

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This course, in the remaining modules, is intended to help you answer the preceding questions

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A Critical Curriculum
on Psychotropic Medications

Module 1

The End

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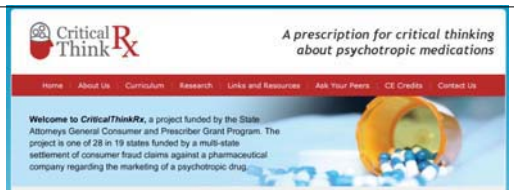

A Critical Curriculum on Psychotropic Medications

Critical Think Rx

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Module 2

Increasing Use of Psychotropics

Public Health Concerns

Part A

Medicating Youth

Surveys and insurance databases show increasing use

5-8 million children in the U.S.
(8-11% of all children)
receive prescriptions
for psychotropic medications

(Medco, 2006; St. Luke's Health Initiatives, 2006)

6

Prescriptions of psychotropics to youths **tripled in the 1990s** and are still rising in this decade

In some drug classes, rates in children rival adult rates

(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

7

Drug treatment without any other form of therapy is becoming the norm

(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

8

A worldwide phenomenon…

…but the proportion of children prescribed psychiatric drugs remains **2 to 20 times higher** in the U.S., Canada, and Australia than in other developed nations

(Wong et al. 2004)

9

In the U.S., "cultural" differences remain

White children are **twice as likely** as Black and Latino children to receive prescriptions

- Difference appears unrelated to socio-demographic, access, or clinical factors, and may relate to parental attitudes

(Cooper et al. 2006; Dos Reis et al. 2005; Leslie et al. 2003)

10

Off-Label Uses and Polypharmacy

The New York Times

November 23, 2006

Proof Is Scant on Psychiatric Drug Mix for Young

11

"Off-label" use common

The practice of administering medications for indications or age groups not approved by the FDA, as indicated on the drug's "label"

(Vitiello, 2001; Zito et al. 2003)

12

75% of all medication use in children is off-label

(Vitiello, 2001; Zito et al. 2003)

13

Concerns about off-label use

"Bearing in mind that some off-label use is perfectly justifiable, it is fair to say that much of it is not justifiable. If there is not evidence presented to the FDA about a given indication, it is certainly a user-beware situation."

- **Jerry Avorn, M.D.**, Professor of Pharmacology, Harvard Medical School, and author, *Powerful Medicines* (2005)

14

Polypharmacy common

40% or more of all psychiatric drug treatments today involve polypharmacy

(Bhatara et al. 2004; Olfson et al. 2002; Safer et al. 2003)

15

Polypharmacy: *concomitant* or *multiple* psychotropic medication use

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Concomitant = ≥ 2 drugs taken on the same day

Multiple = ≥ 2 drugs taken during a given period

Concerns about polypharmacy

Basic empirical support of efficacy in children is lacking for *most individual* medication classes

No studies have established the safety and efficacy of combination treatments in children

(Bhatara et al. 2004; Jensen et al. 1999; Martin et al. 2002; Vitiello, 2001)

18

Increases behavioral toxicity

Behavioral toxicity =
drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis

(Safer, Zito & dosReis, 2003)

19

The "prescribing cascade"

Adverse effects are often **confused with symptoms** of disorders, leading to co-morbid diagnoses, and even more complex drug regimens

(Safer, Zito & dosReis, 2003)

20

Examples of behavioral toxicity

TABLE 4. Single Case Reports of Adverse Drug Events Associated With Use of Concomitant Psychotropic Medication for Youths

Study	Medications	Diagnosis	Age	Gender	Adverse Drug Events
Sallee et al. (89)	Fluoxetine, promethazine, methylphenidate, clonidine	ADHD, conduct disorder, and Tourette's syndrome	9	Male	Death
Preda et al. (90)	Perphenazine, carbamazepine, valproic acid, lorazepam, thioridazine	Bipolar I disorder and adjustment disorder	10	Female	Psychosis
Budman et al. (91)	Pemoline, paroxetine, haloperidol	OCD, ADHD, and Tourette's syndrome	12	Male	Acute dystonia
Levy et al. (92)	Amitriptyline, fluoxetine,	ADHD and conduct disorder	7	Male	Serotonin syndrome
Fisman et al. (93)	Risperidone, clomipramine, erythromycin	ADHD, OCD, and Tourette's syndrome	15	Male	Deteriorated mental state

(Safer, Zito & dosReis, 2003)

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Medicating Preschoolers

22

Similar patterns in preschoolers

Use of most classes of psychotropics among 2-4 year-olds continues to increase

- Almost half of those receiving prescriptions received two or more medications

(Coyle, 2000; Rappley, 2006; Zito et al. 2000)

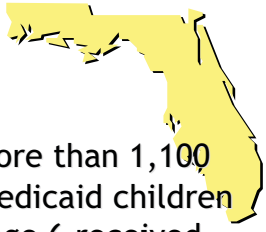
23

Newer drugs top the list

Fastest increases have been in newer drugs without established efficacy or safety profiles

(Pathak et al. 2004; Rappley, 2006; Zito et al. 2000)

24



2006: more than 1,100 Florida Medicaid children under age 6 received atypical antipsychotics

(*St. Petersburg Times*, 2007)

25

Concerns

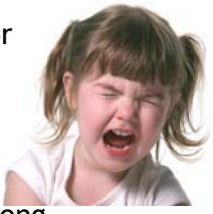
Treatment of preschoolers with psychiatric drugs has barely been studied

(Rappley, 2006 ; Vitiello, 2001; Waller et al. 2005; Zito et al. 2000)

26

Insufficient evidence to…

- Provide guidelines for treatment
- Establish efficacy of treatment
- Guarantee safe use
- Evaluate short- and long-term consequences on development



(Rappley, 2006 ; Vitiello, 2001; Waller, Lewellen & Bresson, 2005; Zito et al. 2000)

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SCIENTIFIC AMERICAN

May 30, 2007

Kids on Meds -- Trouble Ahead

Antidepressants, designed for adults, may be altering the brains of kids who take them

By Paul Raeburn

28

Youths in Foster Care

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CBS EVENING NEWS

Double-click any word (What's this?)

Are Drugs Being Misused On Foster Kids?

There's Growing Concern That Anti-Psychotic Drugs Are Being Misused On Children In Foster Care

msnbc

States wrestle with medicating foster kids

Critics worry psychiatric drugs flow too freely to forgotten children

USA TODAY Home News Travel Money Sports Life Tech

Health and Behavior Inside News

For foster kids, oversight of prescriptions is scarce

Updated 5/2/2006 12:21 AM ET

E-mail | Save | Print | RSS

National foster care

Children in child welfare settings are **2 and 3 times more likely** to be medicated than children in the general community

(Breland-Noble et al. 2004; Raghavan et al. 2005)

31

Group homes

After controlling for demographic *and* clinical factors, youths in group homes still **twice as likely** to be medicated than youths in therapeutic foster care

(Breland-Noble et al. 2004; Raghavan et al. 2005)

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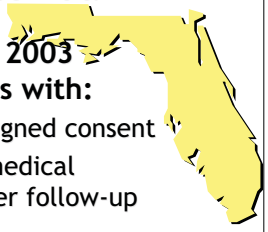
Concerns in Florida



Reports in 2001 and 2003 highlighted problems with:

- Medication without signed consent
- Medication without medical evaluations and proper follow-up monitoring
- High rates of polypharmacy

(Green, Hawkins & Hawkins, 2005; Florida Statewide Advocacy Council, 2003)

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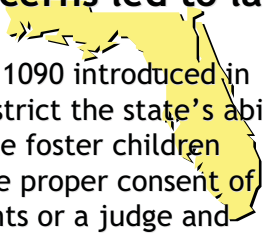
Florida concerns led to law



Senate Bill 1090 introduced in 2005 to restrict the state's ability to medicate foster children without the proper consent of their parents or a judge and required improved tracking of these children

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"No List of Kids on Mood Drugs"

The Miami Herald / el Nuevo Herald (September, 2006)

Child welfare officials acknowledged lacking an accurate list of children in state care receiving psychiatric drugs

- Advocates called use of these drugs in children "chemical restraints" used to control behavior

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Part B

Public Health Concerns

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Numbers of American children on psychotropics: 2006

Stimulants: 3.6 million
Antidepressants: 2 million
Anticonvulsants: 900,000
Antipsychotics: 540,000

The New York Times
(Medco Health Solutions, 2006)

38

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2006 FDA warning on cardiovascular effects also alerts doctors to stimulant-induced psychosis and hallucinations

The New York Times

F.D.A. Strengthens Warnings on Stimulants

By GARDINER HARRIS

39

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2004: FDA issued a **"Public Health Advisory"** about all antidepressants, warning of drug-induced:

- Anxiety and panic attacks
- Agitation and insomnia
- Irritability and hostility
- Impulsivity and severe restlessness
- Mania and hypomania

40

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

FDA "black box" warns:

"Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder and other psychiatric disorders"

41

CBS NEWS FDA Orders Antidepressant Warning

msnbc Home » Health » Mental Health

A Fuller Spectrum of News

Health

FDA urges new warnings on antidepressants

2005: FDA extends "black box" warnings to children and adolescents

2007: FDA extends "black box" warnings to young adults 18-24

42

Antipsychotics

Skyrocketing numbers despite safety concerns

43

44

45

Antipsychotics = Fastest rise

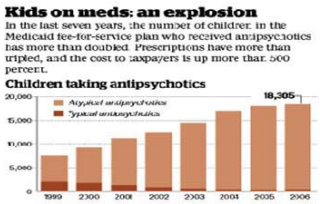
Number of non-institutionalized 6-18 year-olds on antipsychotics:

1993:	50,000
2002:	532,000

(Olfson et al. 2006)

St Petersburg Times (2007)

More than **18,000 kids** on Florida Medicaid prescribed atypical antipsychotics in 2006



47

Nationwide, antipsychotics typically prescribed to children for non-psychotic conditions

Most frequent diagnoses:

- disruptive behavior disorders, including ADHD (38%), and mood disorders (32%)

(Olfson et al. 2006)

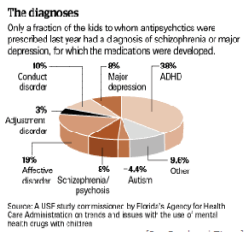
48

In Florida too…

2006: Only 8% of Florida Medicaid children receiving antipsychotics had a diagnosis of psychosis

- Half were diagnosed with attention or conduct disorders

St Petersburg Times (2007)



49

Antipsychotics = polypharmacy

77% to 86% of youths taking antipsychotics do so with other drugs

(Medco, 2006; Olfson et al. 2006)

Safety and efficacy unknown

"We don't know the first thing about safety and efficacy of these drugs even by themselves in these young ages, let alone when they are mixed together."

Dr. Steven Hyman, former NIMH director, Harvard University provost

The Boston Globe (2006)

51

Adverse effects of "atypicals"

	Clozaril	Risperdal	Zyprexa	Seroquel	Geodon	Abilify
Clinical name	Clozapine	Risperidone	Olanzapine	Quetiapine	Ziprasidone	Aripiprazole
Major symptoms reported						
Diabetes	Severe	Mild	Severe	Moderate	Minimal	Minimal
Weight gain	Severe	Moderate	Severe	Moderate	Mild	Mild
Sedation	Severe	Mild	Moderate	Moderate *	Minimal	Minimal
Tardive dyskinesia	None	Minimal	Minimal	Minimal	Minimal	Minimal

(Correll, 2006; *USA Today*, 2006)

52

medco

"Doctors need to be judicious when prescribing antipsychotic drugs to children. The use of these drugs can have the pediatric patient trading a behavioral condition for a lifelong metabolic condition that can lead to significant health complications"

—**Robert Epstein, M.D.**, chief medical officer, Medco

53

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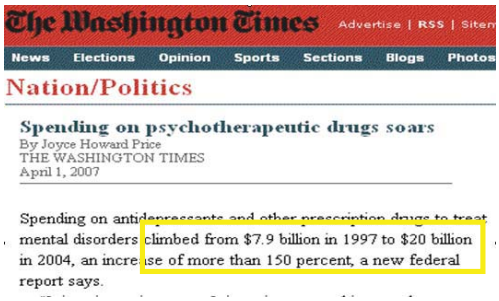
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Nation/Politics

Spending on psychotherapeutic drugs soars

By Joyce Howard Price
THE WASHINGTON TIMES
April 1, 2007

Spending on antidepressants and other prescription drugs to treat mental disorders climbed from $7.9 billion in 1997 to $20 billion in 2004, an increase of more than 150 percent, a new federal report says.

55

2004: 17% of total drug spending for children was for psychotropics

- *greater than cost of antibiotics and asthma drugs*

medco (2004)

State insurance increases likelihood of medication

Medicaid-enrolled children are more likely to:

- Receive psychotropics
- Be treated with multiple medications
- Receive medications as sole treatment

(Goodwin et al. 2001; Martin et al. 2002, 2003)

57

Use of newer antipsychotics grows faster

1996-2001: increased most dramatically in these Medicaid populations:

- Preschool children (61%)
- Ages 6-12 (93%)
- Ages 13-18 (116%)

(Cooper et al. 2004; Olfson et al. 2006; Patel et al. 2005)


Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID'S MENTAL HEALTH DRUG EXPENDITURES

INSPECTOR GENERAL

AUGUST 2003

Medicaid pays more for psychotropic drugs than other Federal buyers…

59

Medicaid programs struggle to contain costs

1997 - 2004: Tripling of Medicaid spending on psychotropics attributed to the expanding use of expensive atypical antipsychotics

(Duggan, 2005; Stagnitti, 2007; OIG, 2003)

Antipsychotics top Medicaid spending on psychiatric drugs

10 state Medicaid programs paid $562 million on 25 psychotropic drugs

- 67% of this total spent on nine antipsychotics

(Duggan, 2005; OIG, 2003; Stagnitti, 2007)

Average prescription price for top 2 antipsychotics, 1993 vs. 2001

1993: Haldol, Mellaril = $29

2001: Zyprexa, Risperdal = $286

(Duggan, 2005)

62

Florida Medicaid (fee-for-service) spending on atypical antipsychotic drugs, 2002-2007

$1.1 billion

(Farley, R., *St. Petersburg Times*, April 12, 2008)

Part D

Conclusions and Recommendations

64

Usage is increasing

Usage of all psychiatric drug classes has skyrocketed during past decade in all age groups, all ethnic/racial groups, all settings

65

Ongoing debate

Debate persists on whether disorders are under- or over-diagnosed, and under- or over-treated, with heated arguments from supporters and critics in professional and public discourse

66

Supporters argue…

- Up to 1/5 of youth have a "DSM-diagnosable disorder"
- Popularly-accepted causes of disorders are neurobiological
- Medications remove "blame"
- Stimulants greatly impact ADHD-like behavior

Critics reply…

- Medication use outpaces research evidence
- Growing use leads to increase in pediatric adverse effects
- Medicating the developing brain may lead to long-term negative changes in functioning
- No pathophysiological variable is associated with any DSM disorder

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Fastest rise: Antipsychotics

Antipsychotics with serious adverse effects growing faster than any other drug class

- More frequently used in polypharmacy and for non-psychotic disorders, with no research evidence

Racial issues

Black children: fastest-growing group being prescribed antipsychotics

- Increase related to enormous rise in the diagnosis of bipolar disorder in this population

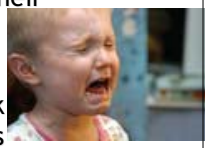
Soaring State Medicaid spending

Largest spending increases on antipsychotics

- Until now, states appear unable to contain such fast-rising drug costs

Young children

Children are particularly vulnerable to harm by psychiatric drugs because their brains are still developing



Research is needed to track subtle changes in children's developing personality resulting from drug's impact on brain

72

Children in foster care

Little empirical evidence exists to support the use of drug interventions in traumatized children

- Clinicians need to consider risk/benefit analysis of drugs vs. evidence of effective psychosocial interventions

73

Children in foster care

Experts recommend antipsychotics should not be considered first-line treatment for childhood trauma because of their serious adverse effects

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A Critical Curriculum on Psychotropic Medications

Module 2

The End

www.CriticalThinkRx.org

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A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

Principal Investigator:
- David Cohen, Ph.D.

Research Coordinator:
- Inge Sengelmann, M.S.W.

Professional Consultants:
- David O. Antonuccio, Ph.D. (psychology)
- Kia J. Bentley, Ph.D. (social work)
- R. Elliott Ingersoll, Ph.D. (counseling & psychology)
- Stefan P. Kruszewski, M.D (psychiatry)
- Robert E. Rosen, J.D., Ph.D. (law)

Flash production and design:
- Sane Development, Inc., and Cooper Design, Inc.

Voice narration and Flash editing:
- Saul McClintock

www.CriticalThinkRx.org

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Module 3

The Drug Approval Process

All drugs intended for prescription in this country must be ***approved*** by the U.S. Food & Drug Administration (FDA)

There are huge financial and health stakes in drug approvals

7

The FDA was established by Congress in 1906 to enforce standards on purity of medicinal compounds

Today, the FDA's **Center for Drug Evaluation and Research (CDER)** oversees testing and approval of medications

8

The CDER conducts no drug tests of its own—drug firms (sponsors) pay for and conduct all tests

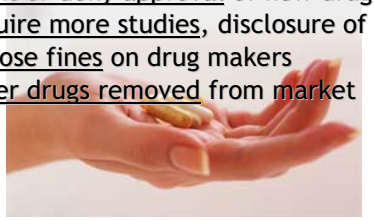
Based on data submitted by sponsors, CDER judges a drug's "efficacy" and "safety"

(Avorn, 2004)

9

Some FDA mandates

- ☑ grant permission to test drugs on humans
- ☑ review data on safety and efficacy
- ☑ set criteria for drug approval
- ☑ grant or deny approval of new drugs
- ☑ require more studies, disclosure of risks
- ☑ impose fines on drug makers
- ☑ order drugs removed from market



10

1938 Federal Food, Drug and Cosmetic Act:

Basis for FDA regulation of drugs

- Passed after 100 deaths in 1937 from a toxin in a batch of sulfa drugs

(Ballentine, no date)

11

FDA's drug testing rules tightened after **thalidomide**, prescribed to pregnant women in Europe in 1960, caused birth defects

12

As a result, 1962 amendments to *Food, Drug, & Cosmetic Act* of 1938 required sponsors to:

- ✓demonstrate efficacy in controlled trials
- ✓report serious adverse effects to FDA
- ✓list all known risks (on drug label and in drug ads to doctors)

13

More recent FDA laws have been controversial

Some scientists, advocacy groups, and legislators often accuse the FDA of treating industry, not the public, as its client

(Hawthorne, 2005; Sharav, 2007)

14

Prescription Drug User Fee Act, 1992

To speed up approval times, FDA collects fees from sponsors

User fees now make up over 50% of CDER's budget

(Avorn, 2007)

Impact of user fees

Since 1992 and the birth of user fees, the FDA has slashed its own testing laboratories and network of independent drug safety experts in favor of hiring more people to approve drugs for the pharmaceutical industry

(Harris, 2004)

16

"User fees have undoubtedly constrained the FDA's independence and influenced its decisions."

Marcia Angell, former editor, *New England Journal of Medicine*

FDA's User-Fee Habit

washingtonpost.com

By Cindy Skrzycki

Tuesday, April 3, 2007; D01

17

Draft Guidance on Direct-to-Consumer Advertising, 1997

After 15 years of industry pressure, the FDA allowed sponsors to advertise prescription drugs directly to consumers

- *DTCA is praised for providing drug information to consumers*
- *DTCA is criticized for increasing drug costs and promoting least effective drugs*

(Gellad & Lyles, 2007; Hollon, 1999)

18

Pediatric Research Equity Act, 2003 & *Pediatric Exclusivity Act*, 2004

FDA can request studies to be conducted on children, giving sponsors an extra 6 months of exclusive marketing for every drug studied

- *Acts are praised for stimulating research on drug effects and indications in children*
- *Acts are criticized for griving drug firms unneeded profits and using kids as guinea pigs for unnecessary drug testing*

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Part B

FDA's Drug Approval Process

20

Few drugs make it to market

5,000 molecules screened in the lab = 1 obtains FDA approval as a medication

From start to finish, sponsor will spend $100 - $400 million to obtain FDA approval

(Goozner, 2004; Ng, 2004)

21

FDA requires that drugs intended for prescription undergo pre-clinical and clinical testing

22

Pre-clinical testing: 2-4 years

A promising molecule is tested in laboratory and on animals

- to establish its main biological activity and
- to rule out that it causes cancer, mutations, and birth defects

23

If drug remains promising after pre-clinical testing, sponsor may apply to start clinical trials on humans

Phase I trials: 1-2 years

Drug is given to 20-80 healthy volunteers to establish safe dosage levels, main adverse effects, "abuse potential"

25

Phase II trials: 2-3 years

Drug is given to 300-500 people with the illness for which the drug is supposed to be marketed

- The goal is to show promising therapeutic effects in order to justify the next phase of trials

26

Phase III trials: 2-4 years

In *randomized controlled trials* (RCTs), 1000-3000 diagnosed patients from many sites are *randomly* assigned to receive either the drug or a placebo

- Neither investigators nor patients are supposed to know who is receiving what ("double-blind")

27

FDA approval requires only 2 positive Phase III trials, even if more trials are negative

Positive trial: on a symptom rating scale, drug-treated group shows *statistically significant* advantage over placebo-treated group

(FDA, 1998)

A drug showing "efficacy"

✓has shown <5% chance of being worse than placebo

✓has *not* shown that it helps patient's condition to remit, or that it works better than another drug

(Avorn, 2004)

29

With 2 positive Phase III trials, sponsor can make a **New Drug Application (NDA)**, requesting FDA approval to market drug for a specific indication and age group covered in the trials

30

FDA reviews pre-clinical and clinical studies and decides whether the drug's benefits outweigh its risks

31

Drug label

Label summarizes information from pre-clinical and clinical trials

Exact contents are <u>negotiated</u> in private by FDA and sponsor

A shortened form must appear in all drug packaging and advertising, except broadcast

Label is considered the authoritative drug information

32

Phase IV trials: Post-marketing surveillance

As a condition for approval, FDA usually requests sponsor to conduct post-marketing trials

These trials evaluate the drug under ordinary conditions, with ordinary patients

Phase IV trials give more realistic view of drug's harms and benefits

33

Part C

Limitations of Clinical Trials

34

To discover new drugs for physical diseases

Researchers start with a *target* of drug action identified by understanding how a disease affects the body at the cellular/molecular levels

35

Not the same process for mental disorders…

Cellular/molecular biology of mental disorders is *unknown*—drugs tested for these problems don't target known biological anomalies

These drugs are selected based on their *effects on animal behavior* and *expected effects on people's complaints and behavior*

(Moncrieff & Cohen, 2005)

36

No biological markers exist

To repeat – mental and emotional problems ***are not*** equivalent to physical diseases

No cause has been shown to be exclusively biological

There is ***no biological marker*** for any DSM "primary mental disorder," including schizophrenia

(Charney et al., 2002)

37

Flaws in clinical trials

Analysts and critics have revealed many problems with the design and conduct of clinical trials of psychotropic drugs

Overall conclusion:

Clinical trials do not provide definite basis to determine benefits or risks of drugs

(Cohen, 2002; Safer, 2002)

38

Trials at all phases neglect most psychoactive effects

Practice: Trials focus on measuring narrowly selected complaints and behavior

Problem: Main psychological alterations produced by drugs remain unknown

(Jacobs & Cohen, 1999; Cohen & Jacobs, 2007)

39

Phase II & III trials are very short

Practice: Most last only 3-8 weeks, and up to 70% of subjects drop out before trial's end

Problem: Only some acute effects are detected—not those emerging over a longer time

(Cohen & Jacobs, 2007)

40

Subjects are wrongly assumed to have the "same" disorder

Practice: In a depression drug trial, a subject meeting DSM criteria for depression is eligible

Problem: 200 distinct symptom combinations = DSM diagnosis of depression

Also, subjects usually meet DSM criteria for *several* diagnoses

The "sameness" of subjects' problems—needed for a valid comparison of treatments—is not established

(Beutler & Malik, 2002; Cohen & Jacobs, 2007; Emslie et al. 2002)

41

Inert pills are used as comparisons

Practice: Drugs with psychoactive effects are compared to inert sugar pills

Problem: Placebos can be active (causing physical sensations) or inert (no sensations)

Because they are more powerful, active placebos are almost never used

Also, sponsors routinely screen and exclude placebo responders from clinical trials

(Abboud, 2004; Fisher & Greenberg, 2003)

42

The "blind" is often broken

Practice: It's assumed that patients and investigators are "blind" to treatment status

Problem: Obvious side effects in drug-treated subjects cue everyone about which treatment they're getting. This breaks the "blind"—making objective studies impossible

(Fisher & Greenberg, 1993)

43

High doses of comparison drugs are used

Practice: When comparing a new drug to an older drug, very high doses of the older drug are used

Problem: The older drug produces more side effects, making the newer drug appear safer

(Geddes et al., 2000)

44

Outcomes are researcher-rated rather than patient-rated

Practice: Main outcome measures are rated by *researchers*

Problem: In all Phase III pediatric trials of antidepressants, *not one of 10* parent- or child-rated scales showed advantage for the drug

(Jureidini et al., 2004)

45

Adverse effects are carelessly investigated

Practice: Most trials elicit side effects by asking subjects general questions once a week, or waiting for subjects to report them *spontaneously*

Problem: This *underestimates* rates of side effects, especially psychological and behavioral ones, giving false impression of drug's safety

(Greenhill et al., 2003)

46

Adverse effects are mis-coded

Practice: Sponsor decides which effects qualify as "adverse drug events" and how to name them

Problem: Many adverse events are coded as something else, giving false impression of drug's safety

(Breggin, 2002)

47

Strattera pediatric trial:

Mis-coding why patients dropped out

What the researcher wrote	How the sponsor coded it	How it was re-coded after FDA reanalysis
"Parents felt 'too many side effects'; stopped drug early; Abdominal pain, nausea, anxiety"	*Protocol Violation*	*Adverse Event*
"Increasing behavior problems, worsening oppositional behavior; depression"	*Physician Decision*	*Adverse Event*

(Lillytrials.com, 2007)

48

Post-treatment ratings unreported

Practice: Sponsor gathers data for weeks *after* subjects stop treatment, but does not submit them to FDA

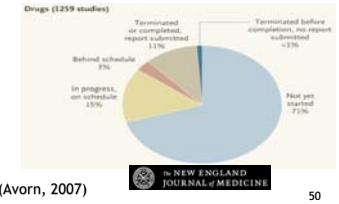
Problem: How subjects rate their treatment *once they're off drugs* may contradict their ratings while *on* drugs. This discrepancy is rarely discussed or explored

(Healy & Farqhar, 1998)

49

Post-marketing trials rarely conducted

As of late 2006, more than 70% of promised Phase IV trials had not yet started…



(Avorn, 2007)

50

The preceding limitations of clinical trials give clinicians and policymakers false ideas about how medications can help and how they can harm people

- FDA approval by itself does not guarantee that a drug is either *safe* or *efficacious* for its intended uses

(Strom, 2006)

51

The increasing involvement of industry in clinical trials has further muddled this worrisome situation

52

Part D

Blurring Science and Marketing

53

Huge payoffs can follow an FDA drug approval

Zyprexa sales since 1996: ***$20 billion***

These create enormous incentives to turn clinical trials into marketing tools

(Smith, 2005)

For the FDA, a clinical trial is a limited test of the efficacy of a product

For the sponsor, it's a ticket to get its product past the FDA hurdle—and possibly to blockbuster status

(Smith, 2003)

55

How sponsors turn trials into marketing tools

- ☑ design studies solely to get positive results
- ☑ suppress and twist negative results
- ☑ publish positive results multiple times

(Quick, 2001)

56

(2008) The NEW ENGLAND JOURNAL of MEDICINE

Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

"According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis showed that 51% were positive."

57

Contract Research Organizations (CROs)

To get drugs approved by the FDA, sponsors outsource clinical trials to CROs, a $15 billion/year business

These private firms make it easier to:

- Enroll thousands of subjects
- Conduct more multi-site trials
- Shield trials from public scrutiny

(Hunley, 2007)

58

Conflicts in research

"It's a house of cards built on a fundamental conflict of interest. The problem is that drug companies have inordinate influence over the evaluation of their own products. That, on the face of it, doesn't make sense."

- **Marcia Angell**, former editor, *New England Journal of Medicine*, author, *The Truth About the Drug Companies*

59

Funder's drugs come out ahead

In 90% of studies pitting one newer antipsychotic against another, the best drug was the study sponsor's drug

THE AMERICAN JOURNAL OF PSYCHIATRY

(Heres et al., 2006)

60

Independent studies don't favor newer drugs

NIMH's (CATIE) study compared 5 antipsychotics in largest schizophrenia trial. Older, cheaper drug worked as well (or as poorly)

- Regardless of drug, ¾ of patients stopped treatment because they did not improve or had intolerable side effects

The NEW ENGLAND JOURNAL of MEDICINE

(Lieberman et al., 2005)

61

The New York Times

November 22, 2002

Madison Ave. Has Growing Role In the Business of Drug Research

By MELODY PETERSEN

"You cannnot separate advertising and marketing from the science anymore."

- **Arnold S. Relman, MD**, Professor Emeritus, Harvard Medical School, and former editor, *New England Journal of Medicine*

THE WEEK

The Best of the U.S. and International Media

The Corruption of Medicine

Several top medical journals recently admitted that studies they published on new medications have been tainted by undisclosed financial ties between researchers and drug companies. Does Big Pharma have too much influence over drug research?
9/22/2006

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Part E

Problems in Drug Safety After Marketing

64

Because of the limitations of clinical trials, detecting adverse effects from drugs falls to **post-marketing surveillance**, when drugs are commonly prescribed, and used for longer periods, in more natural conditions, by more varied patients

(Strom, 2006)

This is when most adverse effects, and a more accurate portrait of the drug's risk-benefit ratio, emerge

Yet such post-marketing monitoring also appears spotty

(Lasser et al., 2002)

66

Newer drugs more likely to have hidden risks

50% of warnings occur within 7 years of a drug's introduction

Half of the withdrawals occur within 2 years

(Lasser et al., 2002)

67

Black Box Warnings

If the adverse drug reaction is serious enough to require extraordinary monitoring or special screening, the FDA will ask the drug sponsor to insert a "*black box warning*" in all marketing and product information to alert clinicians and consumers of the nature of the risk

68

Safety questions are "answered" post-marketing

51% of drugs get label changes

20% of drugs get new black box warnings

3-4% of drugs are withdrawn

(Strom, 2006)

69

Former and current FDA officials, outside scientists, and advocates for patients say the FDA's efforts to monitor the ill effects of drugs on the market are insufficient

70

USA TODAY

Report: FDA so underfunded, consumers are put at risk

(December 3, 2007; http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm)

abc NEWS

FDA Is Broken, Endangers American Lives

Report Blames Congress for Cutting FDA's Budget

December 6, 2004

The New York Times

At F.D.A., Strong Drug Ties and Less Monitoring

Example: Prozac, 2004

Prozac was on the market for 17 years before FDA warned of increased suicidality

Sponsors of several SSRIs have been accused of not disclosing all the data from clinical trials

72

Example: Vioxx, 2004

Vioxx was taken by 20 million Americans before Merck withdrew it after links to heart attacks and strokes

Merck accused of not disclosing all the data from clinical trials

FDA Public Health Advisory: Safety of Vioxx

73

Serious Adverse Events (SAEs)

- Fatal or life-threatening, cause disability or require hospital stay

Only 1% to 10% of all drug-related SAEs are actually reported to the FDA through MedWatch

Medwatch The FDA Safety Information and Adverse Event Reporting Program

(Moore, Cohen & Furberg, 2007)

74

Thousands die annually

Reports to Medwatch of fatal drug reactions tripled between 1998-2005

- Over **80,000** deaths suspected from medications were reported by health professionals and others during that 7-year period

(Moore, Cohen & Furberg, 2007)

75

26,000 deaths suspected to be linked to 15 drugs, including:

3 antipsychotics and

1 antidepressant

Clozaril, Risperdal, Zyprexa, Paxil

(Moore, Cohen & Furberg, 2007)

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Table 4. Most Frequent Suspect Drugs in Death and Serious Nonfatal Outcomes, 1998-2005

Drug Name	Rank/Deaths	Drug Class
Death outcome		
Oxycodone	1/5548	Opioid analgesic
Fentanyl	2/3545	Opioid analgesic
Clozapine	3/3277	Antipsychotic
Morphine	4/1616	Opioid analgesic
Acetaminophen	5/1393	Analgesic
Methadone	6/1258	Opioid analgesic
Infliximab	7/1228	DMARD
Interferon beta	8/1178	Immunomodulator
Risperidone	9/1093	Antipsychotic
Etanercept	10/1034	DMARD
Paclitaxel	11/1033	Antineoplastic
Acetaminophen-hydrocodone	12/1032	Combination analgesic
Olanzapine	13/1005	Antipsychotic
Rofecoxib	14/932	NSAID
Paroxetine	15/850	Antidepressant

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(Moore, Cohen & Furberg, 2007)

Part F

Conclusions and Recommendations

78

FDA's independence in question

As a result of inordinately close ties to drugmakers, the FDA appears to have compromised its independence and its mandate to protect the public from dangerous products

79

Clinical trials provide skewed portrait of drug risks and benefits

Predictable limitations of trials suggest that their positive findings cannot generalize to real-life clinical conditions

Trials are especially poor at detecting adverse effects

80

Most psychological alterations produced by drugs are unstudied

Drugs' main psychological and behavioral effects can remain unknown even years after their approval by FDA and use by millions of people

Clinical trials ≠ objective evaluations of drug effects

Excessive involvement of sponsors in testing drugs may have tainted the research process, turning many clinical trials into "infomercials"

82

Conflicts of interest = suppression of negative trial findings

"Selective reporting of clinical trial results may have adverse consequences for researchers, study participants, health care professionals, and patients."

(Turner et al. 2008)

83

Need for skepticism and vigilance

Professionals should view announcements of clinical trial findings with skepticism and review them critically

84

Use new drugs cautiously

The first users of a newly marketed FDA-approved drug are the true research subjects

Public Citizen recommends waiting 7 years after marketing to use new drugs

"The public misunderstands drug safety, believing that a drug is safe at the time of marketing."

(Strom, 2006)

85

Your role in post-marketing surveillance?

Non-medical professionals and consumers can play an important role in *observing* and *reporting* adverse drug reactions to FDA, thus helping to create a more accurate portrait of medications and their impact on people's lives

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A Critical Curriculum on Psychotropic Medications

Module 3

The End

www.CriticalThinkRx.org

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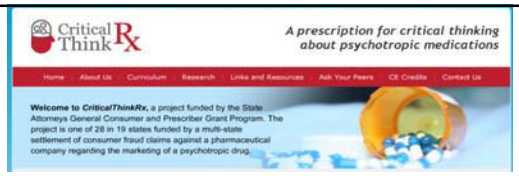


A Critical Curriculum on Psychotropic Medications

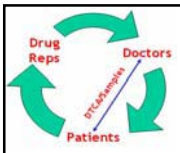
Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - David Cohen, Ph.D.
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

CriticalThinkRx was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®



Module 4

Pharmaceutical Industry Influences on Prescribing

Part A

Expanding Drug Markets

5

Pharmaceutical drugs = Big business

World sales:

$643 billion in 2006

$685 billion projected for 2008

(IMS Health, 2006, 2007; *Pharmaceutical Executive*, 2007; *Los Angeles Times*, 2007) 6

Brand-name drugs

Manufacturer holds an exclusive patent to market them for about 15 years

- 40% of prescription volume
- 90% of revenues

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 7

Generic drugs

Once patent on marketing a brand-name drug expires, drug becomes a "generic," and sells for much less, as other manufacturers may apply to market it

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 8

"Blockbuster" drugs

Generate more than $1 billion of revenue each year

Are heavily marketed, so their manufacturer can make profits during the marketing exclusivity period

7 of the top 10 companies have 1 psychotropic drug among their top 3 blockbusters

(*Pharmaceutical Marketing*, 2006) 9

Antidepressants, antipsychotics, anticonvulsants: among top 6 drug classes sold in U.S.

(*Pharmaceutical Executive*, 2007; IMS Health, 2006)

Growing consensus:

Psychotropics are not popular because they are particularly effective

…"medicalization" and "disease mongering" also stimulate drug use

11

"Medicalization"

- Defining or treating a problem as a ***medical*** disease, requiring ***medical*** treatments

(Conrad & Leiter, 2004; Mintzes, 2002) 12

"Disease mongering"

- Turning ordinary ailments into diseases
- Framing conditions as being severe and widespread
- Seeing mild symptoms as serious
- Seeing risks as diseases

(Moynihan, Health, & Henry, 2002; Moynihan, 2002)

13

Disorders Made to Order

Pharmaceutical companies have come up with a new strategy to market their drugs: First go out and find a new mental illness, then push the pills to cure it.

Brendan I. Koerner
July/August 2002 Issue

MotherJones

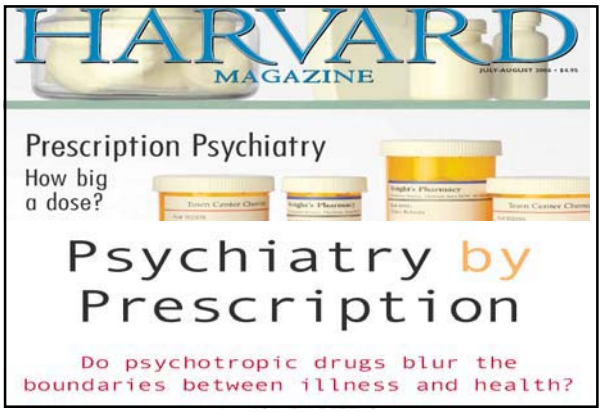
Disease awareness campaigns turn healthy people into patients

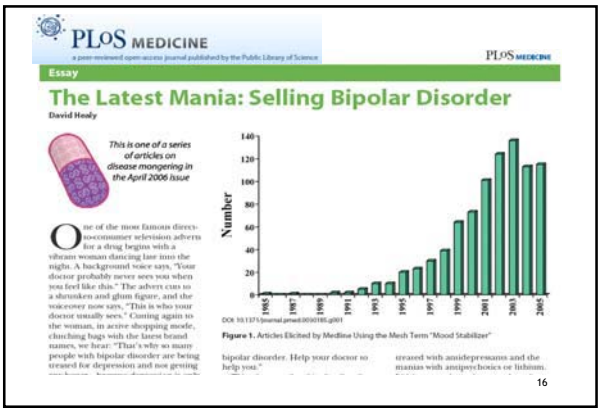
Owen Dyer *London*

DOI: 10.1371/journal.pmed.0030189.g001

Pills are often marketed as a solution to human anxieties and dissatisfactions

14





16

Part B

Marketing Expands Drug Markets

17

Cost of marketing and promoting drugs in U.S.

Industry estimates: $29.9B

Independent estimates: $57.5B

The NEW ENGLAND JOURNAL of MEDICINE

(Donohue, Cevasco & Rosenthal, 2007)

PLoS MEDICINE

(Gagnon & Lexchin, 2008)

18

Drug company marketing targets *all players* in the health care system

19

It influences physicians to prescribe through:

Gifts:

- *free lunches*
- *drug samples*
- *continuing medical education*
- *payments* for lecturing, consulting and research

20

It influences physicians to prescribe by:

- ✓funding countless activities of professional organizations
- ✓drug advertising in professional journals
- ✓paying doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors

21

It influences consumers to seek drugs through:

- ✓direct-to-consumer-advertising (DTCA)
- ✓"disease awareness" campaigns
- ✓funding "patient advocacy" groups
- ✓online medical information and promotions

22

It influences legislators and government agencies to approve drugs and create favorable conditions for drugmakers through:

- ✓lobbying at all levels of government
- ✓large donations to political parties
- ✓payment of "user fees" to the FDA

23

It influences experts to evaluate drugs positively by:

- ✓paying researchers to run clinical trials and develop treatment guidelines
- ✓signing "secrecy agreements" with researchers to conceal negative drug information
- ✓paying academics and researchers to lend their names to articles they have not written ("ghostwriting")

24

Drug Reps

25

100,000 drug reps in the United States

~ 1 for every 6 doctors

(Oldani, 2004; Greene, 2004; Fugh-Berman & Ahari, 2007)

26

Doctors who meet frequently with reps:

- ✓increase prescribing of newer, costlier drugs
- ✓reduce prescribing of generics
- ✓increase nonrational prescribing
- ✓use rep as main information source

(Dana & Loewenstein, 2003; Reist & VandeCreek, 2004, Schwartz et al. 2001; Wazana, 2000)

27

Reps know just which doctors to target and how

Health Information Organizations combine purchased pharmacy data, AMA physician data, and patient data to determine which drugs individual physicians prefer for which diagnoses and which patient groups

This *prescription tracking* is used to tailor marketing to physicians and evaluate effects of promotions on their prescribing behavior

(Fugh-Berman, 2008)

28

Gift-giving

Very effective, *even when doctors don't think so*

29

The Boston Globe

Does a drug firm's free lunch influence doctors?

By Scott Lassman | May 18, 2007

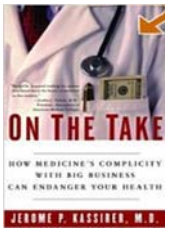
Physicians and the Pharmaceutical Industry

Is a Gift Ever Just a Gift?

JAMA

30

Are doctors "on the take"?



31

The NEW ENGLAND JOURNAL of MEDICINE

A National Survey of Physician–Industry Relationships

Among a sample of 3,200 physicians:

- 83% received food at work
- 78% received drug samples
- 35% were reimbursed for CME
- 28% were paid to give lectures or recruit patients in trials

(Campbell et al., 2007)

32

The New York Times

Psychiatrists Top List in Drug Maker Gifts

By GARDINER HARRIS
Published: June 27, 2007

1997- 2005: drug companies paid Minnesota doctors $57 million

- **psychiatrists received $6.7 million**

(Ross et al., 2007; *The New York Times*, 2007)

33

1 in 3 Minnesota psychiatrists received money from drugmakers

"One in three Minnesota psychiatrists has received funding from drug manufacturers in the past five years, including seven past presidents of the Minnesota Psychiatric Society, two state drug policy advisers and 17 faculty psychiatrists at the University of Minnesota."

(Olson, 2007)

34

The New York Times
May 10, 2007

Psychiatrists, Children and Drug Industry's Role

By GARDINER HARRIS, BENEDICT CAREY and JANET ROBERTS

Psychiatrists receiving money from drug companies more likely to prescribe "off-label" antipsychotics to children

"Free" samples…

- ✓introduce drug into doctor's office
- ✓generate sales, influence brand choice
- ✓Mostly go to wealthy/insured patients
- ✓63% of total promotional spending

Return-on-investment:

$10 in sales for every $1 spent

(Adair & Holmgren, 2005; Backer et al. 2000; Chew et al. 2000; Cutrona et al. 2008; ugh-Berman & Ahari, 2007)

36

Small gifts are powerful

Studies suggest that ***the most powerful form of influence might be small gifts***

The more gifts a doctor received, the more he/she believed that they had no influence on prescribing

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 37

The "gift cycle"

A three-way exchange of gifts between doctors, drug reps, and patients

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 38

"Ask your doctor…"

39

1997: FDA allows full-scale, direct-to-consumer advertising (DTCA) of prescription drugs

- DTCA only allowed in the U. S. and New Zealand

(Gellad et al. 2007) 40

DTCA increases drug use by

- ✓encouraging people to visit doctor
- ✓encouraging patients to request advertised drugs
- ✓influencing doctor's behavior through patient requests

(Gellad et al., 2007; Donohue & Bernd, 2004; Wolfe, 2002; *Consumer Reports*, 2007) 41

DTCA increases spending by

stimulating sales of newer, costlier drugs above older generics

(Gellad et al., 2007; Donohue & Bernd, 2004) 42

Accuracy of DTC ads questioned

1995 to 2004: FDA sent 1,359 warning letters to drug companies for false or misleading advertising

Only 4 FDA staffers review thousands of ads

(Donohue et al., 2007; Zalesky, 2006)

43

Example: 2007 Geodon ad "false and misleading"

2007 FDA letter: maker exaggerated claims of efficacy and did not mention risks of neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes

GEODON "exaggerated claims, downplayed risks"

44

Industry funds "patient advocacy" groups

2005-2006: $29 million to 6 groups
- 7%-91% of the groups' budgets

Groups rarely disclose funding

Funds decline when drugmakers don't benefit

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

45

- ***National Alliance on Mental Illness*** received $11.7 million from 18 drugs firms in three years
- ***Children and Adults with Attention Deficit/Hyperactivity Disorder*** is funded by Shire PLC, the #1 ADHD drugmaker
- ***Depression and Bipolar Support Alliance*** receives more than half its funding from drug firms

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

46

NAMI, CHADD, and DPSA, among "patient advocacy" groups receiving most industry funding, promote view of distress as *chronic brain disease*, requiring latest drugs and neurobiological research

47

Continuing Medical Education

"Educating" to expand markets?

48

Medical Education Communication Companies (MECCs)

earned over $1 billion in 2004 to deliver industry-sponsored continuing medical education (CME)

(Relman, 2001; Elliott, 2004; Wazana, 2000)

49

Industry-sponsored CME highlights sponsor's drugs and is associated with increased prescriptions of those drugs

(Relman, 2001; Elliott, 2004; Wazana, 2000)

50

Concerns in U.S. Senate

Concern over drug firms' influence on CME, and its impact on off-label drug use

COMMITTEE STAFF REPORT TO THE CHAIRMAN AND RANKING MEMBER

USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS

COMMITTEE ON FINANCE
UNITED STATES SENATE

MAX BAUCUS, *Chairman*
CHARLES E. GRASSLEY, *Ranking Member*

APRIL 2007

(Report to Committee on Finance, US Senate, April 2007)

51

"Ghost" Marketing

Industry marketers and scientific journals

52

"Ghostwriting"

Pharmaceutical firms hire MECCs to write academic papers favorable to their products

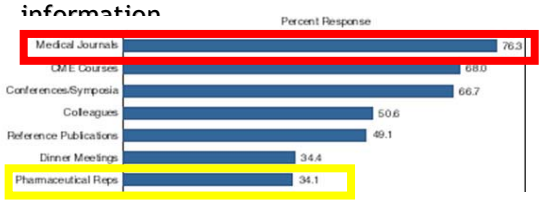
MECCs then hire academics to publish the articles under their name without disclosure about the true source

(Moffat & Elliott, 2007)

53

"Ghostwriting" works because…

~ 76% of doctors consider medical journals their most important source of information



(Source: www.RxPromoROI.org; Fugh-Berman et al. 2006)

54

Even without ghost-writing…

A drug firm may pay a journal $1 million for reprints, creating enormous incentive for the journal to publish a favorable article

- A former editor of *British Medical Journal* called journals "extensions of marketing arms" of drug firms and urged journals to *stop publishing all clinical trials*, and only evaluate them critically

(Moffat & Elliot, 2007; Smith, 2004; *The New York Times*, 2002)

55

56

Pharmaceutical Researchers and Manufacturers of America (PhRMA) represents pharmaceutical and biotechnology companies in the U.S.

PhRMA
New Medicines. New Hope.

57

PhRMA hired hundreds of lobbyists to help pass the Medicare Part D bill in 2004

Originally estimated to cost taxpayers $534 billion, Medicare Part D forbids the government from negotiating drug prices

PhRMA head is Billy Tauzin, former Republican congressman from Louisiana

Drug industry lobbyists outnumber Congressmen 2:1

2006: Drug interests employed about **1,100** lobbyists, including **40** former members of Congress

CBS NEWS
Under The Influence
NEW YORK, April 1, 2007

(Center for Public Integrity, 2007; *CBS News/60 Minutes*, 2007)

59

Large investments in lobbying

2005 - 2006: $182 million spent on federal lobbying

2005 - 2006: $100 million spent on campaign contributions

Sales of top 20 lobbying spenders = 77% of the US drug market

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

60

Defending industry interests

Main goal in 2007:

- Oppose laws that would strengthen FDA's ability to monitor drug safety
- Fight bills that would allow Medicare to negotiate drug prices, which could reduce government drug spending by 60%

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

61

Part C

Conclusions and Recommendations

62

Conclusions

Industry promotion of expensive drugs permeates all phases of the life-cycle of drugs

Deceptive drug marketing is "pervasive, dangerous and primarily aimed at doctors"

63

Skepticism of industry grows

Previously "hidden" practices are increasingly exposed and scrutinized

Government hearings and legislative efforts highlight concerns over public health and public spending

64

Some doctors call for limits

Asking for stringent regulation to eliminate conflicts of interest:

- no gifts, no speaking at industry-sponsored CME, no ghostwriting, disclose research and consulting contracts, replace free samples with vo[illegible] to patients

(Troyen et al., 2006; *Washington Post*, 2006)

Medical students take action

More Med Schools Show Pharma The Door

July 2nd, 2007 8:56 am By Ed Silverman

Last month, the American Medical Student Association ranked med schools based on their freebie policies, using a PharmFree scorecard. Since then, several schools reacted with embarrassment over their rankings.

- **Only 5 of 116 medical schools got an "A" for having a policy restricting drug industry access to students and faculty**

66

But medical schools lag behind

- The International Committee of Medical Journal Editors (ICMJE) requires full disclosure of drug companies' role in research
- But even major journals still can't ensure transparency
- A study of 108 medical schools' agreements to conduct research for drug firms found that ICMJE guidelines were rarely followed
- Researchers have little access to data or power over publishing

(Rivera & Cummings, 2002) (Schulman et al., 2002) 67

States attempt legislation and sue drug firms

Most states have introduced bills or resolutions aimed at marketing

Several states are suing drugmakers for off-label promotion of antipsychotics and for hiding drug risks (see Module 5)

(Reist & VandeCreek, 2004; Zalesky, 2006) 68

9 in 10 Americans favor reforms

Consumer Reports **survey finds strong backing for drug reforms**

As Congress prepares to vote on the most significant prescription drug safety legislation in 45 years, a new *Consumer Reports* poll finds that the American public strongly backs a number of reforms. Safety issues rose to the top, with 9 of every 10 Americans supporting reforms that would require warning labels and follow-up studies on drugs with safety problems, and public disclosure of all clinical drug trials.

ConsumerReports (2007)

69

Recommended reforms to research

Create a public registry of all clinical trials

Fund clinical trials publicly, and cease drugmakers' ties to clinical research

Make *raw* clinical trial data accessible for independent analyses

(Antonuccio & Healy, 2008; NJPIRG Law & Policy Center, 2006) 70

Researchers' commitment?

Because research participants expose themselves to risk, information derived from them should not be misused, suppressed, or distorted

Researchers should promise to make *all raw research data available publicly*, or forego approval from Institutional Review Boards

(Antonuccio & Healy, 2008) 71

Teach prescribers, academics and consumers to:

✓critically evaluate drug marketing

✓rely on independent sources of information

✓implement best practices to minimize industry influence in schools, professional organizations, and mental health providers

(NJPIRG Law & Policy Center, 2006) 72

A Critical Curriculum
on Psychotropic Medications

Module 4

The End

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A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

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Module 5

Specific Drug Classes: Use, Efficacy, Safety

4

5

"Psychotropic" or "psychoactive" drugs

affect the central nervous system and alter feeling, thinking, and behaving

6

"Approved use" means…

FDA has reviewed limited data on safety and efficacy for one indication, usually in one population

A "label" for the drug is established to guide dosage and describe observed side effects

FDA Drug Approvals List

7

Fewer than 10% of psychotropic drugs are FDA-approved for any psychiatric use in children

8

Focus: Stimulants

9

Stimulants approved by FDA for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Adderall, Adderall XR, Dexedrine, Dextrostat	amphetamine, dextroamphetamine	ADHD, narcolepsy	3 +
Concerta, Ritalin, Daytrana, Metadate Focalin, Focalin XR	methylphenidate, dexamethylphenidate	ADHD	6 +
Vyvanse	lisdextroamphetamine		
Strattera (*not considered a stimulant*)	atomoxetine		

10

Stimulants act quickly

Stimulants change behavior *within one hour* in 60-70% of children who take them

11

Long-term evidence of benefits doubtful

APA Report noted lack of data supporting long-term efficacy or safety

- Stimulants show minimal efficacy in general life domains of the child, including social and academic success

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006; MTA Cooperative Group, 2004)

12

Short-term desirable effects of stimulants at usual doses

- ✓Increase alertness and wakefulness
- ✓Induce sense of well-being (euphoria)
- ✓Improve accuracy on brief physical and mental tasks

(Bezchlibnyk-Butler & Jeffries, 2005)

Effects misconstrued as therapeutic in children

- ✓Increased repetitive, persistent behavior
- ✓Decreased exploration and social behavior
- ✓Increased compliance

(Breggin, 1998)

14

Undesirable *behavioral* effects of stimulants

- Nervousness, restlessness
- Insomnia
- Agitation
- Depression, "zombie" look
- Irritability, Aggression
- Psychological dependence
- Mania, Psychosis

(Bezchlibnyk-Butler & Jeffries, 2005)

15

Undesirable *physical* effects of stimulants

- Increased blood pressure
- Dizziness, headaches
- Palpitations
- Stomach cramps, nausea
- Apetite/weight loss
- Stunted growth
- Cardiac arrest

(Bezchlibnyk-Butler & Jeffries, 2005)

16

Stunted growth

Decreases in growth averaging ¾" and 6 lbs. without evidence of rebound 3 years after stopping treatment

(Swanson et al., 2007)

17

Emergency room visits

2,500 children visited ERs in 2004 after taking stimulants for ADHD, most due to accidental overdoses

- 1 in 4 children had heart or blood pressure symptoms including palpitations, chest pain or fainting

(Waters, 2007)

18

2006: FDA warning on stimulants

- ✓increased risk of sudden death in patients with heart problems
- ✓increased aggression, mania and/or psychotic symptoms (including hallucinations)

The New York Times

August 22, 2006

F.D.A. Strengthens Warnings on Stimulants

19

Definite risk of tolerance and dependence

Stimulants prescribed to children are Drug Enforcement Administration (DEA) "Schedule II Drugs," indicating a high risk of tolerance and dependence

RITALIN LA® is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN LA® in a safe place to prevent misuse and abuse. Selling or giving away RITALIN LA® may harm others, and is against the law.

20

Focus: Antidepressants

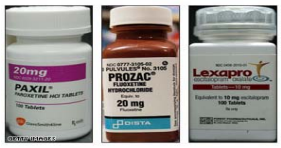
21

FDA-approved antidepressants for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Sinequan	doxepin	OCD	12+
Anafranil	clomipramine		10+
Luvox	fluvoxamine		8 +
Zoloft	sertraline		6 +
Tofranil	imipramine		
Prozac	fluoxetine	Depression, OCD	7 +

22

CDC: Antidepressants most prescribed drugs in U.S.



Antidepressants such as Paxil, Prozac and Lexapro are among America's most-prescribed drugs.

CNN.com /health 2007

23

But are they effective?

Meta-analyses of drug vs. placebo studies show 75-82% of the response was duplicated by placebo

- 57% of studies submitted to FDA failed to show a difference between drug and placebo

(Moncrieff et al., 2004; Kirsch et al., 2002; Kirsch & Sapirstein, 1998)

24

Unimpressive evidence from FDA's complete adult database

"[I]n 189 trials of 53,048 adult subjects with psychiatric disorders … Approximately 50% of subjects who received active drug and 40% of subjects who received placebo were designated as responders."

(Stone & Jones, 2006)

The entire scientific case for antidepressants rests on this 10% difference—which may result from biases in the conduct of clinical trials

25

FDA analysis of pediatric trials concurs

Only 3 of 15 published and unpublished randomized controlled trials show SSRIs as more effective than placebo in depressed children

None of the studies found drugs better on client- or parent- rated measures

(Laughren, 2004)

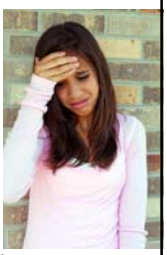
26

No evidence that older antidepressants (tricyclics or MAO inhibitors) have any efficacy with depressed youths

(Somers-Flanagan & Somers-Flanagan, 1996)

27

Short-term desirable effects at usual doses



- ✓Increased physical activity
- ✓Elevated mood
- ✓Decreased expressions of distress such as crying, hopelessness
- ✓Improved sleep and appetite

(Bezchlibnyk-Butler & Jeffries, 2005)

28

Undesirable *behavioral* effects of antidepressants

- Anxiety, nervousness
- Agitation, irritability
- Mood swings, mania
- Aggressiveness
- Thoughts of suicide
- Attempted or actual suicide

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

29

Undesirable *physical* effects of antidepressants

- Gastrointestinal distress (nausea, vomiting, stomach pain, constipation, diarrhea)
- Sexual problems (loss of libido, anorgasmia, erectile dysfunction)
- Sleep disruption (insomnia, hypersomnia)
- Urinary retention
- Blurred vision
- Weight gain
- Headaches, dizziness

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

30

Six clusters of withdrawal effects likely upon abrupt discontinuation of SSRI antidepressants

1. Neurosensory (vertigo, tingling & burning)
2. Neuromotor (tremor, spasms, visual changes)
3. Gastrointestinal (nausea, vomiting, diarrhea, weight loss)
4. Neuropsychiatric (anxiety, depression, crying spells, irritability, suicidal thinking)
5. Vasomotor (heavy sweating, flushing)
6. Other (insomnia, vivid dreaming, fatigue)

(Schatzberg et al., 2006)

31

Antidepressants double risk of suicidality

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2005: FDA issues "black box" warning of "Suicidality in Children and Adolescents":

"Antidepressants increase the risk of suicidal thinking and behavior (suicidality)"

- *(22 RCTs testing 9 antidepressants: **2.3%** rate of serious suicidal events among drug-treated children, vs. **1.2%** among placebo treated—no completed suicides)*

32

"Activation" syndrome: A more common risk

FDA also warns of ***increased agitation, irritability, aggression, worsening anxiety, severe restlessness, and other unusual behaviors*** in youth treated with antidepressants

(Breggin, 2006)

33

Concern over "prescription cascade"

Continued exposure to the drug can lead to effects misinterpreted as psychiatric symptoms (such as mania), leading to increases in dosage or additional drugs—when reducing or stopping the drug would relieve the patient's discomfort

(Breggin, 2006)

34

Focus: Anticonvulsant Drugs

35

Anticonvulsants on U.S. market (antiepileptics, antiseizure drugs)

Brand Name	Generic Name	Yr of intro
Tegretol, Equetro	carbamazepine	1968, 2004
Neurontin	gabapentin	1993
Lamictal	lamotrigine	1994
Depakene, Depakote	valproate	1995
Topamax	topiramate	1997
Trileptal	oxcarbazepine	2000

36

Anticonvulsants FDA-approved for pediatric seizure disorders

Brand Name	Generic Name	Approved Indications	Age
Tegretol, Equetro	carbamazepine	NO PSYCHIATRIC INDICATIONS	Any
Gabitril	iagabine		12 +
Depakote Depakene	divalproex sodium, valproate		10 +
Topamax	topiramate		
Neurontin	gabapentin		3 +
Lamictal	lamotrigine		2 +
Trileptal	oxcarbazepine		

37

Anticonvulsants widely promoted as "mood stabilizers"

Use started in 1980s-1990s due to dissatisfaction with lithium and antipsychotics in treatment of Bipolar Disorder

Use spread rapidly with the promotion of "mood stabilizer" expression and of Bipolar Disorder diagnosis in children

(Healy, 2006)

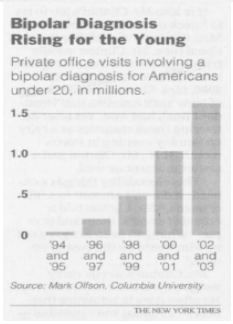
38

39

The New York Times

Bipolar Illness Soars as a Diagnosis for the Young

40-fold increase in less than a decade



(Moreno et al., 2007)

40

Polypharmacy without psychotherapy

More than 90% of children diagnosed with Bipolar Disorder received more than 1 psychoactive drug

Less than 40% received psychotherapy

(Moreno et al., 2007)

41

Scant empirical support

No studies confirm the efficacy and safety of anticonvulsants to treat Bipolar Disorder in children and adolescents

*"Despite the frequent use of antiepileptic drugs in the treatment of **juvenile bipolar disorder**, migraine, and neuropathic pain, the data are insufficient to make recommendations regarding the efficacy of antiepileptics in these conditions in children and adolescents."* *(Golden et al., 2006)*

(Kowatch et al., 2000, 2005; National Institute of Mental Health, 2000; Ryan, Bhatara & Perel, 1999)

42

Most trials are open, small, and show limited response in youth

Half of all participants in an open trial of lithium, divalproex, or carbamezepine did not respond to treatment

- 58% received *at least one* mood stabilizer *plus* a stimulant, an atypical antipsychotic, or an antidepressant

(Lopez-Larson & Frazier, 2006)

43

Desired behavioral effects of anticonvulsants

✓Reduce aggression and impulsivity

✓Calm restlessness and excitability

(Bezchlibnyk-Butler & Jeffries, 2005)

44

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2008: FDA warns anticonvulsants *double risk* of suicidal behavior or ideation

Risk is highest in treatment of epilepsy—which rules out psychiatric status as confounding variable

45

Undesired *behavioral* effects of anticonvulsants

- Depression, sedation
- Hostility and irritability
- Anxiety, nervousness
- Hyperactivity
- Abnormal thinking
- Confusion and amnesia
- Slurred speech
- Sedation, sleepiness

(Bezchlibnyk-Butler & Jeffries, 2005)

46

Undesired *physical* effects of anticonvulsants

- Nausea and dizziness
- Vomiting and abdominal pain
- Headaches and tremors
- Fatal skin rashes
- Hypothyroid
- Blood disorders
- Pancreatitis, liver disease
- Birth defects and menstrual irregularities
- Withdrawal seizures

(Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al., 2003)

47

Birth defects of concern given new patient profiles

Anticonvulsants cross placenta and increase the risk of fetal malformations and cognitive impairments in children exposed in utero

- *Highest rates for valproate and carbamazepine*

(Adab et al., 2006)

FDA black-box warnings

Depakote	Liver toxicity (particularly for under 2 yrs of age); birth defects; pancreatitis
Tegretol	Aplastic anemia and agranulycytosis (severe reduction in white blood cells)
Lamictal	Serious rash requiring hospitalization; Stevens-Johnson Syndrome for under 16 yrs of age (fatal sores on mucuous membranes of mouth, nose, eyes and genitals)
All anticonvulsants	Suicidal ideation and behavior

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50

"Atypical" (newer, 2nd generation) antipsychotics on U.S. market

Brand Name	Generic Name	Yr of intro
Clozaril	clozapine	1989
Risperdal	risperidone	1994
Zyprexa	olanzapine	1996
Seroquel	quetiapine	1997
Geodon	ziprasidone	2001
Abilify	aripriprazole	2002
Invega	paliperidone	2007

51

FDA-approved psychiatric indications of atypicals

Risperdal	Autism, bipolar mania, schizophrenia	5 +
Abilify	Schizophrenia	10+
Clozaril	Treatment resistant schizophrenia	Adults only
Zyprexa	Bipolar mania, schizophrenia	
Seroquel		
Geodon		
Symbyax		
Invega		

52

FDA-approved psychiatric indications of typicals for children

Brand Name	Generic Name	Psychiatric Indication	Age
Orap	pimozide	Tourette's Disorder (for Haldol non-responders)	12 +
Haldol	haloperidol	Schizophrenia, Tourette's Disorder	3 +
Mellaril	thioridazine	Schizophrenia	2 +

Typicals make up less than 5% of FL Medicaid prescriptions of antipsychotics

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"Typical" & "Atypical" antipsychotics

Since 1950s, antipsychotics were used to treat psychoses, despite high toxicity and limited effectiveness

Newer, expensive "atypical" antipsychotics were heavily promoted in the 1990s as safer and more effective

54

Yet, newer no better than older…

The NEW ENGLAND JOURNAL of MEDICINE

2005: largest-ever schizophrenia treatment study finds atypicals neither more effective *nor* better tolerated than older drug

- 75% of patients quit either drugs within 18 months due to inefficacy or intolerable side effects

(Lieberman et al., 2005)

55

Non-psychotic diagnoses in children treated with atypicals

Diagnosis	% of Florida Medicaid children on antipsychotics (2006)
ADHD / Conduct Disorder	48
Nonpsychiatric, Anxiety, Other Psychiatric	27
Bipolar / Depression	13
Schizophrenia / Psychosis	8
Austism / Mental Retardation	4

Times (2007)

56

"Aggression" said to account for most of the antipsychotic prescribing in children and adolescents

(Patel et al., 2005)

57

But do antipsychotics effectively control aggression?

The latest randomized-controlled trial found ***placebo more effective*** than either a typical (haloperidol) or atypical (risperidone) antipsychotic to reduce aggression in patients with intellectual disability

Trial had no drug company sponsorship

(Tyrer et al., 2008)

58

"Antipsychotic drugs should no longer be regarded as acceptable routine treatment for aggressive behavior in people with intellectual disability."

(Tyrer et al., 2008)

59

Few pediatric clinical trials of atypicals for *any* indication

As of 2006, only a few studies of direct AAP comparisons with placebo

Most studies are short-term (3-6 weeks) and results favor the funder's drugs

(McDonagh et al., 2006)

60

"There are no studies that have shown (atypicals) are safe, or for that matter, that they are effective for children…The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness."

Ronald Brown, Chair,
2006 American Psychological Association
Task Force on Psychotropic Drug Use in Children

St Petersburg Times (2007)

61

Dopamine-blocking action of all antipsychotics explains

- ✓indifference, sedation, drowsiness, apathy
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased abnormal movements
- ✓cognitive and motor impairments
- ✓confusion and memory problems
- ✓depression, mood swings, agitation

(Bezchlibnyk-Butler & Jeffries, 2005)

62

Desirable effects of antipsychotics at usual doses

- ✓suppress psychotic symptoms (delusions, hallucinations, agitation)
- ✓suppress manic symptoms (euphoria, expansiveness, irritability)

(Bezchlibnyk-Butler & Jeffries, 2005)

63

Effects misconstrued as therapeutic

- ✓increased indifference
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased compliance with social norms

(Bezchlibnyk-Butler & Jeffries, 2005)

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Undesirable *behavioral* effects of antipsychotics

- Cognitive and motor impairments
- Sedation, drowsiness
- Confusion and memory problems
- Anxiety
- Depression, mood swings
- Abnormal thinking
- Hostility, aggression

(Bezchlibnyk-Butler & Jeffries, 2005)

65

Undesirable *physical* effects of antipsychotics

- Weight gain, high blood sugar
- Abnormal movements (all body parts)
- Diabetes
- Cardiac problems
- Liver problems, jaundice
- Neuroleptic malignant syndrome
- Death

(Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al., 2003; Meyer, 2001)

66

Hormonal dysfunctions

Elevated prolactin levels cause:

- ✓sexual and menstrual disturbances
- ✓infertility
- ✓decreased bone density

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

67

Extrapyramidal symptoms (abnormal movements)

Akathisia: inner distress, rocking, pacing, agitation

Dystonia: sudden, bizarre muscle spasms

Dyskinesia: rhythmic movements of face, mouth and tongue, sometimes of hands and feet

Parkinsonism: rigid muscles, loss of facial expression, unsteady gait, drooling

(Campbell, Rapaport & Simpson, 1999)

68

Tardive dyskinesia risk highest for typical antipsychotics

Long-lasting abnormal movements affect 12% to 35% of children who receive typical antipsychotics for more than 3 months

(Campbell, Rapaport & Simpson, 1999)

69

Weight gain and diabetes

50% of patients on antipsychotics gain 20% of their weight (primarily as fat)

Weight gain linked to "metabolic syndrome"

3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says

By ERICA GOODE
Published: August 25, 2003

The New York Times

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

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Neuroleptic malignant syndrome

Can occur with any antipsychotic agent, at any dose, at any time

Symptoms: extreme muscular rigidity, high fever, & altered consciousness

1-2% rate per year

Fatal if untreated

(Bezchlibnyk-Butler & Jeffries, 2005; Silva et al., 1999)

71

3 atypicals suspected in nearly 4,500 deaths reported to FDA, 1998-2005

Clozaril:	3,277 deaths
Risperdal:	1,093 deaths
Zyprexa:	1,005 deaths

(Moore, Cohen & Furberg, 2007)

72

FDA "black-box" warnings

All atypicals	Increased mortality in frail elderly
Clozaril	Serious risk of agranulocytosis (severe drop in white blood cells), seizures, myocarditis, and other cardiovascular and respiratory effects
Seroquel	Risk of suicidality in children and adolescents

73

"For many adults, and a small number of children, these agents can be an important component of treatment. However, it's so rare to find an example where evidence-based alternatives were exhausted prior to starting an atypical antipsychotic in a child that I have not found one yet in three years of searching."

Mark E. Helm, MD, MBA
Medical Director, Evidence-Based Prescription Drug Program
University of Arkansas Medical Sciences
College of Pharmacy, 2007

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Part B

Lawsuits against drug makers shed light on illegal promotion and serious risks

The New York Times

December 18, 2006

Drug Files Show Maker Promoted Unapproved Use

By ALEX BERENSON

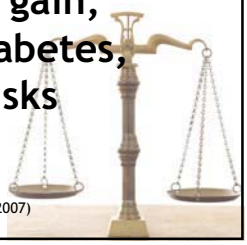
75

States sue drug makers for illegal marketing of unapproved uses

to recover money states paid to purchase atypical antipsychotics and the costs of medical care for the people injured by these drugs

(Pringle, 2007; Kesselheim & Avorn, 2007)

Patients sue, charging that drug makers did not adequately warn about severe weight gain, pancreatitis, diabetes, and other risks



(Pringle, 2007; Kesselheim & Avorn, 2007)

The New York Times

January 5, 2007

Lilly Settles With 18,000 Over Zyprexa

By ALEX BERENSON

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Zyprexa lawsuits

2007: Several states sue Eli Lilly for downplaying or hiding data linking use of the drug to weight gain and hyperglycemia

- *Most of those states' Medicaid spending on antipsychotics is for Zyprexa*

79

2007: Zyprexa settlements top $1.2 billion, *so far*

Eli Lilly has paid more than **$1.2 billion** to settle 30,000+ Zyprexa lawsuits

- The settlements required data on rates of adverse effects be kept *secret*

(Berenson, 2008)

80

2008: Feds, Eli Lilly negotiate $1 billion Zyprexa fine

If a deal is reached, it would be the largest fine ever paid by a drug company for breaking the federal laws governing how drugmakers can promote their medicines

The New York Times
Thursday, February 7, 2008

Lilly Considers $1 Billion Fine To Settle Case

81

Department of Justice

FOR IMMEDIATE RELEASE
FRIDAY, SEPTEMBER 28, 2007
WWW.USDOJ.GOV

2007: Bristol-Myers Squibb pays $515 million over illegal marketing and pricing of Abilify, Serzone, other drugs

82

Litigation has

☑ exposed shady practices of pharmaceutical manufacturers

☑ uncovered previously hidden data about adverse events

☑ helped doctors reassess risks and benefits of some drugs and think critically about the available "evidence"

(Kesselheim & Avorn, 2007)

83

Part C

Conclusions and Recommendations

84

Evidence "poor" for the use of psychotropics in children

- *Little or no evidence of efficacy and safety* of long-term use of these drugs in children
- *Clear evidence of harm* and risk of serious adverse events, including death
- *Risk-benefit ratio especially poor* for antidepressants, anticonvulsants, and antipsychotics

85

Need to rethink risk-benefit ratio

Risks for adverse events, including death, increase with the number of concomitant drugs administered

Risks for adverse events are higher in children, who are receiving adjusted adult dosages of drugs rarely studied in children

(Brown & Sammons, 2002; Riddle, Kastelic & Frosch, 2001; Vitiello, 2001) 86

Side effects leading to multiple medications?

After initial medication, side effects may be viewed as mental disorders and drugged, in a "prescribing cascade" of polypharmacy that keeps children at risk with no sign of behavioral improvement

87

Available evidence does not justify use of psychotropic drugs as **first-line** treatments for children and adolescents

Reassess all cases?

Given known risks and dearth of valid studies showing benefits, cases of children receiving psychiatric medications should be reassessed

Children are involuntary patients. To support continuing psychotropic drug treatment, ***rock-solid*** rationale should be provided in every single case

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A Critical Curriculum on Psychotropic Medications

Module 5

The End

www.CriticalThinkRx.org

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A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - David Cohen, Ph.D.
- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

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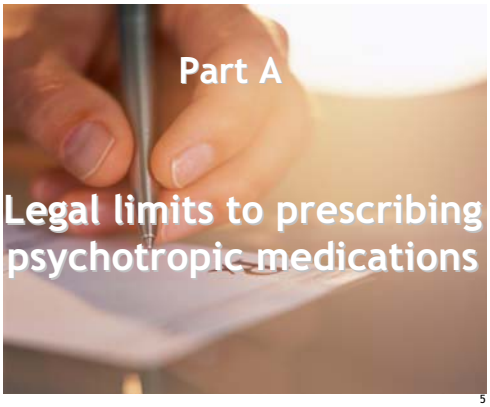
Module 6

Non-Medical Professionals and Psychotropic Medications:

Legal, Ethical and Training Issues



5

Who can prescribe?

Most states grant full or partial prescriptive authority to licensed **physicians, dentists, advanced nurse practitioners, pharmacists, podiatrists,** and **optometrists**

(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004)

6

Who cannot prescribe?

Social workers, mental health counselors, and most psychologists are not authorized to **prescribe, dispense, or administer** any medication

(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004)

7

Discussing *__any and all__* medication issues with clients is *OK*

For example, Florida and California *__do not__* prohibit non-medical professionals to discuss any medication issue with clients

A review of case law indicates that this could not be construed as practicing medicine without a license

(Cohen, 2007; Ingersoll, Bauer, & Burns, 2004; Littrell, 2003; Litrell & Ashford, 1995)

8

Psychologists have gained limited authority to prescribe in 2 states and 1 U.S. territory

New Mexico (2002)

Louisiana (2004)

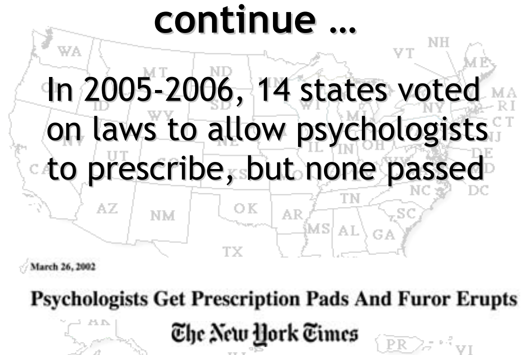
Guam (1998)

Specially-trained Department of Defense psychologists also may prescribe

9

Psychologists' efforts continue …

In 2005-2006, 14 states voted on laws to allow psychologists to prescribe, but none passed



(Goode, 2002; Long, 2005; McGrath et al., 2004; Norfleet, 2002)

Issue is debated…

- Who needs psychologists to prescribe?
- What special training is needed?
- Is it simply about more money?
- Is psychology selling its soul for a mess of (pharmaceutical) pottage?

but the discussion has shifted from "__Should__ psychologists prescribe?" to "__When__ will they prescribe and __how__ should they prepare?"

(Heiby, 2002; Kenkel, 2006; Sanua, 2003)

11

Are counselors next?

Among members of the American Mental Health Counselors Association,

- 41% would like to pursue independent prescription privileges
- 64% would like to obtain dependent privileges
- > 90% want psychopharmacology training in their curriculum

(Scovel, Christensen, & England, 2002)

How about social workers?

Survey of a national sample of 176 practitioners in late 1990s

- 52% opposed to obtaining prescription privileges
- 19% in favor
- the rest said "maybe" or did not respond

(Piotrowski & Doelker, 2001)

Professional associations' stances

American Psychological Association supports psychologists' efforts to gain prescriptive authority

National Association of Social Workers views prescription as beyond the scope of the profession

American Psychiatric Association actively opposes all such initiatives from non MDs

Part B

Ethical and Legal Issues:

Competence and Training
Informed Consent
Confidentiality

15

Professional *competence* is a core principle in the codes of ethics and standards for practice of various helping professions

(ACA, AMHCA, APA, NASW)

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To maintain competence, professional codes recommend

Education and training
Consultation
Supervision
Continuing education

(ACA, AMHCA, APA, NASW)

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Competence requires

- ✓knowledge of valid information relevant to practice
- ✓regular critical review of literature and emerging information
- ✓participation in relevant and unbiased CE

(ACA, AMHCA, APA, NASW)

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No specific standards address working with clients and others around medication-related issues

In the absence of standards, Codes advise exercising careful judgment and taking responsible steps to ensure competence and protect clients from harm

(ACA, AMHCA, APA, NASW)

19

Knowledge = Competence
Training = Knowledge

Without knowledge about drugs, counselors, psychologists and social workers are ill-prepared to meet their clients' needs

Psychopharmacology should be part of training for non-medical practitioners

(Barnett & Neel, 2000; Bauer, Ingersoll & Burns, 2004; Bentley, 2005; Carlson, Thaler & Hirsch, 2005; Dziegielewski & Leon, 1998; Farmer, Walsh & Dziegielewski, 1998; Ingersoll, 2000)

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Knowledge increases confidence and empowers non-medical professionals to participate fully in multidisciplinary environments

(Farmer, Walsh & Bentley, 2006; Dziegelewski, 1998; Littrell, 2003)

Education vs. indoctrination

Students & practitioners must be *educated* rather than *indoctrinated*, and should be exposed to controversies, uncertainties in knowledge, and well-argued alternatives to popular views

(Dziegelewski, 1998; Gomory & Lacasse, 2001; Litrell, 2003)

22

Special guidelines needed

Use of polypharmacy

Integrating psychosocial and biological therapies

Specific groups, such as children, older persons, pregnant women

Ethical and critical thinking skills in the age of "Big Pharma"

(Buelow & Chafetz, 1996; Chafetz & Buelow, 1994; Dunivin & Southwell, 2000; Freimuth, 1996; Levant & Shapiro, 2002; Smyer et al., 1993)

23

24

Why obtain informed consent?

Informed consent is the bedrock of professional practice in a free society

- It promotes the **right to self determination, prevents harm** and provides for the **client's best interest**

(Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Littrell & Ashford, 1995; Littrell, 2003)

25

What is informed consent?

A systematic ***process*** intended to guarantee the client's right to choose, to privacy and to safety

(Dell et al 2008; Littrell & Ashford, 1995; Litrell, 2003; Strom-Gottfried, 1998)

What is *not* informed consent?

Having a client sign-off on services without a clear understanding of the information, including uncertainties about the treatment

(Cohen & Jacobs, 2000; Littrell & Ashford, 1995; Reamer, 2003) 27

Validity of consent forms

Blanket consent forms lack specificity and have been challenged in court

Signing a blank consent form to be completed later *is not* valid consent

(Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 28

Standards for valid consent

1. Avoid coercion and undue influence
2. Assess client competence to consent
3. Specify procedures or actions in the form
4. Inform clients of the right to refuse or withdraw consent
5. Provide adequate information on risks, benefits **and** alternatives to treatment

(Reamer, 2003) 29

Coercion or undue influence

Practitioners who *want* clients to agree to treatments or procedures may be exercising undue influence and will jeopardize validity of their consent

(Dell et al 2008; Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 30

"Adequate" information

- ✓Critical findings on usefulness, ineffectiveness and **reported information on harm**
- ✓Description of the hoped-for benefits and **how success will be evaluated**
- ✓**Alternatives** to treatment being proposed
- ✓Costs of treatment

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 31

Knowledge of alternatives

Lack of knowledge about the alternatives to proposed treatment **invalidates** informed consent

*Competence by providers in a variety of treatment methods is **essential** to informed consent*

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 32

Encourage questions

Informed consent should serve to empower clients to make intelligent decisions about their care, not protect practitioners from liability

*Practitioners must ensure the persons receiving the information understand it, and should **encourage questions***

(Littrell, 2003; Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Tan et al., 2007) 33

Competence to consent

"The capacity to act on one's own behalf, to understand and weigh potential outcomes, to anticipate future consequences of a decision."

(Tan et al., 2007) 34

Assessing competence to consent

In youths, assessment considers intelligence and cognitive functioning, maturity, impact of any distress, seriousness and urgency of situation, and impact of youth's relationships

Refusing to consent does not mean incompetence

(Dell et al 2008; Tan et al 2007)

Cognitive capacity of children

By about age 9, children reach the same conclusions as adults, but by different strategies

By about age 14, minors show the same risk-benefit reasoning as adults and can participate in the consent process

(Dell et al 2008; Spetie & Arnold, 2007)

Respect for autonomy

Older children and adolescents should participate in the consent process in order to protect them from being subjected to treatment procedures against their will, and to respect their developing autonomy and personhood

(Dell et al 2008; Spetie & Arnold, 2007)

37

Third-party representation

Those who cannot give consent require a third party to act "in their best interests"

There are many views on just what this means…

(Spetie & Arnold, 2007)

38

What about preschoolers?

Are parents fully able to carry out their advocacy role?

Their capacity to act in their young child's best interest warrants careful evaluation

(Dell et al 2008; Spetie & Arnold, 2007)

39

"The clinician must be watchful for caregivers who may have ulterior motives and want a child to be medicated for their own convenience, or because pharmacotherapy may simply be 'easier' than behavioral therapy, or as is more often the case, caregivers who have <u>unrealistic expectations</u> about what benefits a treatment may potentially hold for the child."

(Dell et al., 2008, p. 105)

Constitutional right to refuse or withdraw consent

Clients have the right to refuse or withdraw consent at any time and must be informed of this right

State and federal courts have consistently ruled that it is unfair to allow forced medication without "adequate" procedural guidelines

(Bentley, 1993)

41

Forced treatment remains a most controversial issue

Although a fixture of mental health interventions, involuntary treatment must be <u>*literally*</u> **"option of last resort"**

Opponents of forced treatment assert that it violates one's fundamental human rights, creates distrust of helpers, and undermines the foundation for recovery

(Bassman, 2005)

42

Taking psychotropic medications, having a psychiatric diagnosis, or experiencing major distress, does not by itself provide grounds for being denied the right to refuse or withdraw consent

(Bentley, 1993)

43

Confidentiality

44

Confidentiality vs. privacy

U.S. Constitution guarantees **privacy** rights, not confidentiality, to the individual

Confidentiality is essential to develop trust between client and professional

(Corcoran, Gorin & Moniz, 2005; Hanson & Sheridan, 1997; Millstein, 2000)

45

"Duty to protect"

However, the state can breach confidentiality if it has a rationale for seeing the information, such as the "duty to protect" client or others from harm

(Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

46

Relinquishing confidentiality

Managed care organizations and publicly-funded payers require information from providers about clients'

- psychiatric diagnoses
- treatment procedures
- progress and outcomes

(Bilynsky & Vernaglia, 1998;
Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

47

Ethical mandates

Clients must be informed of, ***and authorize***, all disclosures made to insurers and advised of the potential risks of such disclosure ***before*** disclosure is made

(Reamer, 2001; Millstein, 2000)

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Part C

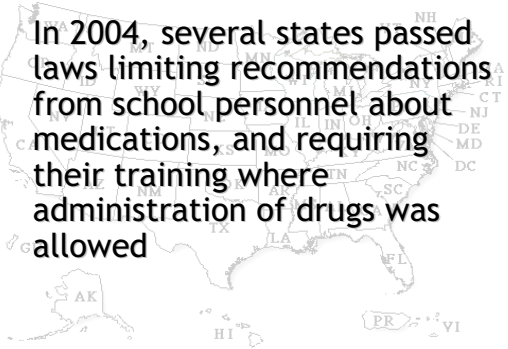
Emerging Legislative Issues

Concerns over medicating children lead to new laws

49

States respond to concerns

In 2004, several states passed laws limiting recommendations from school personnel about medications, and requiring their training where administration of drugs was allowed



2005: U.S. House of Representatives passes *Child Medication Safety Act* (H.R. 1790)

- Bill seeks to *protect children from being forced to take psychotropic drugs as a pre-condition for* attending public school, and intends to restore parental authority over decisions about their children's health

51

Florida limits school's roles F.S. 1006.0625

Public schools cannot require students to receive psychotropic medication as a condition for attending school

"Any medical decision made to address a student's need is a matter between the student, the student's parent, and a competent health care professional chosen by the parent."

52

F.S. 39.407 places limits on medicating children in state custody

Children under state care can be medicated **only** after obtaining ***express and informed consent*** from the parent, or, if parental rights have been terminated, receiving authorization from a judge

Florida and other states now require state agencies to keep list of foster care children on meds—but no register in U.S. tracks health effects of prescriptions on kids

53

Mental health screening debate

Joining the list of issues hotly debated is a 2003 Presidential task force recommendation to screen all school-aged children for mental health problems

(President's New Freedom Commission Report on Mental Health, 2003)

Early detection or pharmaceutical ploy?

Pros: early detection and treatment of disorders

Cons: invalid diagnoses and screening instruments; drug companies attempt to increase market share for psychiatric drugs

55

Part D

Psychotropic Medications and Children:

"First Do No Harm"

56

"Children and adolescents are deemed vulnerable populations, at risk of being harmed by unethical or suboptimal practice and research and are in need of protection."

(Spetie & Arnold, 2007, p. 15)

57

Medications have socio-cultural implications and impact children's identities

(Dell et al, 2008; Floersch, 2003)

58

How do children interpret their taking drugs?

To make sense of everyday medication treatment, children develop "illness narratives"

They may learn to see themselves as "defective" and unable to control their actions

(Dell et al 2008; Floersch, 2003)

59

Medication "messages"

"Better living through chemistry":

Children learn to use drugs to deal with behavioral, emotional, academic and social difficulties

(Dell et al 2008; Floersch, 2003; Jacobs, 2006)

60

Competent practice involves listening and responding to how youths make sense of their medication experience

This requires therapeutic and personal interpretation

(Dell et al 2008; Floersch, 2003; Rappaport & Chubinsky, 2000)

61

In child and adolescent psychiatry, medication decisions are infrequently guided by scientific knowledge, as data on safety and efficacy for most psychotropics in youths remains limited

(Jensen et al., 1999: Matsui et al. 2003; Spetie & Arnold, 2007; Vitiello, 2003)

"The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness"

Ronald Brown, Chair,
2006 American Psychological Association (APA)
Working Group on Psychoactive Medications for Children and Adolescents

St Petersburg Times (2007)

63

"Whether one subscribes to the Hippocratic dictum 'first, do no harm' or takes a risk-benefit approach to treatment, it is impossible to discount possible unwanted treatment effects."

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006, p. 27)

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Part E

Conclusions and Recommendations

65

Non-medical professionals may neither prescribe, dispense, or administer drugs, but they may *discuss* any medication-related issue with their clients, including how their clients can attain their goals with the use or non-use of medications

66

Legal implications

Even professionals who do not prescribe are being called to testify in court about matters that directly concern treatment of clients with psychotropic medications

67

Training for competence

To remain competent in this emerging field requires basic education and training, including critical perspectives on drug use and marketing

68

Professionals working with children receiving psychotropic drugs must take responsibility for their education, and be accountable to clients and society for *their own decisions* about medication-related issues

69

Ethical standards

A practitioner's involvement in referring children for medication, encouraging medication compliance, and monitoring effects, must rest on the *highest* ethical standards

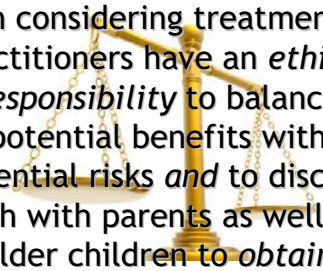
70

Can anyone ethically reassure clients about the safety of psychiatric drugs for children when information is not yet available?

(Littrell, 2003)

71

Balancing risks and benefits



When considering treatments, practitioners have an *ethical responsibility* to balance potential benefits with potential risks *and* to discuss both with parents as well as older children to *obtain informed consent from both*

72

"The potential for benefit from these medications must be balanced against the risks of not only the physical side effects, but also the social stigma, cost, inconvenience, and even family disapproval that can accompany even the most seemingly clear-cut, evidence-based treatment recommendation."

(Dell et al., 2008, p. 99)

Given all the known risks associated with psychotropic drugs, attempting psychosocial therapies to treat problems in children ***prior to considering medication*** is an ***ethical priority***

74

"First do no harm"

Use of psychotropic medications that have been *reported to have serious adverse effects in children—**including death**—should be halted* until research demonstrates that both short- and long-term benefits outweigh the already known risks

Avoid psychotropic drug use in young children until

- ✓evidence-based psychosocial interventions have been exhausted
- ✓rationally-anticipated benefits outweigh the likelihood of risks
- ✓parents/guardians are fully informed
- ✓close monitoring is in place

(Vitiello, 2001)

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A Critical Curriculum on Psychotropic Medications

Module 6

The End

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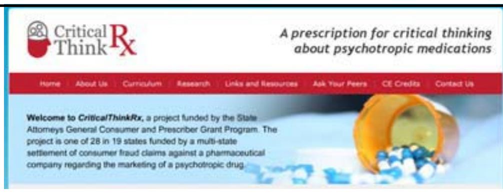

A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - David Cohen, Ph.D.
- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

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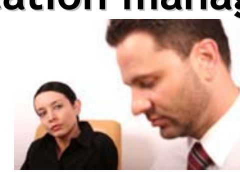
Module 7

Medication Management: *Professional Roles and Best Practices*

Part A

Non-medical roles and medication management



Historical roles of non-medical helpers

To serve as resources for physicians and allied professionals:

- First, giving clients information about their medications;
- Then, identifying obstacles to compliance;
- Later, advocating for clients

(Bentley, Walsh, & Farmer, 2005)

6

A 2001 national survey of clinical and mental health social workers identified 31 possible tasks and activities related to medication

(Bentley, Walsh, & Farmer, 2005)

Survey found some tasks "frequently" performed with clients

- ✓Discussing clients' feelings about taking medications
- ✓Making referrals to physicians
- ✓Discussing how medications may work with other interventions

(Bentley, Walsh, & Farmer, 2005)

8

Tasks "often" performed with clients

- ✓Helping weigh pros and cons of taking medication
- ✓Monitoring clients' compliance with medication
- ✓Discussing medication problems

(Bentley, Walsh, & Farmer, 2005)

9

Tasks "rarely" performed

- ✓Assessing and documenting adverse effects
- ✓Educating about medications
- ✓Suggesting changes in medications to physicians

(Bentley, Walsh, & Farmer, 2005)

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Assuming roles is complicated by:

- ✓priority of some professional values and ethics, such as client's right to self-determination
- ✓questions about validity of medical model for explaining human distress
- ✓gaps and uncertainties in evidence about medications
- ✓influence of pharmaceutical companies on the entire mental health system

(Walsh, Farmer, Taylor & Bentley, 2003)

11

Increasing demands to regulate medicated clients clash with professional values, creating a "professional dissonance"

(Taylor & Bentley, 2005)

12

Public and professional attitudes

Overall, the public does not embrace psychiatric medications as a solution to children's problems

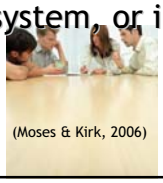
- *70% of adult Americans refuse to use medication for children labeled "oppositional" or "hyperactive"*
- *Only 10% see medication as the most effective component of treatment, and 66% believe it is used as a substitute for other interventions*

(McLeod, et al. 2004)

Practitioners divided

Some find drug treatment of youth helpful or essential

Others find drugs used as a form of social control, misused as a remedy for frustrated parents or overtaxed system, or ineffective



(Moses & Kirk, 2006)

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Helping parents find solutions

When faced with a distressed child, parents may perceive few options in a world where insurers, medical providers and schools pressure them to medicate their children

(McLeod et al., 2004)

16

Unbiased sources of information

Non-medical professionals should serve as "unbiased sources of information" to help parents find the right solutions for their children and to promote alternatives based on critically-evaluated evidence

(Bradley, 2003; Buccino, 2006; McLeod et al., 2004)

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"Vigilant and critically minded"

Non-medical professionals are urged to maintain an ***"informed but critical"*** stance by developing adequate knowledge about the benefits and adverse effects of psychotropic drugs, and remain ***"vigilant, and critically minded"***

(Moses & Kirk, 2006, pp. 220-221)

18

Yet be familiar with basic psychopharmacology

including uses, side effects, dosages, and drug interactions in order to be effective in this complex environment

(Bradley, 2003; Buccino, 2006)

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Part B

Evolving roles in medication management

In today's *collaborative, multi-disciplinary environment*, non-medical practitioners are called upon to play many roles on behalf of clients taking medication

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Physician's Assistant

Traditionally the most common role for professionals legally limited in their scope of work with medications, they

- Help clients follow doctor's recommendations
- Not expected to give advice about decisions involving the prescription

(Bentley & Walsh, 2006)

Consultant

Evaluates client to assess for referral to physicians

Prepares clients to talk with the prescribing physician

Monitors client's subjective experience of medication

Assesses client's ability to pay for expensive drugs

(Bentley & Walsh, 2006)

23

Counselor

Coaches and teaches by providing information and advice about medications

Teaches problem solving, helps identify alternatives, assists in making decisions

(Bentley & Walsh, 2006)

24

Monitor

Helps client observe positive and negative effects of medication

Evaluates client's medication responses, in psychological, interpersonal, and social realms, and effects on self-image and identity

Discusses the monitoring process with clients, families and physicians

(Bentley & Walsh, 2006) 25

Advocate

Presents client's expressed wishes to those in the medical or mental health system

Ideally, has a peer relationship with the physician and participates in all phases of medication decision-making

Possesses knowledge of psychopathology, medications, and related laws and regulations

(Bentley & Walsh, 2006) 26

Teacher

Provides educational materials and other information to clients about:

- The purposes, actions and effects of medications
- Problem-solving regarding medication issues and adverse effects
- Practical suggestions to help clients take medication appropriately

(Bentley & Walsh, 2006) 27

Researcher

Conducts and publishes research in medical and non-medical literature about the full range of psychotropic medication issues

(Bentley & Walsh, 2006) 28

An emerging clinical role: *easing clients off meds*

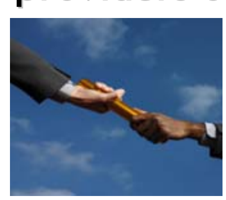
Helping clients withdraw from psychiatric drugs or helping simplify medication regimen

Contingent on practitioner competence and a "rational, person-centered" approach

Guidelines exist for non-medical practitioners to recognize and address discontinuation effects

(Cohen, 2007; Meyers, 2007; Rivas-Vasquez et al., 1999) 29

Effective collaboration with clients, physicians and other providers of care



Traditional

Reflects dominance of medical profession

Characterized by limited, unclear or subservient roles of non-medical professionals

(Bentley & Walsh, 2006, Bronstein, 2003)

Interdisciplinary

Improves services to the client and work satisfaction for professionals

- May not translate in all environments and training in effective models is needed

(Bentley & Walsh, 2006; Bronstein, 2003)

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Transformational

Enhances the contributions of all members of a team

Assumes non-hierarchical relationships where physicians integrate psychosocial aspects of care and involve non-medical professionals in decision-making

(Bentley & Walsh, 2006; Bronstein, 2003)

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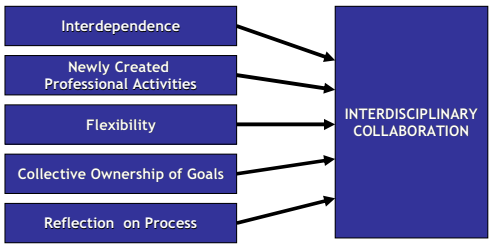
Components of an Interdisciplinary Model



(Bronstein, 2003)

34

Elusive qualities of successful collaboration?

- A favorable political and economic climate
- Shared vision, attainable goals
- Open and frequent communication
- Trust, adaptability, respect
- Clear roles but flexibility in assuming them
- Competent, well-trained practitioners
- A leader with strong interpersonal skills

Unfortunately, these qualities may be absent in interdisciplinary settings

(Bentley & Walsh, 2006; Bronstein, 2003)

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Collaboration to enhance client's self-determination

Collaboration between clients, families and professionals as ***partners*** in the helping process is key to respecting the client's right to self-determination

When partnership with other professionals is difficult, focus should be on empowering clients with information so that they make choices in collaboration with prescribers

(Bentley & Walsh, 2006; Cohen, 2007; Slavin, 2004; Weene, 2002)

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Needed—but difficult to accomplish: A balance between…

- ✓the rights of individuals, families and society
- ✓the costs and benefits of using psychotropic medication
- ✓the non-medical practitioner's role in medication management and the legitimacy and uniqueness of other helping professions

(Bentley & Walsh, 2006) 37

Integrating drugs and psychosocial treatment introduces complex dynamics that require attention and management

Managing parallel treatment requires navigating

- ✓the relationships among client, prescriber and therapist
- ✓competing ideologies held by providers

(Bentley & Walsh, 2006; Bradley, 2003) 39

Dimensions of partnership in medication management

Dimension	Traditional model	Partnership model
Goals of medication	Reduce symptoms	Improve quality of life; emphasis on client priorities
Who selects medication	Physician provider	Client collaboration to help define options
Education focus	Increasing compliance	Improving client's ability to manage recovery
Monitoring and evaluating	Physician evaluates clinical status and compliance	Client and providers evaluate range of outcomes and options
Self-care by client	Largely ignored in mental health	Integrated into consultations with client and family
Control and status	Providers control processes and hold status positions	Emphasis on client control, and client's experiences valued
Refusal and reluctance	Seen as related to denial and paranoia	Seen as a right to be respected in all but emergency situations

(Bentley & Walsh, 2006, p. 223) 40

Part C

Tools for Competence

Assessments, Referrals, Court Affidavits and Medication Monitoring

Comprehensive assessments

Understanding the person in the context of their experiences

Working Definition

An ongoing, systematic data collection about a client's functioning

A process of problem selection and specification guided by a person-in-environment, systems orientation

(Jordan & Franklin, 2003)

43

An individualized process

views the whole person in context, including all factors contributing to their distress and strengths, and changes required to improve coping and mastery

- the person's own perspective is key to understand their situation

(Austrian, 2005; Jordan & Franklin, 2003)

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Elements of assessment

1. ***Exploration*** of client's unique story and facts
2. ***Inferential thinking*** to evaluate meaning of the facts of their story
3. ***Evaluation*** to assess client functioning, strengths and weaknesses in context
4. ***Problem definition*** based on the first three steps and in collaboration with client
5. ***Intervention planning*** based on preceding four steps and in context of environment

(Austrian, 2005; Jordan & Franklin, 2003)

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Mental status examination

☑Appearance, speech, attitude, motor behavior

☑Mood, range and appropriateness of affect

☑Hallucinations, depersonalization, derealization

☑Remote, recent, and immediate memory

☑Level of consciousness, orientation

☑Impulse control

☑Judgment and insight

(Austrian, 2005; Jordan & Franklin, 2003)

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"Integral" assessment approach requires knowledge of

- the client's experience (the individual viewed subjectively/from within)
- the client's behavior (the client viewed objectively/from without)
- the client's culture (the client's system viewed subjectively/from within)
- the client's social system (the client's system viewed objectively/from without)

(Marquis, 2008; Ingersoll, 2002)

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Referrals

Best practices in referring clients for psychiatric evaluation

Few empirical evaluations

Few researchers have investigated effective referral practices, despite frequency of this activity

Tentative guidelines are offered

(Bentley, Walsh & Farmer, 2005)

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Quality referrals

1. Establish and maintain collaborative relationships with prescribers
2. Share ***up-to-date*** information about medications with clients and families
3. Help clients and families articulate and manage the meaning of medication
4. Prepare clients and families for the medication evaluation
5. Follow up on the referral
6. Manage legal and ethical concerns

(Bentley, Walsh & Farmer, 2005)

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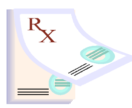
- Prescription
- Reason for the prescription
- Expectations of benefit
- Probability of benefits
- Alternative treatments available
- Risks of the medication
- Expenses involved (direct/indirect)
- Decision



(Chewning & Sleath, 1996, in Bentley & Walsh, 2006)

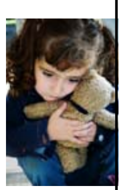
51

A medication evaluation should be requested only if the child's symptoms do not improve or worsen significantly <u>after</u> good psychosocial interventions have been attempted

52

If drugs are considered, <u>all</u> practitioners should evaluate if there is <u>clear evidence</u> of favorable <u>benefit-to-risk ratio</u>

Drugs unapproved for that age group <u>cannot be recommended</u> without special consideration



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Affidavits to judges regarding medication suggestions for children in state care

A recommended checklist

Psychosocial situation and stressors

1. Describe the observed behaviors of concern & who has observed them, when and where
2. Describe past, recent, or chronic stressors in the child's life that may be contributing to any of the observed behaviors

55

Psychosocial assessment

3. Summarize the results of your own assessment of this child's situation: what, in your judgment, could explain how this child is now acting?

4. If the child has been on medication, could the symptoms be adverse effects of the medication? List sources to justify your conclusion

56

Assessment of interventions

5. Describe any previous interventions to address the problems identified in your assessment
6. Describe how these interventions have been evaluated, and their results
7. What other interventions might address this child's problems? To what extent are they available for this child? Why or why not?

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Medication history

8. List medications (names, dosages, times per day) the child takes now and over the past 2 years
9. Have you participated in evaluating the child's progress on medication? What specific goals have been expected, how has their attainment been evaluated?

58

Medication monitoring, evaluation

10. Have you evaluated for adverse effects, behavioral or other? Have you used any rating scales? How well, in your ***own*** careful, overall judgment, is this child tolerating his or her medication?

59

Informed consent

11. Do you have any information on this child's attitude to the medication?
12. How have the risks and benefits of the medication, as well as those of alternate interventions, been assessed and discussed with parents or caregivers?

60

Future monitoring

13. If the child is placed on medication, describe your specific role in monitoring its effects.
14. What reasons do you have to expect that the proposed medication will be beneficial to this child?

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Medication monitoring

Attending to anticipated and unanticipated effects

Monitoring helps clients and families

- Keep track of medication effects
- Cope with bothersome effects
- Solve medication-related issues
- Make decisions about treatment using critically-evaluated information
- Prevent medication errors

(Shojania, 2006)

63

Clients may not know

Clients typically fail to link behavioral drug effects to their drug, and may incorrectly believe they are suffering from additional unrelated physiological or psychological symptoms

Do not dismiss unusual effects, watch out for amplified usual effects, and educate clients about risk of "prescribing cascade"

(Otis & King, 2006)

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Formal monitoring essential

Without formal monitoring, only a fraction of drug problems are recognized

Structured medication reviews have been shown to be <u>more valid</u> and improve client's quality of life

(Otis & King, 2006; Greenhill et al, 2004; Jordan et al., 2004; Kalachnik, 1999)

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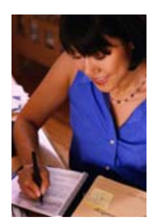
Tools for monitoring

Drug effect checklists — existing or individualized for client's situation *(see checklist handout in website)*

- Use before starting the medication
- Use after starting the medication



(Jordan et al., 2004)

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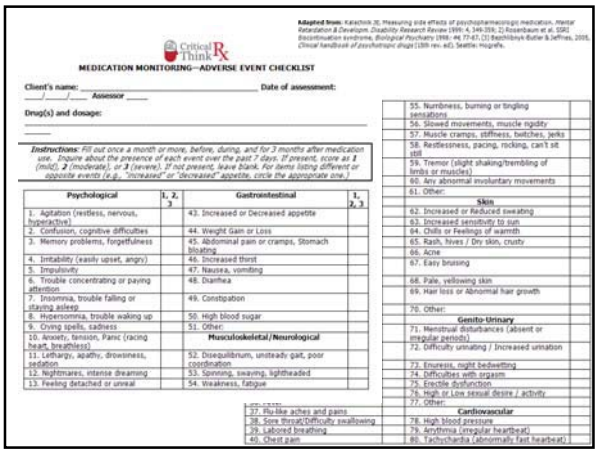

Adapted from: Kalachnik JE. Measuring side effects of psychopharmacologic medication. Mental Retardation & Developm. Disability Research Review 1999; 4: 349-359; 2) Rosenbaum et al. SSRI discontinuation syndrome, Biological Psychiatry 1998; 44: 77-87; 3) Bezchlibnyk-Butler & Jeffries, 2006, Clinical handbook of psychotropic drugs (18th rev. ed). Seattle: Hogrefe.

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MEDICATION MONITORING—ADVERSE EVENT CHECKLIST

Client's name: _____ Date of assessment: ___/___/___ Assessor ____

Drug(s) and dosage:

_____

_____

Instructions: Fill out once a month or more, before, during, and for 3 months after medication use. Inquire about the presence of each event over the past 7 days. If present, score as 1 (mild), 2 (moderate), or 3 (severe). If not present, leave blank. For items listing different or opposite events (e.g., "increased" or "decreased" appetite, circle the appropriate one.)

Psychological	1, 2, 3	Gastrointestinal	1, 2, 3
1. Agitation (restless, nervous, hyperactive)		43. Increased or Decreased appetite	
2. Confusion, cognitive difficulties		44. Weight Gain or Loss	
3. Memory problems, forgetfulness		45. Abdominal pain or cramps, Stomach bloating	
4. Irritability (easily upset, angry)		46. Increased thirst	
5. Impulsivity		47. Nausea, vomiting	
6. Trouble concentrating or paying attention		48. Diarrhea	
7. Insomnia, trouble falling or staying asleep		49. Constipation	
8. Hypersomnia, trouble waking up		50. High blood sugar	
9. Crying spells, sadness		51. Other:	
10. Anxiety, tension, Panic (racing heart, breathless)		**Musculoskeletal/Neurological**	
11. Lethargy, apathy, drowsiness, sedation		52. Disequilibrium, unsteady gait, poor coordination	
12. Nightmares, intense dreaming		53. Spinning, swaying, lightheaded	
13. Feeling detached or unreal		54. Weakness, fatigue	
		55. Numbness, burning or tingling sensations	
		56. Slowed movements, muscle rigidity	
		57. Muscle cramps, stiffness, twitches, jerks	
		58. Restlessness, pacing, rocking, can't sit still	
		59. Tremor (slight shaking/trembling of limbs or muscles)	
		60. Any abnormal involuntary movements	
		61. Other:	
		Skin	
		62. Increased or Reduced sweating	
		63. Increased sensitivity to sun	
		64. Chills or Feelings of warmth	
		65. Rash, hives / Dry skin, crusty	
		66. Acne	
		67. Easy bruising	
		68. Pale, yellowing skin	
		69. Hair loss or Abnormal hair growth	
		70. Other:	
		Genito-Urinary	
		71. Menstrual disturbances (absent or irregular periods)	
		72. Difficulty urinating / Increased urination	
		73. Enuresis, night bedwetting	
		74. Difficulties with orgasm	
		75. Erectile dysfunction	
		76. High or Low sexual desire / activity	
		77. Other:	
		Cardiovascular	
		78. High blood pressure	
		79. Arrhythmia (irregular heartbeat)	
		80. Tachycardia (abnormally fast heartbeat)	

37. Flu-like aches and pains			
38. Sore throat/Difficulty swallowing			
39. Labored breathing			
40. Chest pain			

Systematic monitoring must be carried out to evaluate the wide-ranging effects of medications on behavior, mood, as well as physical and emotional development

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Children should be evaluated for

Emotional development (to examine whether the drug induces or worsens certain problems)

Cognitive development

Physical growth (i.e., weight and height)

Pubertal development (to examine drug effects on course of puberty)

(Greenhill et al., 2003)

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Medication guidelines for child welfare

Medication should only be used as part of a comprehensive treatment plan integrating behavioral interventions

- not used in lieu of other treatments or supports
- based on adequate information, including full biopsychosocial and medical assessment
- resting on informed consent

(Bellonci & Henwood, 2006)

70

With children (*after rock-solid justification for medication has been provided*)

✓adjust doses to a minimum to minimize side effects

✓periodically attempt to take child off medication

✓avoid polypharmacy

✓continually reassess risk-to-benefit ratio

(Bellonci & Henwood, 2006)

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Medical monitoring schedule

Children on psychotropic medications should be seen no less than every three months *at a bare minimum*

FDA guidelines for antidepressants require more frequent monitoring due to risks

(Bellonci & Henwood, 2006)

72

Red flags: Additional monitoring concerns

- ☑Children under five years of age
- ☑Children on 2 or more medications
- ☑Children in state custody

(Bellonci & Henwood, 2006)

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"Psychotropic medications for young children should be used only when anticipated benefits outweigh risks. Parents should be fully informed and decisions made only after carefully weighing these factors. Children and adolescents must be carefully monitored and frequently evaluated as the side effects common to some medications are particularly difficult for children."

National Alliance for Mental Illness (NAMI) Policy Research Institute, 2004

Part D

Conclusions and Recommendations

Beyond biology…

…medications affect the psychological and social concerns of clients, leading non-medical providers to be increasingly involved in medication issues

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What is needed?

Education and training about psychiatric medications for non-medical professionals

Guidelines regarding responsibilities with respect to medication, including dealing with ethical and legal issues such as obligations to report adverse effects

Improved collaboration with *clients as partners* and with medical providers as part of interdisciplinary teams—though key concern remains empowering clients to make their own decisions

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Training on

- ☑ the impact of meanings of medication-taking
- ☑ monitoring clients for adverse effects
- ☑skills in educating clients about risks and benefits of psychotropic medications
- ☑ finding and critically evaluating research on specific medications
- ☑ understanding the strong ideological, economic and political influences on prescription writing in the U.S.

78

Research on

- ☑ how medications and psychosocial interventions interact
- ☑ how medications affect child's self-control, self-image, and personal responsibility (autonomy)
- ☑ how medications affect therapeutic relationships

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Module 7

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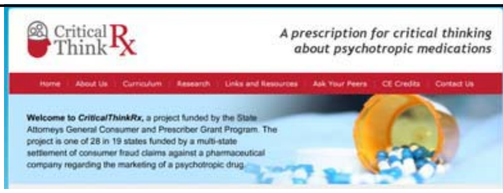

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Critical Think Rx

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Principal Investigator:
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Professional Consultants:
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- R. Elliott Ingersoll, Ph.D. (counseling & psychology)
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- Robert E. Rosen, J.D., Ph.D. (law)

Research Coordinator:
- Inge Sengelmann, M.S.W.

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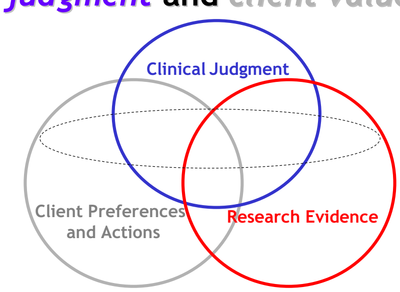
Module 8

Alternatives to Medication: *Evidence-Based Psychosocial Interventions*

Part A

What is Evidence-Based Practice?

The integration of ***best research evidence*** with ***clinical judgment*** and ***client values***



(Gambrill, 2006)

6

A philosophy *and* a process designed to unite research and practice in order to

maximize chances to help clients

minimize harm to clients (in the name of helping)

(Gambrill, 2006)

Deeply participatory

EBP is "anti-authoritarian"—it urges all involved to question claims about what is known *and unknown* about treatments

(Gambrill, 2006)

8

EBP difficulties

- ☑ Threats to business-as-usual
- ☑ Limited training and supervision
- ☑ Concerns about cultural sensitivity
- ☑ Worries that "cook book" methods mask real-world complexity

(Barratt, 2003; Chorpita et al. 2007; Duncan & Miller, 2006)

9

An intervention should have *at least some* unbiased observations or tests supporting its usefulness with particular problems and clients

10

Some criteria for judging an intervention

- ☑ Sound theoretical basis
- ☑ Low risk for harm
- ☑ *Unbiased* research exists
- ☑ Therapist and client concur

11

Available "evidence" no guarantee of usefulness

Published evidence is influenced by funding sources, researcher biases, and conventional wisdom

Statistically significant differences between treatment groups means simply that more clients in one group had some type of response (partial to complete)

(Hoagwood et al. 2001; Ingersoll & Rak, 2006)

12

However, on average, *all major therapies produce equivalent results.*

Clients' improvement may result from *factors common to every therapy*

(Elkins, 2007; Hubble, Duncan, & Miller, 1999) 13

Most improvement has little to do with therapy or technique

Factor	% improvement explained
Client + outside therapy factors	87
Client-therapist alliance	8
Therapist allegiance to model	4
Therapist technique	1

(Hubble, Duncan, & Miller, 1999; Wampold, 2001) 14

Healthy skepticism

"We would do well … to remain optimistically humble on the matter of evidence-based practices in mental health" by accepting that all assumptions are "provisional and reversible"

(Norcross, Beutler & Levant, 2006, p. 11) 15

A clinician's "rubric" for EBP

"Adhere when possible, adapt when necessary, assess along the way"

(Amaya-Jackson & DeRosa, 2007, p. 388)

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Choosing proper interventions rests on

☑ a clear understanding of the problem from a person-in-situation perspective

☑ addressing the complexity of the problem

☑ a policy of **"First, do no harm"**

Part B

Deconstructing the Diagnosis:

What is this child's problem in behavioral terms?

Bio-psycho-social or bio-bio-bio?

- ✓Complex problems in living reduced to “brain disorders”
- ✓Complex life events reduced to “triggers”
- ✓Medicalization of distress and disability leading to false hopes of “quick fix” via pills

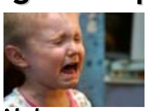
(Read, 2005) 19

We often ignore environmental influences on behavior

- ☑ Poor parenting, neglect, abuse
- ☑ Schools’ failure to motivate children
- ☑ Poverty, lack of access to resources
- ☑ Violence in media, society, neighborhood
- ☑ Culture’s emphasis on instant gratification
- ☑ Drug culture (“take,” not “talk”)
- ☑ Lack of tolerance for differences

(Bentley & Collins, 2006) 20

Children’s distress:
“Disorders” or complex adaptations to distressing life experiences?

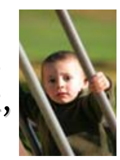


*By seeing children as real persons with their own view of their situation, one ascribes a different **meaning** to their behavior*

(Donovan & McIntyre, 1990) 21

“Understanding” rather than “diagnosing”

A developmental-contextual approach views actions as “communicative”: attempts by individuals to cope, adapt, struggle with their life experiences



(Donovan & McIntyre, 1990) 22

Here’s a list of feelings and behaviors from DSM-IV-TR criteria of “disorders” commonly diagnosed in children

Note the similarities…

“Attention-Deficit/ Hyperactivity Disorder (ADHD)”

Feels:
- Angry, irritable, frustrated

Acts:
- Fidgets, squirms
- Easily distracted, forgetful (difficulty thinking, concentrating)
- Interrupts others (acts impulsively)
- Acts aggressively

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"Major Depressive Disorder"

Feels:
- Sad, empty
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Eats, sleeps too little (or too much)
- Moves, speaks slowly
- Acts impulsively
- Acts aggressively
- Easily distracted (difficulty thinking, concentrating)

25

"Anxiety Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Cries, throws tantrums
- Freezes, clings
- Fidgets (psychomotor agitation)

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"Conduct Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Bullies and threatens
- Fights
- Steals, lies
- Runs away
- Destroys property

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"Oppositional Defiant Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Disobedient
- Loses temper
- Argues with adults
- Annoys people
- Refuses to follow rules

28

"Bipolar Disorder"

Feels:
- Alternating sad and euphoric
- Alternating fearful and reckless
- Angry, irritable, frustrated

Acts:
- Easily distracted (difficulty thinking, concentrating)
- Moves, speaks fast (agitation)
- Acts impulsively
- Acts aggressively
- Does not sleep well

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"Psychotic Disorder"

Feels:
- Sad, empty
- Blunted feelings, expressionless
- Angry, irritable, frustrated
- Afraid, anxious

Acts:
- Apathetic
- Refuses to speak
- Dresses inappropriately
- Cries frequently
- Sees or hears things

30

"Post-Traumatic Stress Disorder"

Feels:
- Sad
- Afraid, anxious
- Angry, irritable, frustrated
- Helpless, guilty, shameful

Acts:
- Agitated, impulsive, re-enacts trauma
- Hypervigilant: distrustful, withdraws
- Dissociated: forgets and can't focus

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"Reactive Attachment Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Watchful, frozen
- Avoids attachments
- Seeks approval or can't be comforted
- Disregards danger cues

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The common elements

Experiencing negative emotions
(sadness, fear, anger, irritability)

Difficulty controlling oneself
(impulsivity, aggression, inattention)

Seeing self and world negatively
(hopelessness, helplessness, shame, withdrawal)

33

What are we medicating?

Negative emotions leading to disruptive actions—especially under stressful conditions that tax the child's adaptive capacities

(Schore, 1994, 2003)

34

Most commonly medicated

Impulsive aggression

"a key therapeutic target across multiple disorders"

(Jensen et al. 2007, p. 309)

35

DSM's scientific value seriously challenged in all disciplines

✓ internal inconsistency in the manual (rejects categorical approach in intro but then lists 300+ categories)

✓ overlap between categories leads to "co-morbidity"—with no increase in understanding

✓ persistent problems of unreliability, especially with children's diagnoses

✓ lack of fit between categories and empirically observed symptom clusters

(Caplan, 1995; Duncan et al. 2007; Maj, 2005; Kirk & Kutchins, 1992, 1994; Jacobs & Cohen, 2004; Mirowsky & Ross, 1990)

36

More recent DSM critiques…

- ✓ more behaviors now seen as "mental disorders" (from 106 in 1952 to 365 in 1994)
- ✓ political lobbying determines inclusion or exclusion of diagnoses
- ✓ all DSM task force members on mood and psychotic disorders tied to drug industry
- ✓ practitioners focus on diagnosis rather than client, losing client's actual story
- ✓ still no "gold standard" validity—no specific bio-marker linked to *any* disorder

(Andreasen, 2006; Tucker 1998; Charney et al. 2005; Kutchins & Kirk, 1998)

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Critical list of DSM "accomplishments"

- ☑ increases people's interest to classify psychosocial problems as medical disorders
- ☑ Helps justify more studies to see how many people can fit how many DSM categories (which often change)
- ☑ led to modest increase in diagnostic reliability since 1980
- ☑ now used by most practitioners in main schools of thought—mostly to obtain third-party reimbursement?
- ☑ brings financial revenues to the American Psychiatric Association from sales of DSMs and training materials
- ☑ strengthened psychiatry's leadership in mental health system (as official definer of mental distress)

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Part C

Empirically-supported psychosocial interventions for children and adolescents

Focus: Trauma, Resilience and Child Welfare

Trauma and early loss

For thousands of children every year, loss and trauma due to disrupted attachments to biological parents result in foster care placements

(Jones Harden, 2004; Racussin et al. 2005)

41

Additional, placement-related traumas

- ✓ Emotional disruption of out-of-home placement
- ✓ Adjusting to a foster care setting
- ✓ Relative instability of foster care
- ✓ High turnover of workers

(Jones Harden, 2004; Racussin et al. 2005)

42

Neurobiology of attachment

Brains develop in a *socially dependent manner*, through secure attachments and *consistent*, *competent* adults attuned to the needs of the child

(Schore, 1994, 2001, 2003; van der Kolk, 2003)

43

Child's "job": to form close, trusting attachments with caregivers

Adolescent's "job": to expand attachments using secure base with caregivers

(Gunnar et al. 2006; Mash & Barkeley, 2006; Moran, 2007; Wolfe & Mash, 2006)

44

Trauma, abuse, and neglect

- ☑ disrupt a child's ability to form secure attachments
- ☑ impair brain development and regulation
- ☑ make self-control difficult
- ☑ alter identity and sense of self

(Bowlby, 1988; Cook et al. 2005; Courtois, 2004; Creeden, 2004; Jones Harden, 2004; van der Kolk, 1994)

45

Resilience

The ability to function well despite living or having lived in adversity rests mainly on normal cognitive development and involvement from a caring, competent adult

(Agaibi & Wilson, 2005, Masten et al. 1990; Schofield & Beek, 2005)

46

- ✓Risk and protective factors in the foster child, foster-families, agencies, and birth family interact to produce upward or downward spirals

- ✓Understanding resilience helps create interventions that produce positive turning points in children's lives

(Schofield & Beek, 2005)

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Three key elements

1. Secure base: *is child strengthening sense of security and able to use foster-parents as a secure base?*
2. Sense of permanence: *is placement stable and foster-parents offering family membership?*
3. Social functioning: *is child functioning well in school, with peers?*

(Schofield & Beek, 2005)

48

Treatment goals

✓Enhance sense of personal control and self-efficacy

✓Maintain adequate level of functioning

✓Increase ability to master, rather than avoid, experiences that trigger intrusive re-experiencing, numbing, and hyper-arousal

(Ford et al. 2005; Kinniburgh et al. 2005) 49

What could help?

Activating child's internal reparative mechanisms through *dyadic interventions* and creating secure attachments

- dyadic therapy mobilizes the completion of interrupted biological and emotional developmental processes

(Amaya-Jackson & DeRosa, 2007; Courtois, 2004; Ford et al. 2005; Pearlman & Courtois, 2005) 50

A sensorimotor approach

Children's internal stimuli, can trigger dysregulated arousal, causing emotions to escalate

- Integration of cognitive, emotional and sensorimotor levels is crucial for recovery

(Ogden, 2006) 51

Why would this help?

Child develops the ability to take in, sort out, process, and interrelate information from the environment — leading to self-organization of internal states and self-control of behavior

(DeGangi, 2000; Kinniburgh et al. 2005; Schore, 2003; van der Kolk, 2006) 52

How would this help?

By enhancing children's:

✓social skills

✓ability to understand and express feelings

✓ability to cope with anger and distress

✓ability to problem-solve and think helpful thoughts

✓skills to self-direct and create goals

(Bloomquist, 1996; Kinniburgh et al. 2005) 53

Alternatives to medication

☑ Consistent, structured, <u>supportive</u> adult supervision

☑ Opportunities for self-expression and physical activity, to give children a sense of mastery over their minds and bodies

(DeGangi, 200; Faust & Katchen, 2004) 54

Helpful activities

- ☑ Teaching problem-solving and pro-social skills
- ☑ Modeling appropriate behaviors
- ☑ Teaching self-management
- ☑ Helping children learn to comply and follow rules

(DeGangi, 2000; Faust & Katchen, 2004)

55

Helpful interactions

- ☑ Desensitizing hyper-reactivity
- ☑ Promoting self-calming and modulation of arousal states
- ☑ Organizing sustained attention
- ☑ Facilitating organized, purposeful activity

(DeGangi, 2000)

Expected outcomes

Children learn to develop appropriate responses, self-organization and control, which in turns leads to

MASTERY AND SELF-ESTEEM

(Kinniburgh et al. 2005)

57

Many treatment alternatives

<u>Symptom-focused</u>: Behavioral, cognitive-behavioral, and interpersonal therapies, attachment-based therapies, trauma-focused therapies

<u>System-focused</u>: Treatment foster care (TFC), Multi-dimensional treatment foster care (MTFC)

(Farmer et al. 2004; Racussin et al. 2005)

<u>Focus</u>: Dysregulated "moods"

"Depression" and "Anxiety"

60

The New York Times

Talk Therapy Pivotal for Depressed Youth

February 6, 2007

In Rigorous Test, Talk Therapy Works for Panic Disorder

By BENEDICT CAREY

61

Link to child maltreatment

Abuse leads to "hypervigilance" to threat, resulting in anxiety and hopelessness

Neglect results in dysregulated "moods"

(Greenwald, 2000; Lee & Hoaken, 2007)

62

"Traumatized children tend to communicate what has happened to them … by responding to the world as a dangerous place by activating neurobiologic systems geared for survival, even when objectively they are safe"

(van der Kolk, 2003, p. 309)

Therapy or no therapy?

Some 30-40% recover without intervention

Approximately 50% of treated patients improve within 8 weeks

A friendly sympathetic attitude and encouragement are key

(Roth & Fonagy, 1996)

64

Consensus strongly favors cognitive-behavioral therapy (CBT) as **first-line** treatment *above* medications

(APA Working Group, 2006; March, 1995; Roth & Fonagy, 1996; Velting et al. 2004)

65

Other effective interventions

1. Interpersonal psychotherapy
2. Psychodynamic psychotherapy
3. Exposure-based contingency management
4. Problem-solving and coping-skills training

(APA Working Group, 2006; Roth & Fonagy, 1996)

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Patient preference

When given a choice, patients express a preference for psychosocial interventions over medications

(APA Working Group, 2006)

67

"Bipolar Disorder" and "Schizophrenia"

68

Very rare in children (~1%)

Diagnosis controversial:

- no laboratory "test"
- "symptoms" may be manifestations of ordinary developmental differences

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Irwin, 2004; Findling, Boorady & Sporn, 2007; Roth & Fonagy, 1996)

69

High risk of over-diagnosis

NIMH Review: 95% of 1500 children referred for high clinical suspicion of childhood-onset schizophrenia did not meet DSM criteria after careful inpatient observation *off all medications*

No evidence that they would have developed psychosis if left untreated

(Shaw & Rapoport, 2006)

70

Link to child maltreatment

Child abuse and neglect considered a causal factor for psychosis and "schizophrenia"

- Content and severity of psychotic symptoms related to severity of past abuse

(Cepeda, 2007; Morrison et al. 2005; Read & Ross, 2003; Read et al. 2004, 2005)

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Many children improve when treated with family-based psychosocial interventions, *even without medications*

- High rates of "relapse" observed on medication

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Findling et al. 2007; Irwin, 2004; Roth & Fonagy, 1996)

72

Effective psychosocial treatments

Child- and Family-Focused CBT combined with interpersonal and "social rhythm" therapy to stabilize mood, activities and sleep

Community support and social acceptance through day programs and sports/cultural activities

(Findling et al. 2007)

73

Who recovers and why?

Psychiatric literature is mostly silent about the characteristics of people who fully recover from psychosis and how and why they do so

(Siebert, 2000)

74

Focus: Disruptive behaviors

Disruptive behaviors: the most frequent reason for referral of children to mental health services

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006)

76

For disruptive behaviors and conduct "disorders"

☑ Family-based behavioral interventions

(APA Working Group, 2006; Brestan & Eyberg, 1998; Diamond & Josephson, 2005; Kazdin, 2005, 2000, 2000b; Kazdin & Weisz, 2003; Thomas, 2006)

The New York Times (2006, December 22)

TROUBLED CHILDREN

Parenting as Therapy for Child's Mental Disorders

TJ Van de Wal's attention deficit problems have improved in response to parenting techniques, his mother Dawn, right, said.

78

Effective parenting: the most powerful way to reduce child and adolescent problem behaviors

(Caspe & Lopez, 2006; Johnson et al. 2005; Kumpfer et al. 2003) 79

Strongest evidence base

1. Parent management training (PMT)
2. Problem-solving skills training (PSST)
3. Brief strategic family therapy (BSFT)
4. Functional family therapy (FFT)

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006; Farley et al. 2005; Kazdin, 2003; Kazdin & Whitley, 2003; Springer 2006; Thomas, 2006) 80

Goals of parent training

- ☑ Promote parent competencies & strengthen parent-child bonds
- ☑ Increase consistency, predictability & fairness of parents
- ☑ Produce behavior change in children

(Kazdin, 2003; McCart et al. 2006; Webster-Stratton & Reid, 2003) 81

"Problem" children or "problem" adults?

Coercive parenting was the only factor linked to children's failure to improve their conduct after family treatment

(Webster-Stratton, Reid & Hammond, 2001) 82

Maltreatment consistently linked to aggressive behaviors

- ☑ History of trauma virtually *universal* in youth with conduct "disorders"

(Greenwald, 2000; Lee & Hoaken, 2007) 83

Children in foster care

- ✓have socio-emotional problems ***3 to 10 times more often*** than other kids
- ✓Coercive interactions only result in escalation of aggressive behaviors

(Nilsen, 2007) 84

Parent-training in child welfare

Promising programs exist to train biological and foster parents

Goal is to break the cycle of coercive parenting and child oppositional behavior

(Barth et al. 2005; Nilsen, 2007)

85

"ADHD"

Large evidence base exists for behavioral interventions, incl. parent training, social skills training, and school-based services

- Results equivalent to stimulant medications ***<u>without the health risks</u>***

(APA Working Group; Chronis et al. 2004, 2006)

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Focus:
Mentoring

Children's development depends upon reciprocal activity with others with whom they have a strong and lasting bond

(Jones Harden, 2004; Rhodes et al. 2006)

Mentorship

A relatively long-term, non-expert relationship between a child and non-parental adult, based on acceptance and support, aiming to foster the child's potential, where change is a desired but not predetermined goal

(Dallos & Comley-Ross, 2005; Rhodes et al. 2006)

Significant effects

Meta-analysis of 55 studies found significant effects of mentoring programs

- Community-based programs more effective than school-based programs

(DuBois & Silverthorn, 2005)

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Mentoring in foster care

Survey of 29 programs found mentoring provides a bridge to employment and higher education, helps with transitional problem-solving

(Mech, Pryde & Rycraft, 1995)

91

Common factors for success

- ☑ Frequent contacts
- ☑ Emotional closeness (attunement)
- ☑ Longer duration
- ☑ Structured activities
- ☑ Ongoing training for mentors

(DuBois & Silverthorn, 2005; Gilligan, 1999; Rhodes et al. 2006) 92

Mentors enhance resilience

Sensitive mentoring increased self-esteem and well-being, reduced aggression and opened new relationships beyond care system

- *prevents negative outcomes as youth leave foster care*

(DuBois & Silverthorn, 2005; Gilligan, 1999; Lemon et al. 2006; Legault et al. 2005; Rhodes et al. 1999, 2006; Schofield & Beek, 2005) 93

Reduces violence

"Having someone to count on when needed" softened the impact of trauma and reduced likelihood of youth engaging in violent offenses

(Maschi, 2006) 94

Part D

Conclusions and Recommendations

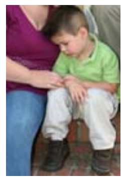
Medicalized approach to distress and disability pathologizes children's behaviors and ignores the context of their experiences

- "Understanding" rather than "diagnosing" changes the meaning of those behaviors and can lead to more helpful interventions

96

Abuse, neglect and trauma disrupt secure attachment and impair the child's ability to self-regulate

- "Repair" occurs through the formation of secure attachments, rather than by medication



Irritability, impulsivity and aggression appear in criteria for most DSM diagnostic labels used on children

- We are medicating children's negative emotions and immature self-control

98

Growing consensus

Just Say 'No' to Drugs as a First Treatment for Child Problems

(Duncan, Sparks, Murphy, & Miller, 2007)

99

Attempt psychosocial interventions *before* initiating medication

Ample evidence supports their use as effective first-line options for children's behavioral problems, *with no apparent risk of medical harm*

100

Fundamental issues of efficacy and safety of psychotropic medications in children remain unresolved

Therefore, medicating children should be avoided

101

A Critical Curriculum on Psychotropic Medications

Module 8

The End

Critical Think Rx
www.CriticalThinkRx.org

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Facing Foster Care in Alaska

Mental Health Services and Foster Care

Facing Foster Care in Alaska
Mental Health Services

Our Mission is to improve the foster care system through sharing our experiences, supporting and educating youth and social services and implementing positive change in society as a whole.

In 2003, a group of dedicated foster care youth and alumni from across Alaska came together to share their issues and form a Youth Advisory Board. In 2004, the group adopted the name Facing Foster Care in Alaska (FFCA). FFCA is dedicated to improving the lives of children and youth in foster care through developing and sustaining a statewide organization that will continue to work towards supporting foster youth and improving the foster care system. FFCA members are dedicated to advocating for improvements in the areas of education, mental health, permanency, disproportionality, independent living, and the overall well-being of children and youth in Alaska's foster care system.

Since their inception, the members of FFCA have been speaking out about mental health and treatment services of children and youth in foster care, and offering alternative solutions. With overwhelming feedback from youth and alumni of foster care regarding the issues of mental health and treatment services, the members FFCA came together in November of 2008 to brainstorm ideas and create possible solutions or alternatives to traditional treatment. This document encompasses their ideas and gives insight into what youth and alumni across Alaska believe is the best way to deal with the issues they face when being placed in foster care.

The content of this document reflects only the opinions and ideas of Facing Foster Care in Alaska members, and should not be viewed as the opinions or ideas from any state or private agencies.

Facing Foster Care in Alaska
Mental Health Services

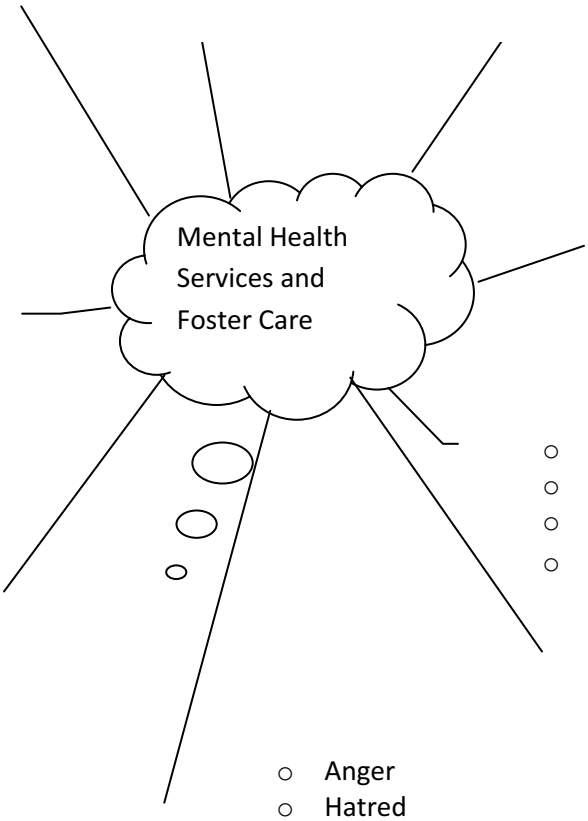
- Uncomfortable
- Hard to explain to peers
- Bull shit
- Miscommunication
- Too young for drugs

- confusion
- false accusations
- loss of personality
- breaks up families
- loss of support systems (friends)
- counseling

- Worse Afterwards
- Groups NA, AA
- No Advocating What-so-ever
- Subjective Hearing
- Subjective opinion thinking

- Addiction
- Flashbacks
- Suicides
- Runaways
- Depression

- Lies & deception
- Untrustworthy
- Messes with life
- Makes you worse
- Hard to cope



- Not enough research
- Guinea pigs
- Other alternatives
- Treatment center-last

- Psycho Roommates
- Stereotypes
- No Choice
- No Mutual Support
- Constant Labeling
- Judging

- Overrated
- No reason
- Forced
- Negative effects

- More money
- Criticism
- Therapy
- Friends-Shitty School
- Med. Adjustment

- Over medicating
- Disorders
- Prolific diagnosis
- North star
- Embarrassment
- Switching SW
- Taking away childhood

- Constant changes w/treatment plan
- Bad communication
- Comic strip story time
- Abandonment
- Hazard-don't really know side affects

- Anger
- Hatred
- Not confidential
- Exhaustion
- Diagnosis
- No independence
- No freedom

- Misdiagnosing
- Treatment facilities
- Brain washing
- Manipulation
- Disconnected
- In hell
- Ashamed

- Hard to remember for busy schedule
- misconceptions
- Normality's-shouldn't we be like this?
- Test subjects
- Profit centers
- Rehab centers
- Unreasonable delays of service

Youth and alumni were asked to share thoughts and ideas around what came to mind when they heard the words, "Mental Health" and "Treatment Services."

Alternatives and Possible Solutions

The decreased use of psychiatric medications

In their 2008 Policy Agenda, FFCA members called for Decreased use of Psychotropic Medication for Alaska's foster youth. Many of Alaska's youth and alumni complain about being prescribed psychotropic medications after entering the foster care system for symptoms of depression, anxiety, trauma, attachment issues, and misbehavior. The youth and alumni of FFCA feel that these are all normal symptoms of child maltreatment and dealing with all that comes out of being placed in foster care. There has been a national focus on the use of psychotropic medications being over-prescribed for children and youth in foster care. FFCA members have also complained about side-effects caused by these medications resulting in a decreased ability to focus on their education as well as function in everyday society. The youth and alumni of FFCA would like to see that the prescription of psychotropic medications for Alaska's foster children and youth is decreased and reviewed more closely.

The right to be informed

Many of Alaska's foster children and youth don't know their rights in regards to mental health and treatment services. The members of FFCA believe that service providers should inform children and youth in foster care about their rights in regards to their treatment plan. During the November 2008 FFCA retreat, one member commented that he did know his rights, but if he did refuse medication he would be placed in North Star. FFCA members would like to see that all children and youth in foster care are informed of their rights and the repercussions if they choose not to comply with their treatment plan.

Building Relationships

The members of FFCA believe that one of the best ways to deal with the emotional issues they face when entering foster care is through building and maintaining healthy relationships with family, friends, and permanent connections with a caring adult. The bulleted list below outlines the ideas FFCA members came up with regarding relationships.

- Trust Building opportunities
- Freedom
- Personal time
- Family Relationships/connections/visits
- Mentors
- Having good listeners
- Supporting dreams/hopes
- Non-judgmental relationships
- Permanent connection
- Getting to know us
- Talking/venting
- Acknowledgment
- Praise
- Constant affective communication
- Not relishing diagnosis/medication
- Cut out the unnecessary
- Understanding
- More homes
- Preparation for the real world
- Being placed in a stable understating home
- Extra time with peers
- Keeping siblings together
- Listen to what we have to say
- Pay attention to our needs
- We need more communication w/family & friends
- Do not separate youth and children
- If meds are absolutely necessary inform us what there for and what the side effects are
- Effective communication with social workers and GAL's

Creating a plan with the client/self determination

Over the years, FFCA members have continuously complained about treatment plans being written for them rather than with them. Many of the youth and alumni speak out about how they have no idea what's in their treatment plan or case plan. The members of FFCA believe that they cannot affectively work on their treatment plan or case plan if they do not know what is in it or don't have a say in the process of creating it. FFCA would like to see that service providers are working with children and youth to develop a plan that outlines what the children and youth feel they need to work on in order to become productive members of society.

The right to be "Normal"

Many of Alaska's foster children and youth complain about standing out among their peers and not being able to participate in the same activities as other young people. They say they are constantly going to appointments for counseling, medication adjustments, group therapy, family therapy, ect. The members of FFCA believe that the best treatment for depression, anxiety, attachment issues, and other behaviors that are often diagnosed in foster children and youth, can be treated by giving them the opportunity to be involved with school, community, and family events. The bulleted lists below outlines the ideas that FFCA members came up with as alternatives to the various therapy and other treatment related appointments.

Extra Curricular Activities

- Sports/Clubs
- Banking/financial skills
- Therapeutic activities
- Massage
- Journaling
- Self advocacy/empowerment
- No drugs
- Foster home with a pet
- FFCA
- Service Projects

Self Expression

- Star watching
- Poetry
- Music
- Art
- Cooking
- Life skills
- Freedom/choice

Definitions (According to FFCA)

Youth- A young person in foster care

Alumni- A person who was in foster care at some point during their life

For more information about Facing Foster Care in Alaska please visit

http://www.alaskacasa.org/facing_foster_care_in_alaska.htm

or

http://www.myspace.com/ffca

This document was drafted by FFCA President Amanda Metivier using the feedback from the FFCA members that attended that November 2008 FFCA retreat in Anchorage. For questions regarding the content of this document please contact Amanda Metivier at facing_fostercare@yahoo.com or call 230-8237.

James B. Gottstein, Esq.

406 G Street, Suite 206
Anchorage, Alaska 99501
Jim.Gottstein@psychrights.org
James.B.Gottstein@gottsteinlaw.com
jg@touchngo.com
907-274-7686

Curriculum Vitae

(September 12, 2008)

Experience:

1985-Present:	Owner - Law Offices of James B. Gottstein
1995-Present:	CEO - Touch N' Go Systems, Inc.
2002-Present:	President/Chief Executive Officer (since 2005) & Board Member, Law Project for Psychiatric Rights (PsychRights®)
2004-Present:	Treasurer & Board Member of the Board of Directors, National Association of Rights Protections and Advocacy (NARPA)
2005-Present:	Board Member, International Center for the Study of Psychiatry and Psychology (ICSPP)
2002-Present	Board Member, Peer Properties, Inc., (currently President).
1991-Present:	Board Member, The Gottstein Family Foundation
2003-2007	President & Board Member, CHOICES, Inc.
2003-2007	President & Board Member, Soteria-Alaska, Inc.
2003-2005:	Board of Directors - Alaska World Affairs Council
1998-2004:	Member - Alaska Mental Health Board
1998-2002:	Board of Directors - Alaska Mental Health Consumer Web
1986-1996:	Board of Directors - Mental Health Consumers of Alaska
1983-1985:	Staff Attorney - Carr-Gottstein Inc.
1982-1983:	Associate Attorney - Delaney, Wiles, Hayes, Reitman and Brubaker
1980-1982:	Partner - Goldberg and Gottstein
1978-1980:	Associate Attorney - Robert M. Goldberg and Associates

Bar Memberships

1994:	United States Supreme Court
1978:	Alaska
1978:	United States District Court, District of Alaska
1978:	United States Court of Appeals; Ninth Circuit

Education:

1978 (Class of '77):	J.D., Harvard Law School
1974:	B.S., Business Administration with Honors (Finance), University of Oregon.

Publications:

- Involuntary Commitment and Forced Psychiatric Drugging In the Trial Courts: Rights Violations as a Matter of Course, 25 *Alaska Law Review* 51 (2008).

- How the Legal System Can Help Create a Recovery Culture in Mental Health Systems, contributed chapter in R. Halgin, *Clashing Views in Abnormal Psychology*, 5th Ed., McGraw Hill, New York, New York, (2008): 17-29.

- Rights and Alternatives: Enforcing legal rights as a mechanism for creating non-medical model alternatives, contributed chapter in Beyond Psychiatry (2007), P. Lehmann & P. Stastny, Eds., 308-17.

- Psychiatrists' Failure to Inform: Is There Substantial Financial Exposure? James B. Gottstein, Esq., JD, Ethical Human Psychology and Psychiatry, Volume 9, Number 2, 2007.

Presentations

- "Advocacy and the Transformation Triangle," International Network Towards Alternatives in Recovery (INTAR) conference on International Recovery Perspectives: Action on Alternatives, University of Toronto, June 6, 2008, Toronto, Canada.

- Panel member Soteria--The Proven Model for Recovery Communities, "The Development of Soteria-Alaska,"INTAR conference on International Recovery Perspectives: Action on Alternatives, University of Toronto, June 5, 2008, Toronto, Canada.

- "Over-Prescription of Psychiatric Drugs: Changing an Irrational Policy," Contemporary Social Policy and Change, University Alaska Anchorage, April 2008.

- Roundtable, Program in Psychiatry and the Law @ BIDMC Psychiatry of Harvard Medical School, October 24, 2007, Boston, Massachusetts.

- "Forced Psychiatric Drugging: A Misguided Atrocity," Hampshire College, Massachusetts, October 22, 2007.

- "The Transformation Triangle," Region Ten Consumer Advisory Council 2nd Annual Conference, Charlottesville, Virginia, October 17, 2007.

- "The Psychiatric Drugging of America's Children: Legal Rights of Children and Parents," ICSPP Annual Conference, October 14, 2007.

- *Myers*, *Wetherhorn* & More: Litigating for Consumer Driven Services," Mental Helath Consumer and Family Education & LeadershipConference, May 17, 2007.

- Psychiatric Drugs in America: Who's Crazy? Or Through the DSM Looking Glass, ANT A655 Advanced Medical Anthropology, March 26, 2008, University of Alaska Anchorage.

- Strategic Litigation to Achieve Meaningful Change: The *Myers* Case, Alaska and a National Initiative, National Association of Rights Protection and Advocacy (NARPA) annual conference, November 16, 2006, Baltimore, Maryland.

- "The Public Mental Health System, University of Alaska Anchorage, November 2, 2006.

- The Public Mental Health System: Analysis and Suggestions for Improvement, Alaska Pacif University, October 26, 2006, Anchorage, Alaska.

- A Coordinated Campaign To Successfully Change the Mental Illness System, ICSPP annual conference, October 9, 2006, October 9, 2006.

- Panel member: "Free Your Mind A discussion about psychiatric rights and how we value people in our communities," David A. Clarke School of Law, Washington, DC, October 6, 2006.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change,"Harvard & Yale Clubs, April 4, 2006, Anchorage, Alaska.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change," Alaska Mental Health Consumer Web, March 31, 2006, Anchorage, Alaska.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change," NAMI-Anchorage Annual Meeting, March 16, 2006.

- "Multi-faceted Grassroots Efforts to Bring About Meaningful Change to Alaska's Mental Health Program," National Association of Rights Protection and Advocacy (NARPA) annual conference, November 19, 2005, Hartford, Connecticut.

- "Involuntary Mental Health 'Treatment:' Utilizing Valid Scientific Information and Client Views to Win Cases," Massaschusetts, Mental Health Law Unit Continuing Legal Education for the Committee for Public Counsel Services, November, 2005, Boston, Massachusetts.

- Member of Panel Discussion of Involuntary Treatment in the U.S., International Society for the Psychological Treatment of Schizophrenia and Other Psychoses, November, 2005, Boston, Massachusetts.

- "Grass Roots, Multi-Organizational Efforts in Support of Human Rights in Mental Illness," International Center for the Study of Psychiatry and Psychology, Flushing, NY, October 8, 2005.

- "Involuntary Commitment and Medication in Alaska: or Just Because I'm Paranoid Doesn't Mean They Aren't After Me," SWK 643 Human Diversity and Special Populations, University of Alaska Anchorage, September 19, 2005.

- "Human Rights in Mental Health: Let's Do It," MindFreedom Action Conference, April 30, 2005, Washington, DC.

- "Forced Psychiatric Drugging in Alaska," presented to the Health Law Section of the Alaska Bar Association, February 3, 2005.

- "PsychRights' Legal Campaign Against Forced Drugging and How You Can Participate," International Center for the Study of Psychiatry and Psychology, Flushing, New York, October 10, 2004.

- "Involuntary Commitment in Alaska and Beyond," Alaska Libertarian State Convention, April 24, 2004, Anchorage, Alaska.

- "The Law Project for Psychiatric Rights: Progress and Directions," for the National Rights Protection and Advocacy (NARPA) Conference, November 23, 2003, Austin, Texas.

- Co-presented Alaska Mental Health Board's FY 2005 Request for Recommendations to the Alaska Mental Health Trust Authority, August, 2003.

- Alaska Mental Health Board Budget Committee's "Mental Health Budget Summit," parts 1 and 2 on March 8, 2003, in Juneau Alaska and April 11-12, 2003 in Anchorage, Alaska, respectively.

- "Unwarranted Court Ordered Medication: A Call to Action," for the National Rights Protection and Advocacy (NARPA) Conference (off-agenda), November, 2002, Portland, Oregon.

- Board Training at the Family and Consumer Conference, May 2, 2002, in Anchorage, Alaska.

- "Real Estate in the Land of the Midnight Sun," presented to the International Real Estate Society's International Congress, July 27, 2001, Girdwood, Alaska.

- "Protecting Your Privacy On-Line: Privacy, Threats, and Countermeasures," co-presented with Lara Baker, September 7, 2001, in Anchorage, Alaska.

- Board Training at the Family and Consumer Conference, April 13, 2001, in Anchorage, Alaska.

- Alaska Mental Health Board's Program and Evaluation Committee's Report on the Alaska Psychiatric Institute, presented as chair of the committee to the full board, February 16, 2000, Fairbanks, Alaska.

- Internet Strategies for the Paralegal in Alaska: A paralegals guide to the information super-highway," for the Institute for Paralegal Education, November 1998, in Anchorage, Alaska.

- "Grant Writing, 1, 2, 3," various times 1998-2002, in Anchorage, Alaska.

- "Web Page Design," Alaska Mental Health Consumer Web various times, 1998-2002.

- "Lawyers and the Internet," October 23, 1995, in Anchorage, Alaska.

- Many public presentations on the Alaska Mental Health Trust Lands litigation and proposed settlements, including radio and television appearances and testimony to legislative committees, 1986-1994

Chambers of
Dana Fabe
Chief Justice

Supreme Court
State of Alaska

303 K Street
Anchorage, Alaska
99501-2083

(907) 264-0622
FAX (907) 264-0554

June 28, 2007

James Gottstein
Law Office of James B Gottstein
406 G St., Suite 206
Anchorage, AK 99501

Dear Mr. Gottstein:

Thank you for agreeing to serve on the Probate Rules Subcommittee on Involuntary Commitments and the Involuntary Administration of Psychotropic Medication. We look forward to receiving your help and expertise in revising the procedural rules that govern these difficult and important cases. Judge Morgan Christen will be chairing the subcommittee, and her staff will be contacting you to schedule the first meeting. Again, thank you for your assistance in this important work.

Sincerely,

Dana Fabe
Chief Justice

DF:jmh

cc: Stephanie Cole, Administrative Director
Judge Morgan Christen
Doug Wooliver, Administrative Attorney

The Washington Post

Debate Over Drugs For ADHD Reignites

Long-Term Benefit For Children at Issue

By Shankar Vedantam
Washington Post Staff Writer
Friday, March 27, 2009; A01

New data from a large federal study have reignited a debate over the effectiveness of long-term drug treatment of children with hyperactivity or attention-deficit disorder, and have drawn accusations that some members of the research team have sought to play down evidence that medications do little good beyond 24 months.

The study also indicated that long-term use of the drugs can stunt children's growth.

The latest data paint a very different picture than the study's positive initial results, reported in 1999.

One principal scientist in the study, psychologist William Pelham, said that the most obvious interpretation of the data is that the medications are useful in the short term but ineffective over longer periods but added that his colleagues had repeatedly sought to explain away evidence that challenged the long-term usefulness of medication. When their explanations failed to hold up, they reached for new ones, Pelham said.

"The stance the group took in the first paper was so strong that the people are embarrassed to say they were wrong and we led the whole field astray," said Pelham, of the State University of New York at Buffalo. Pelham said the drugs, including Adderall and Concerta, are among the medications most frequently prescribed for American children, adding: "If 5 percent of families in the country are giving a medication to their children, and they don't realize it does not have long-term benefits but might have long-term risks, why should they not be told?"

The disagreement has produced a range of views among the researchers about how to accurately present the results to the public. One e-mail noted that an academic review of the group's work, called the Multimodal Treatment Study of Children With ADHD (MTA), asked why the researchers were "bending over backward" to play down negative implications for drug therapy.

Peter Jensen, one of Pelham's fellow researchers, responded that Pelham was biased against the use of drugs and was substituting his personal opinion for science.

Jensen said Pelham was the only member of the team of researchers who took away "the silly message" that the study raised questions about the long-term utility of drugs, but interviews and e-mails show that Pelham was not alone.

The MTA was designed to test whether children diagnosed with attention-deficit hyperactivity disorder, or ADHD, do better when treated with drugs, with drugs plus talk therapy, with talk therapy alone or with routine medical care alone. Children with the disorder have trouble paying attention, are restless and hyperactive, and are sometimes disruptive in school.

The initial 14-month analysis published in 1999 randomly assigned children to one of four treatment options and showed clearly that those treated with medication did much better than those who got only talk therapy or routine care. The drugs' manufacturers distributed thousands of reprints of the article to physicians at a

time when diagnoses of ADHD were spiraling upward. Because children given drugs alone appeared to do about as well as those treated with both drugs and talk therapy, the study skewed treatment in the direction of medication.

In a second phase of the study, the researchers followed the children and compared how they fared, but researchers no longer randomly assigned them to the various treatment options, making this phase less scientifically rigorous.

In August 2007, the MTA researchers reported the first follow-up data, which by then no longer showed differences in behavior between children who were medicated and those who were not. But the data did show that children who took the drugs for 36 months were about an inch shorter and six pounds lighter than those who did not.

A news release issued by the National Institute of Mental Health (NIMH) at the time, however, presented the results in a more favorable light. The release, dated July 20, 2007, was titled "Improvement Following ADHD Treatment Sustained in Most Children." The release noted that the initial advantages of drug treatment were no longer evident, but it quoted Jensen as saying this did not mean that long-term drug therapy was ineffective.

Jensen said, "We were struck by the remarkable improvement in symptoms and functioning across all treatment groups." And rather than saying the growth of children on medication was stunted, the release said children who were not on medication "grew somewhat larger."

As the MTA study continued to find smaller and smaller behavioral differences between children who were medicated and those who were not, use of the drugs soared. Pelham said most parents and doctors took away the message that the study had found drug therapy effective over the long run. In 2004, physicians wrote 28.3 million prescriptions for ADHD drugs; last year, they wrote 39.5 million, according to data provided by IMS Health.

With the MTA having followed the children for eight years, the latest data have confirmed that there are no long-term differences between children who were continuously medicated and those who were never medicated. Some of the data were published online yesterday in the Journal of the American Academy of Child and Adolescent Psychiatry.

In a telephone interview, Jensen denied that the researchers had misled the public, pointing out that some children getting the drugs did do better over the long term. Looking at overall results was not as useful as studying how particular groups of children fared, he said.

Jensen and another co-author, L. Eugene Arnold at Ohio State University, who are both psychiatrists, emphasized the importance of individualizing treatment -- and warned parents against abruptly terminating drug therapy.

The subgroup analysis found that children in homes that were socially and economically stable did the same in the long term with or without medication. Children from troubled or deprived backgrounds slid backward as soon as the intensive therapy stopped and they went back to their communities. About one-third -- those with the least impairment to begin with -- continued to improve over the long term.

Jensen and co-author Benedetto Vitiello at the NIMH said drugs may not have shown an overall long-term benefit because the quality of routine care that children received may have been inferior to the care they got during the initial part of the study. Jensen said the take-home message is that community care needs improvement.

Brooke Molina, also a co-author and a University of Pittsburgh associate professor of psychology and

psychiatry, argued in an e-mail that if the researchers wanted to draw attention to subgroups that might be helped by medication over the long run, they also should acknowledge that "long-term treatment with medication may not be efficacious" for others.

In an interview, Molina said the data do not "support that children who stay on medication longer than two years have better outcomes than children who don't." In an e-mail she shared with Pelham, she noted that academic "reviewers thought we were bending over backward (inappropriately) to dismiss the failure to find medication effects at 8 years."

James Swanson, another MTA co-author and a psychologist at the University of California at Irvine, said he believes that the researchers have been open about the diminishing benefits of medication therapy. He cited a variety of scientific publications in which he and others reported data showing that medications lost effectiveness over time and stunted growth.

"If you want something for tomorrow, medication is the best, but if you want something three years from now, it does not matter," he said. "If you take medication long-term beyond three years, I don't think there is any evidence that medication is better than no medication."

Pelham, who has conducted many drug therapy studies, said the drugs have a valuable role: They buy parents and clinicians time to teach youngsters behavioral strategies to combat inattention and hyperactivity. Over the long term, he said, parents need to rely on those skills.

A yet-to-be-published study, Pelham added, found that 95 percent of parents who were told by clinicians to first try behavioral interventions for ADHD did so. When parents were given a prescription for a drug and then told to enroll their children in behavioral intervention programs, 75 percent did not seek out the behavioral approaches.

Post a Comment

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D APR 0 2 2009

MAR 16 2009

Case No. 3AN-08-10115 CI

ORDER GRANTING STATE OF ALASKA'S MOTION TO STAY DISCOVERY

Having reviewed the State of Alaska's and the remaining above-named defendants' Motion to Stay Discovery and any responses thereto, IT IS SO ORDERED:

Discovery in this matter is hereby STAYED pending the court's decision on the Department's Motion for Judgment on the Pleadings.

DATED this 31st day of March, 2008.

Jack W. Smith
Superior Court Judge

I certify that on 4-1-09 a copy of the above was mailed to each of the following at their addresses of record. Hottstein, Kraly, Bakalar

R Meek
Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Law Project for Psychiatric Rights, Plaintiff, vs. State of Alaska, *et al*, Defendants	Case No. 3AN 08-10115CI

MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

COMES NOW, Plaintiff in the above captioned action, and hereby moves to amend the Amended Complaint, as follows:

1. Insert, ", and has citizen-taxpayer standing to bring this action" at the end of Paragraph 4.

2. Add a new paragraph, ¶236, as follows:

236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

3. Amend ¶B of the Prayer for Relief to read as follows:

B. Permanently enjoin the defendants and their successors from:

1. authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with Paragraph A of this prayer for relief, and

2. approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

This motion is accompanied by a memorandum in support hereof.

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Law Project for Psychiatric Rights,	)	
	)	
Plaintiff,	)	
vs.	)	
	)	Case No. 3AN 08-10115CI
State of Alaska, *et al*,	)	
	)	
Defendants	)	

MEMORANDUM IN SUPPORT OF
MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), has moved to amend the Amended Complaint, as follows:

1. Insert, ", and has citizen-taxpayer standing to bring this action" at the end of Paragraph 4. (Citizen-Taxpayer Amendment).

2. Add a new paragraph, ¶236, as follows:

> 236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:
>
> (a) are not medically necessary, or
>
> (b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or
>
> (c) both.

(Medicaid Violation Allegation).

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

3. Amend ¶B of the Prayer for Relief to read as follows:

B. Permanently enjoin the defendants and their successors from:

1. authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with Paragraph A of this prayer for relief, and

2. approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

(Medicaid Violation Injunction).

These three amendments are technical in nature and the desirability of making them arose out of the briefing on the Motion for Judgment on the Pleadings filed by the defendants, State of Alaska, *et al* (State) and dated March 12, 2009. In its Opposition to Motion for Judgment on the Pleadings, filed March 31, 2009, which is hereby incorporated herein by reference, PsychRights indicated that this motion for leave to amend would be forthcoming.[1]

A. CITIZEN-TAXPAYER AMENDMENT

In its Motion for Judgment on the Pleadings, the State apparently made the

[1] *See*, pages 3-4 and note 63.

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

argument that the current complaint in this action was deficient for failing to allege that PsychRights has citizen-taxpayer standing. Assuming *arguendo*, that the Amended Complaint is technically insufficient for failing to include the allegation that PsychRights has citizen-taxpayer standing, the Citizen-Taxpayer Amendment makes the allegation. It appears allowance of such an amendment is mandatory under *Prentzel v. State, Dept. of Public Safety*.[2]

B. MEDICAID VIOLATION AMENDMENT

Footnote 63 of PsychRights Opposition to Motion for Judgment on the Pleadings states:

> In reviewing the status of the pleadings, PsychRights realized it should add to the relief requested to effectuate ¶22 of the Amended Complaint, to wit that the State be enjoined from paying for outpatient psychiatric drugs for anything other than indications approved by the Food and Drug Administration (FDA) or included in the following compendia: (a) American Hospital Formulary Service Drug Information, (b) United States Pharmacopeia-Drug Information (or its successor publications), or (c) DRUGDEX Information System. A motion to amend the complaint to include this relief will be forthcoming shortly.

In preparing such amendment PsychRights realized that in addition to amending the Prayer for Relief, the complaint in this action could be benefitted by including a specific allegation that the above Medicaid requirement is being violated. The Medication Violation Amendment accomplishes this. There are many other allegations that indirectly establish the State's violations of Medicaid rules, but it seems desirable to include the explicit allegation of the Medicaid Violation Amendment.

---

[2] 53 P.3d 587, 590-91 (Alaska 2002).

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

In *Prentzel*,[3] the Alaska Supreme Court held, "a party should be permitted to amend if there is no showing that amending would cause injustice." There is no injustice here. The State has been on notice of the Medicaid violation claim since the Amended Complaint was filed in September, 2008, when the current ¶22 was added.

C. MEDICAID VIOLATION INJUNCTION

The third amendment, the Medicaid Violation Injunction, adds to the Prayer for Relief the appropriate remedy for the State's alleged violation of Medicaid requirements. The requested injunction against such violation is the logical relief and could be ordered under the "Such other relief as the court finds just in the premises," prayer for relief,[4] but it seems desirable to also include the proposed explicit language. The same lack of injustice standard with respect to the Medicaid Violation Allegation applies here and the amendment to add it to the prayer for relief should be permitted.[5]

D. CONCLUSION

For the foregoing reasons, PsychRights Motion for Leave to Amend Complaint (Citizen-Taxpayer Standing/Medicaid Injunction) should be granted.

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein, ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

[3] 53 P.3d at 590-91.
[4] §E. of the Prayer for Relief.
[5] *Prentzel*, 53 P.3d at 590-91.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	Case No. 3AN-08-10115 CI

STATE OF ALASKA'S CONDITIONAL NON-OPPOSITION TO MOTION FOR LEAVE TO AMEND COMPLAINT

The State of Alaska and the remaining above-named defendants do not oppose plaintiffs' Motion for Leave to Amend Complaint, filed April 3, 2009, in the above-captioned matter. However, the Department explicitly reserves the argument that the mere assertion of standing to bring this action does not confer standing. This position

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

is set forth at length in the Department's Reply to plaintiff's Opposition to Motion for Judgment on the Pleadings, filed contemporaneously herewith.

Dated this 10 day of April, 2009, at Juneau, Alaska.

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: Stacie L. Kraly for
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: Stacie L. Kraly
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	Case No. 3AN-08-10115 CI

STATE OF ALASKA'S REPLY TO PLAINTIFF'S OPPOSITION TO MOTION FOR JUDGMENT ON THE PLEADINGS

The State of Alaska and the remaining above-named defendants (hereinafter "the Department"), reply as follows to PsychRights' Opposition to the Department's Motion for Judgment on the Pleadings.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

I. ARGUMENT

A. The Department's Motion is in Good Faith and Procedurally Proper.

As a threshold matter, the Department addresses PsychRights' assertion that the Department's motion is untimely and/or made in bad faith. Trial in this matter is set for February 2010, almost a year from the Department's filing. Clearly the motion is not an eleventh-hour maneuver calculated to obstruct discovery and delay trial. To the contrary, it was the Department's attempts to prepare for a deposition and comply with PsychRights' discovery requests that prompted the Department to ask the court to decide this dispositive jurisdictional issue so that the parties can move forward. Regardless, the assertion that a party lacks standing implicates the court's subject matter jurisdiction under the actual controversy requirement of the Declaratory Judgment Act. The court not only can—but must—address such an assertion at any time.[1] The Department's motion is both proper and timely.

B. PsychRights Cannot Establish Citizen-Taxpayer Standing

PsychRights concedes it lacks interest-injury standing (i.e. an adverse interest in the outcome of the litigation), dismissing this argument as extraneous and claiming that the Department's sole ground for its motion is an asserted lack of citizen-taxpayer standing.[2] But PsychRights fails to achieve even citizen-taxpayer standing,

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[1] See Alaska Rule of Civil Procedure 12(h)(3). "*Whenever* it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter the court shall dismiss the action." (emphasis added).

[2] Opposition at p. 1.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

because notwithstanding its unsubstantiated prediction that the State would exact retribution and punishment against a truly adverse litigant,[3] the corporation has shown no adversity of interest, is unaffected by the challenged conduct, and advances no compelling argument that it is an appropriate plaintiff. It is well-established that in order to establish citizen-taxpayer standing in Alaska's courts, a plaintiff must show:

> "... [T]hat the case in question is one of public significance and the plaintiff is appropriate in several respects. This appropriateness has three main facets: the plaintiff must not be a sham plaintiff with no true adversity of interest; he or she must be capable of competently advocating his or her position; *and he or she may still be denied standing if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit.*[4]

PsychRights makes a number of arguments, none of which supports standing. Initially, PsychRights argues that it will amend its Complaint to allege citizen taxpayer standing, that there are issues of public significance raised in the Complaint, that there are no more directly affected plaintiffs likely to bring suit, that the State would not be a proper plaintiff, and that that no affected child or parent would be likely to sue. However, simply making these statements does not make them true.

1. Amending the Complaint is insufficient to establish citizen-taxpayer standing.

PsychRights clearly seeks to avoid an adverse ruling by arguing that the Department's motion is based upon a mere technicality. To wit, by simply amending the

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3 *Id.* at p. 13-14.

4 *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1034 (Alaska 2004) (emphasis added); *Keller v. French*, Slip. Op. 13296 (April 3, 2009).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

Complaint to assert standing, PsychRights will have standing and therefore can defeat the Department's motion. While courts routinely grant leave to amend pleadings, as PsychRights has recently asked the court to do,[5] simply asserting standing does not confer standing. If merely typing a sentence in a complaint were sufficient to confer standing then everyone would do so and the black letter law of standing would be rendered meaningless. Establishing standing to bring suit is not a mere technicality – PsychRights statement it has citizen-taxpayer standing does not moot defeat this motion.

2. While the Complaint may raise issues of public significance, PsychRights is not best suited to seek redress from the courts; there are more appropriate plaintiffs, such as the parents and children who are allegedly harmed by the State's practices.

According to PsychRights, the most important relief sought in the case is an injunction against the State directing the Department to—in so many words—do what PsychRights wants and believes is in the best interests of children in state custody.[6] However, PsychRights still does not explain how a corporate entity unconnected to any affected individual, in a state where there is no procedure for a *qui tam* action, possesses citizen-taxpayer standing to assert claims on behalf of children in State custody and/or Medicaid recipients and demand that the court impose a series of sweeping remedies. PsychRights argues that there is no one more directly affected to bring this suit than itself, because if a minor or parent brought suit, the State would somehow retaliate

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[5] Alaska Rule of Civil Procedure 15. See also *Prentzel v. State, Dept. of Public Safety*, 169 P.3d 573 (Alaska 2007).

[6] Opposition at p. 8.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

against such a litigant and the relief that PsychRights is seeking could not be obtained. This is not the case, and PsychRights supplies no basis for these assertions.

A review of the pleadings in this case and of the PsychRights website leaves no doubt that PsychRights believes it is authorized to seek judicial relief for the alleged wrongs stated in its Complaint.[7] However, the advocacy and interest that PsychRights so clearly espouses does not render it the only—let alone the most appropriate—plaintiff to bring this case. PsychRights' beliefs, no matter how strongly held, do not give the corporation standing to sue for redress of any and all of the alleged wrongs related to psychotropic medication and children. Parents and children themselves are the best suited to address these issues and questions on behalf of themselves. PsychRights may believe that there are wrongs to be righted, but PsychRights' advocacy mission to "stop the forced drugging" of children in this State is simply insufficient to subject the defendants to litigation.

In a case just decided by the Alaska Supreme Court last week, the question of citizen-taxpayer standing was discussed and the analysis presented there clearly favors dismissal in this case. In *Keller v. French*[8], the Alaska Supreme Court was asked to address whether the plaintiff in that case (five state legislators) had standing to bring suit against other state legislators claiming a violation of the fair and just treatment clause. After considerable procedural maneuvering at the superior court and Supreme Court levels, an appeal remained related to two issues – whether the plaintiffs had standing to

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7 See www.psychrights.org.

8 Slip Opinion 13296, April 3, 2009.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

sue and whether the entire case was not justiciable. The bases for standing in that case were predicated upon "citizen-taxpayer standing. In the *Keller* case, the court agreed that the plaintiffs were not sham plaintiffs and that the issue was one of public significance, but did not agree that plaintiffs were best suited to bring suit. While the plaintiffs argued there were no other potential plaintiffs, the court held that argument ignored the persons who were truly at risk from the investigation by the senate – those people who had been subpoenaed to appear and the Governor herself. As stated by the court, "that individuals who are more directly affected have chosen not to sue despite their ability to do so does not confer citizen-taxpayer standing on an inappropriate plaintiff." [9]

Additionally, the defendants in the *Keller* case argued that the plaintiffs were "attempting to assert the individual rights of potential or 'imaginary' third parties." The Supreme Court stated emphatically that the Court has "never allowed citizen-taxpayer standing to be used that way." [10] the Court further stated "'[g]enerally, a litigant lacks standing to assert the constitutional rights of another." [11]

This case is particularly germane to the instant matter, and as elaborated further below, Psych Rights is attempting to assert the rights of individuals and imaginary third parties, which is not appropriate. Additionally, Psych Rights is not an

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[9] *Id.* at page 9.

[10] *Id.* at page 11.

[11] *Id.* Citing to *State ex. rel. Dept's of Transp & Labor v. Enserch Alaska Constr., Inc.*, 787 P.2d 624, 630 n. 9 (Alaska 1989) (citing *Falcon v. Alaska Pub. Offices Comm'n*, 570 P.2d 496, 475 n. 20 (Alaska 1977) *Wagstaff v. Superior Court*, 535 P.2d 1220, 1225 (Alaska 1975).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

appropriate plaintiff to seek redress of the alleged ills and wrongs in the Complaint. There are better and more directly affected individuals who should bring this case. The fact that they (the parents and children who are directly affected) have not sued does not impart citizen-taxpayer standing on Psych Rights. Like *Keller* plaintiffs, Psych Rights lacks citizen-taxpayer standing and this case should be dismissed.

3. The State has sued the pharmaceutical industry under its consumer protections powers and continues to do. Therefore, the State would be a proper plaintiff as to the allegations against the pharmaceutical industry.

On this latter point, its worth noting that contrary to PsychRights' assertions, the Office of the Attorney General has been far from derelict in protecting Alaska's citizens—specifically Medicaid recipients—from wrongdoing by the pharmaceutical industry[12]. As PsychRights is aware, the consumer protection section of this Office recently brought a lawsuit against the pharmaceutical giant Eli Lilly to address the company's illegal marketing of the psychotropic medication Zyprexa, and

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[12] It appears that PsychRights is seeking to sue on behalf of the State to protect its citizens against the predatory pharmaceutical industry. As stated above, in order for this type of action to occur there would need to be some sort of *qui tam* authority by which PsychRights stands in the proverbial shoes of the State. No such statute exists in Alaska at this time, nor is there any way for a private citizen or corporate entity to seek relief under Alaska consumer protection laws, which is precisely what PsychRights is attempting to do. Alaska's citizens are being ably protected through successful litigation against the pharmaceutical industry as evidenced by cases brought by the consumer protection section of the Department of Law. (See http://www.law.state.ak.us/pdf/newsetters/2008-03-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2006-10-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-10-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-07-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2005-12-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-10-MR.pdf).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

settled the case against the company for $15 million dollars.[13] In prior lawsuits, the State has sued 41 pharmaceutical manufacturers for inflated drug pricing, settling with at least one of the manufacturers for $1.5 million, and took on both Pfizer and Merck pharmaceutical companies for their misleading drug marketing.[14] The State is also continuing to explore litigation against the manufacturers of Seroquel, Abilify, Geodon, and Risperdol. So the State of Alaska and PsychRights are very much aligned with respect to curbing the illegal and misleading conduct of the pharmaceutical industry.

C. The State Has Not Abdicated its Duties with Respect to Children in State Custody.

PsychRights also makes erroneous assertions and conclusions about the State's conduct toward children in state custody and the conduct of the Department of Law and the courts on this subject, based upon the Department's arguments in the opening motion. As described in the opening motion, under existing law the Department's use of and payment for psychotropic medication for children in state custody must be accomplished through parental/guardian consent and/or a court order.[15] Yet PsychRights accuses the Department of abdicating its custodial responsibilities because the Department has identified the pharmaceutical industry—not the named

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[13] 3AN-06-5630 CI. PsychRights attempted to obtain sealed court records in this case.

[14] See Department of Law links cited at n. 10. 3AN-06-12026 CI (*State of Alaska v. Alpharma Branded Products Division, Inc. et al.*); 3AN-05-14292 CI (*State of Alaska v. Merck and Company*, Inc.).

[15] Motion at p. 3-6.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

defendants—as the genuine target of this Complaint. PsychRights' opposition only supports the Department's position:

> Psychiatrists ought to be able to rely on the information they receive through medical journals and continuing medical education. The State ought to be able to trust that psychiatrists recommending the administration of psychiatric drugs are basing these recommendations on reliable information. Unfortunately, neither of these things, which ought to be true, are true. Thus, one of the key questions in this case is why psychiatrists are prescribing and custodians are authorizing the administration of harmful psychotropic drugs of little or no demonstrated benefit to children and youth. *The answer is that the pharmaceutical companies have been very effectively illegally promoting their use... the drug companies have provided the psychiatrists with inaccurate information. PsychRights will develop this in discovery and through presenting the evidence to this Court.*[16]

This statement goes squarely to the issue of standing and PsychRights' propriety to bring this action against the named defendants. By PsychRights' own admission, blame lies with the pharmaceutical industry. Even assuming *arguendo* that everything in the Complaint were true and every remedy requested should be implemented, if the answer to the problem (to paraphrase PsychRights) lies with a corrupt industry that has misled medical professionals and the public, including, presumably, the named defendants, how can the State rectify those alleged misdeeds in the context of this ligation brought by PsychRights, which lacks standing to sue? In other words, the State is the easy—but not actual—target of this Complaint. That is the point the Department was trying to make in its motion—not, of course, that the Department is not responsible for the welfare of children in its care. PsychRights'

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[16] Opposition at p. 21 (emphasis added).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

attempt to twist the State's position is inflammatory, and it is not supported by the facts and the law.

II. CONCLUSION

In sum, PsychRights concedes it has no true adversity—the crux of standing—yet asks the court to make the procedural and substantive leap of allowing a corporation to stand in the shoes of the State and prosecute what is effectively an unauthorized *qui tam* action on behalf of the public, against State defendants whom PsychRights has admitted are not the true cause of the conduct alleged.

The concept of standing in this case goes beyond its mere assertion: the doctrine addresses the substantive propriety of PsychRights to bring this lawsuit against the named defendants for the claims the corporation asserts. The court should evaluate the propriety of individual plaintiffs with respect to citizen-taxpayer standing on a case-by-case basis.[17] Citizen-taxpayer is appropriate where "no one seemed to be in a better position than the plaintiffs to complain of the illegality" of the conduct in question.[18] As argued in its opening motion, a policy agenda and a sweeping critique of alleged state actions perpetrated on unnamed individuals—by persons Psych Rights itself claims are not ultimately responsible for the alleged misconduct—do not constitute the "true adversity of interest" required to maintain citizen-taxpayer standing. There are more

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[17] *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1037 (Alaska 2004); *Keller v. French*, Slip. Op 6532 (April 3, 2009).

[18] 736 P.2d at 328 (citing *State v. Lewis*, 559 P.2d 630 (Alaska 1977)).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

appropriate, adverse plaintiffs who could raise such issues and because of their true adversity, would be able to do so less abstractly.

The Department's arguments regarding standing and the court's jurisdiction in this matter are not refuted. PsychRights lacks standing and the complaint should be dismissed.

Dated this 10th day of April, 2009, at Juneau, Alaska.

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Law Project for Psychiatric Rights, Plaintiff, vs. State of Alaska, *et al*, Defendants	)	REC'D APR 16 2009 Case No. 3AN 08-10115CI

ORDER GRANTING
MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

Having reviewed the Motion for Leave to Amend Complaint (Citizen-Taxpayer Standing/Medicaid Injunction) filed April 3, 2009, by Plaintiff, the Law Project for Psychiatric Rights, and any responses thereto, including the conditional non-opposition with reservation, it is hereby ORDERED that the motion is GRANTED.

DATED this 14th day of April, 2009.

Jack W. Smith
Superior court Judge

I certify that on 4-15-09 a copy of the above was mailed to each of the following at their addresses of record. Gottstein, Kaaly, Backalar

R Meade
Secretary/Deputy Clerk

LAW PROJECT FOR PSYCHIATRIC RIGHTS,
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

APR - 3 2009

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS,

Plaintiff,

vs.

STATE OF ALASKA, et al.,

Defendants.

Case No. 3AN-08-10115CI

BEFORE THE HONORABLE J. SMITH
DECISION ON RECORD

Pages 1 - 22
Wednesday, May 27, 2009
11:15 A.M.
Anchorage, Alaska

ANCHORAGE, ALASKA; WEDNESDAY, MAY 27, 2009
11:15 A.M.
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THE COURT: All right. This is the time for the Court to place on record its decision in defendant's motion for judgment on the pleadings in case 3AN-08-10115CI, which is captioned Law Project for Psychiatric Rights, an Alaska Nonprofit Corporation, vs. The State of Alaska, Sarah Palin, Governor of the State of Alaska, the Alaska Department of Health and Social Services, William Hogan as Commissioner of the Department of Health and Social Services, Tammy Sandoval, the director of the Office of Children's Services, Steve McComb, Director of the Division of Juvenile Justice, Melissa Witzler-Stone, Director of the Division of Behavioral Health, Ron Adler, Director/CEO of the Alaska Psychiatric Institute, and William Streur, Deputy Commissioner and Director of the Division of Health Care Services, as defendants.

Plaintiff, an Alaska nonprofit corporation, is a public interest law firm whose mission is described as mounting a strategic litigation campaign against forced psychiatric drugging and electroshock treatment of minor patients.

Plaintiff filed a 54-page Complaint arguing that the current procedures employed by the state in authorizing psychiatric medication and treatment of juveniles violates the constitutional rights of Alaskan children and youth.

Plaintiff seeks, one, a declaratory judgment that Alaskan children and youth have the constitutional and statutory right not to be administered psychotropic drugs unless and until evidence-based psychosocial interventions have been exhausted, rationally anticipated benefits of psychotropic drug treatment outweigh the risks, the person or entity authorizing administration of the drugs is fully informed of the risks and potential benefits, and close monitoring of and appropriate means of responding to treating-emergent effects are in place.

Two, an injunction against the defendants and their successors from authorizing or paying for the administration of psychotropic drugs to Alaska children and youth without conformance with paragraph 1 and approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that are not medically necessary or for indications that

are not approved by the Food and Drug Administration or included in the American Hospital Formulary Service drug information, the United States Pharmacopoeia Drug Information or Drugdex Information System or both.

And three, order that all children and youth in state custody currently being administered psychotropic drugs and all children and youth to whom the State of Alaska currently pays for the administration of psychotropic drugs be assessed in accordance with and brought into compliance with the specifications of CriticalThinkRX, which the Court will describe as the training program to educate individuals involved in prescribing and administrating psychotropic medications about, quote, critical thinking, end quote, of alternatives, especially nonmedication action. And that training must be by a contractor knowledgeable of the CriticalThinkRX curriculum. And such other relief as the Court finds just in the premises.

Plaintiff filed the action, the Complaint, on September 2nd, 2008. An Amended Complaint was filed on September 29, 2008. Defendant filed this motion for judgment on the pleadings on March 16, 2009. Oral argument was not requested by either

party.

The defendant argues in its motion that pursuant to Alaska Rules of Civil Procedure 12(c), that judgment on the pleadings is appropriate because plaintiff failed to meet the actual controversy requirement under the Declaratory Judgment Act because plaintiff lacked standing to sue.

Defendant argues that AS 22.10.020, subparagraph G, explicitly requires the presence of an actual controversy before the Court may issue declaratory relief and that this matter does not meet the actual controversy requirement because plaintiff lacks standing to sue. Therefore, defendant argues the Court should dismiss the Complaint.

Defendant recognizes that Alaska case law has broadly interpreted the concept of standing to promote liberal access to the courts. See Brause vs. State of Alaska, Brause is B-R-A-U-S-E, at 21 P3d 357, an Alaska Supreme Court case from 2001.

In fact, in Alaska a complaint seeking declaratory relief requires only a simple statement of facts demonstrating that the Superior Court has jurisdiction and that an actual justiciable case or controversy is presented. And again, that's from Brause.

To this end, Alaska courts recognize two forms of standing, an interest injury standing, and citizen taxpayer standing. That's from North Kenai Peninsula Road Maintenance Service Area vs. Kenai Peninsula Borough at 850 P2d 636, an Alaska Supreme Court case from 1993.

However, Defendant argues that even under Alaska's liberal requirements, Plaintiff satisfies neither type of standing. Defendant argues that to establish interest injury standing, a plaintiff must have an interest adversely affected by the conduct complained of.

Generally, a plaintiff may not assert another's constitutional rights unless a special relationship exists between the plaintiff and the third party. See Gilbert v. State at 139 P3d 581, another Alaska Supreme Court case from 2006.

Here plaintiff does not assert interest injury standing or claim an adverse interest, nor does plaintiff claim any sort of relationship at all to any relevant individual. Therefore, defendant argues plaintiff has not asserted standing under the interest injury doctrine.

Finally, defendant argues plaintiff also lacks citizen taxpayer standing. Defendant argues

that while the criteria for citizen taxpayer standing in Alaska are liberal, plaintiff has shown no true adversity of interest.

Furthermore, there clearly exist parties more affected by the challenged conduct who are better suited to pursue these claims. Defendant argues plaintiff is not a child in need of aid, does not allege guardianship of such a child, and has not purported to represent a child or class of children subject to the department's duty of care.

Plaintiff is engaged in a campaign to change the manner and procedure under which the department operates without any alleged harm inflicted by the department on plaintiff or anyone plaintiff represents.

Defendant concludes that a policy agenda and a sweeping critique of alleged state actions perpetrated on no one in particular do not constitute the true adversity of interest required to maintain citizen taxpayer standing. Defendant asserts there are more appropriate plaintiffs to raise such issues and because of their true adversity would presumably be able to do so in a more concrete manner.

Plaintiff, in opposition to the motion, argues that under the standard espoused in Trustees

for Alaska vs. State at 736 P2d 324, an Alaska Supreme Court case from 1987, it has citizen taxpayer standing to pursue these claims.

Plaintiff argues that this case raises issues of public significance and that there is no more directly affected plaintiff likely to bring this suit, and plaintiff argues it has therefore satisfied the adversity requirement. Plaintiff also argues it is able to competently advocate the position asserted.

Finally, plaintiff argues that the state, represented by the attorney general, would not be a proper plaintiff to pursue these claims. Contrary to the defendant's assertion that representation of the general public interest of children in state custody rests with the attorney general, plaintiff argues the state has ignored its responsibilities and refused to take appropriate action.

Plaintiff argues the state has ignored its responsibilities by not acting on the issues in this case, and therefore the state would not be a more appropriate plaintiff for bringing this suit.

Plaintiff argues there is every reason to presume that no affected child, youth, parent or guardian is likely to sue in this case because none

of these parties have yet to file a suit, and it is likely they will never bring this claim. Plaintiff argues these children and youth, as well as their parents, lack the resources to file suit, and the potential for being subjected to an award of attorneys fees against them is a powerful disincentive to bringing suit.

Plaintiff argues the Law Project for Psychiatric Rights was founded in late 2002 in order to mount a strategic litigation campaign against forced psychiatric drugging and electroshock therapy and notes that because it is the adults in their lives rather than they who are making the decisions, children are essentially forced to take phychiatric drugs, and thus this lawsuit fits squarely within the psych rights mission. Therefore, plaintiff claims it has adversity.

Plaintiff also argues that the motion for judgment on the pleadings is untimely, that Rule 12(c) requires that a motion for judgment on the pleadings be brought within such time as to not delay the trial and that the instant motion filed on March 12, 2009, some six months after the action was commenced, is going to interfere with the trial, which is set to commence on February 1, 2010.

In its reply, defendant reiterated that plaintiff lacks citizen taxpayer standing to pursue these claims. Defendant argues the parents and children themselves are the best suited to address these issues and questions on behalf of themselves.

Defendant argues that Keller v. French, a slip opinion at 13296 from April 3rd, 2009, an Alaska Supreme Court case, supports granting its motion in this case.

The Alaska Supreme Court in that case held that the plaintiffs did not have citizen taxpayer standing because there were other potential plaintiffs better suited to bring suit and plaintiffs were truly -- plaintiffs who were truly at risk from the actions at issue.

As the Court stated in that case, individuals who are more directly affected have chosen not to sue despite their ability to do so, and that does not confer citizen taxpayer standing on an inappropriate plaintiff.

Looking at the law surrounding this case, the Court would note the following. Under Alaska Civil Rule 12(c), a party will prevail on a motion for judgment on the pleadings if there are no allegations in the plaintiff's pleading that, if

proven, would permit recovery. Accordingly, a 12(c) motion only has utility when all material allegations of fact are admitted in the pleadings and only questions of law remain.

One of the issues that needs to be decided is whether plaintiff has standing. In Alaska, it has been held that all that is required of a complaint seeking declaratory relief is a simple statement of facts demonstrating that the Superior Court has jurisdiction and that an actual justiciable case or controversy is presented. See Ruckle vs. Anchorage School District at 85 P3d 1030, an Alaska Supreme Court case from 2004, which was quoting Jefferson vs. Asplund at 458 P2d 995, a prior Supreme Court case from 1969.

Under Alaska case law, the actual case or controversy language encompasses a number of more specific reasons for not deciding cases, including lack of standing, mootness and a lack of rightness.

Standing in Alaska is not a constitutional doctrine. Rather, it is a rule of judicial self-restraint based on the principle that courts should not resolve abstract questions or issue advisory opinions.

And again, see Trustees For State of

Alaska -- or for Alaska versus the state that was cited previously.

The basic requirement for standing in Alaska is adversity. Alaska case law has discussed two differing kinds of standing, interest injury standing and citizen taxpayer standing.

Under the interest injury approach, a plaintiff must have an interest adversely affected by the conduct complained of. Plaintiff has not argued it has an interest injury standing in this case. However, in order to determine if a party has citizen taxpayer standing, the court must examine each case and decide if several criteria have been met.

First, the case in question must be one of public significance. The plaintiff raising constitutional issues is likely to meet this first requirement. See Sonemann vs. State at 969 P2d 632.

Here it seems clear that plaintiff's Complaint raises questions of public significance. The asserted issue involves state and federal constitutional rights, state laws, municipal codes, and some unknown number of Alaska children and youth potentially impacted. Defendant indicates that the Complaint may in fact raise issues of public

significance.

Second, the plaintiff must be an appropriate party to bring the case. And again, see Trustees for Alaska vs. State.

This appropriateness has three main facets. First, plaintiff must have a truly adverse interest. Second, plaintiff must be capable of competently advocating the position asserted. And third, plaintiff may still be denied standing if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit.

Therefore, what needs to be determined is whether or not the plaintiff in this case is the appropriate party to bring this action.

For the plaintiff to be the appropriate party as noted above, it must have an adverse interest, be capable of competently advocating its position, and there must not be a party more directly affected who has or is likely to bring suit.

Let's stop for a second.

(Off record.)

THE COURT: Plaintiff's sincerity in opposing the alleged state's practice seems unquestioned. However, that adversity is based on

plaintiff's mission statement, which, if accepted, would indicate any individual or group can create adversity by simply creating a nonprofit and drafting a mission statement opposing whatever issue they wish to challenge.

Plaintiff's attorney, Mr. Gottstein, is also its founder, president and CEO. Mr. Gottstein has been practicing law in Alaska since 1978. From 1998 to 2004, Mr. Gottstein served on the Alaska Mental Health Board. Without going into further detail regarding the experience of plaintiff and its counsel, it seems clear plaintiff is capable of competently advocating the position asserted by plaintiff.

But plaintiff apparently has no individual client or group of clients or their custodians who have actually had either psychotropic medications or electroshock therapy administered against their wishes.

Plaintiff starts with the premise that children and juveniles are being forced to undergo phychiatric medication and/or electroshock therapy, that their parents, their guardians, the state and the health care providers are allowing or doing this without determining the best interests of the

children or juveniles; and that they, as plaintiffs, can ensure a more appropriate decision is made if allowed to identify these children and juveniles.

Certainly plaintiff can espouse its identified mission effectively, but approaching an issue with the foregone conclusion that children and juveniles are being forcefully medicated and treated by their parents, guardians, health care providers and/or the state raises concerns plaintiffs -- that plaintiff has an inherent bias to use of medication or therapies that may in fact be the most beneficial to the recipient.

The last factor determining whether plaintiff is an appropriate party is whether or not there is a more directly affected plaintiff who has or is likely to bring suit. The parties highly contest this factor.

The Court in Trustees for Alaska vs. The State stated that taxpayer citizen standing has never been denied in any decision of this Court except on the basis that the controversy was not of public significance or on the basis that the plaintiff was not a taxpayer.

But starting with that case, the Court set out the requirement that no more appropriate

plaintiff exists, and since that time, a line of cases has denied citizen taxpayer standing where a more appropriate plaintiff has or is likely to bring suit. In Trustees, the Court reasoned that the crucial inquiry is whether the more directly concerned potential plaintiff has sued or seems likely to sue in the foreseeable future.

In Clevin vs. Yukon-Koyukuk School District, a former school administrator filed suit against the school district, challenging his reassignment to a position of lower pay and responsibility. That's at 853 P2d 518, Alaska Supreme Court case from 1993.

The Court finds -- this Court finds the analysis in that case instructive. One of the main issues before that court was whether an employee who starts a grievance process and subsequently resigns has standing to force the employer to continue with the process and remedy problems presumably for the benefit of those employees who remain.

Upon review, the Court determined that Clevin lacks citizen taxpayer standing. The Court stated, "Because the Yukon-Koyukuk School District's remaining employees are certainly in a better position to raise the grievances Clevin cites and because we have no reason to believe that current

Yukon-Koyukuk School District employees would be indisposed to press legitimate grievances, we agree with the trial court that Clevin has failed to establish citizen taxpayer standing."

The Court would note that plaintiffs in this case have failed to establish any parent or guardian with a legitimate grievance on behalf of their juvenile or child has declined to sue.

In Fannon vs. Matanuska Susitna Borough at 192 P3d 982, another Supreme Court case from 2008 cited by the parties, the Court finds it's distinguishable that the plaintiffs in this case have not established any legitimate claim has gone unpursued.

Finally, in a very recent decision, the Supreme Court reviewed a case involving a claim that a legislative investigation into the Governor's dismissal of the public safety commissioner violated the Alaska Constitution's fair-and-just-treatment clause. See Keller v. French previously cited, but it's at opinion No. 6352, April 3rd, 2009.

After the investigation began, the group of five state legislators, the Keller plaintiffs filed a complaint claiming the investigation was improper for a number of reasons. Shortly thereafter, a different

group of state employees who had been subpoenaed to appear before the senate judiciary committee commenced a separate lawsuit. The Court referred to them as the Kiesel plaintiffs.

Upon review, the Supreme Court held that the five legislators did not have standing to claim there was a violation of the fair-and-just-treatment clause. The Court determined that the Keller plaintiffs were truly adverse and capable of competently advocating their position but that there was nonetheless a substantial question here as to whether other persons who are more directly affected have sued or are likely to sue.

In deciding that the Keller plaintiffs lacked standing, the Court stated that the Kiesel plaintiffs were among the classes of persons in this investigation most obviously protected by the fair-and-just-treatment clause.

The Kiesel plaintiffs were more directly affected by the investigation, and they had actually sued some of the defendants. The Court reasoned that the Kiesel plaintiffs did not allege any violation of the fair-and-just-treatment clause, but had they thought they were being mistreated, there would have been far more appropriate plaintiffs to make that

claim than the Keller plaintiffs, none of whom self-identified as either a witness or a target of the investigation.

In addition, the Supreme Court in that case discussed the Governor's potentially more appropriate plaintiffs, stating, quote: Even if the Governor did not intend to sue, there is no indication that if she thought her rights were being violated she would be unable to do so. The Keller plaintiffs do not contend that the Governor or any other potential plaintiffs were somehow limited in their ability to sue. That individuals who are more directly affected have chosen not to sue despite their ability to do so does not confer citizen taxpayer standing on an inappropriate plaintiff. End quote.

In this case, plaintiff argues parents or guardians are unlikely to sue, but that statement reflects plaintiff's opinion that parents and guardians are incapable of recognizing what plaintiffs identify as, quote, forced, end quote, medication and treatment.

Plaintiff seeks to be placed in the role of decision maker for the children and juveniles receiving psychotropic medication and electroshock therapy in lieu of parents or guardians. Otherwise,

clearly they are not the most appropriate plaintiff.

Let's stop for a second.

(Off record.)

THE COURT: As the Court concluded in Keller, it appears the Keller plaintiffs are attempting to assert the individual rights of potential or imaginary third parties, and the Court in that case indicated they had never before allowed citizen taxpayer standings to be used in that way.

Comparing the present case with those discussed above, it becomes clear that the facts of this case support a finding of plaintiff lacks standing.

There is no adversity of interest with plaintiff except as they created with their mission statement. And just like in Ruckle and Keller, there appears to be a more directly affected party here that would make a more appropriate plaintiff than the Law Project.

As defendant argues, the affected children, their parents or guardians or even the state would make a more appropriate plaintiff if a legitimate grievance existed.

The motion for judgment on the pleadings is granted in this case. Parties will be given a copy

of the disk with the Court's decision, and this case will be dismissed.

We'll be off record.

(Proceedings adjourned at 11:39 a.m.)

* * * * *

CERTIFICATE

I, DIANE M. BONDESON, Registered Professional Reporter and Notary Public in and for the State of Alaska, do hereby certify that the foregoing pages numbered 1-21 are a true, accurate and complete transcript of proceedings in Case No. 3AN-08-10115CI, Law Project for Psychiatric Rights vs. State of Alaska, transcribed by me from a copy of the electronic sound recording to the best of my knowledge and ability;

And further, that I am not a party to nor have I any interest in the outcome of the action herein contained.

IN WITNESS WHEREOF, I have hereunto set my hand this SIXTH day of JUNE, 2009.

_____

Diane M. Bondeson, RPR

My Commission Expires 9/6/10

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D MAY 28 2009

Case No. 3AN-08-10115 CI

ORDER GRANTING STATE OF ALASKA'S MOTION FOR JUDGMENT ON THE PLEADINGS

Having reviewed the State of Alaska's and the remaining above-named defendants' Motion for Judgment on the Pleadings and any responses thereto, IT IS SO ORDERED:

The defendants' Motion is GRANTED. Plaintiff has failed to present an actual case or controversy under the Declaratory Judgment Act and lacks standing to bring this action. Accordingly, the Complaint is hereby dismissed with prejudice.

DATED this 27th day of May, 2009.

Jack W. Smith
Superior Court Judge

I certify that on 5.27.09 a copy of the above was mailed to each of the following at their addresses of record. (List names if not an agency)
☐ CSED ☐ AG ☐ PD ☐ DA Gittlen

Deputy Clerk / Secretary

MAR 16 2009

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUN 17 2009

Case No. 3AN-08-10115 CI

JUN 05 2009

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

FINAL JUDGMENT

THIS COURT, having dismissed the action brought by plaintiff in this case upon motion of the defendants on May 27 2009, and being otherwise fully advised,

HEREBY ORDERS that final judgment is entered with prejudice in favor of the defendants in this case, and against plaintiff Law Project for Psychiatric Rights.

THE COURT FURTHER ORDERS that, after proper application, the Attorney General's Office shall recover attorney's fees from and have judgment against plaintiff, as follows: to be determined after filing per CR 79 and 82

i. Attorney's Fees $ _____;

Date awarded _____;

Judge _____.

ii. Costs: _____;

Date awarded _____;

Judge _____.

iii. **TOTAL JUDGMENT** $_____.

iv. Post-Judgment Interest Rate: _____.

DATED this 16th day of June, 2009.

Jack W. Smith
Superior Court Judge

I certify that on 6-16-09 a copy of the above was mailed to each of the following at their address of record. [illegible]

Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	REC'D JUN 24 2009 Case No. 3AN-08-10115 CI

MOTION FOR AWARD OF ATTORNEY'S FEES

On June 16, 2009, the court entered final judgment for defendant State of Alaska, Department of Health and Social Services, and the remaining above-named defendants in the above-captioned matter ("Department"). Pursuant to Rule 82(b)(2) of the Alaska Rules of Civil Procedure, the Department hereby moves for a total fee

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

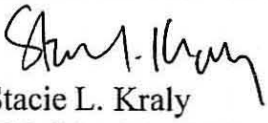
award of $3,876.00 in attorney's fees. This fee claim reflects the Rule 82(b)(2) prevailing party schedule.

This motion is supported by the accompanying affidavit of counsel, memorandum of law, and Exhibit A, detailing the time spent litigating this matter.

Dated this 22nd day of June, 2009.

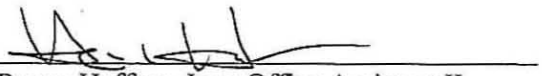
DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: 
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

Certificate of Service
I hereby certify that on this day of June 22, 2009, true and correct copies of the foregoing MOTION, MEMO, AFFIDAVIT, EXHIBIT A, and proposed ORDER were served via U.S. mail, first class, postage prepaid to the following attorney of record:

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, AK 99501


H. Raven Haffner, Law Office Assistant II

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

Case No. 3AN-08-10115 CI

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR AWARD OF ATTORNEY'S FEES

INTRODUCTION

On May 27, 2009, this court dismissed plaintiff's lawsuit in favor of the State of Alaska, Department of Health and Social Services, and the remaining above-named defendants (hereinafter the "Department"). The court entered a final judgment

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

on June 16, 2009. As the prevailing party in this action, the Department moves for an award of attorney's fees pursuant to Civil Rule 82.

ARGUMENT

I. The Department is Entitled to Fees Under Civil Rule 82(b)(2)

Alaska Civil Rule 82 provides that defendants who are prevailing parties in cases that do not go to trial are entitled to an award of 20 percent of their actual reasonable fees.

> In cases in which the prevailing party recovers no money judgment, the court shall award the prevailing party in a case … resolved without trial 20 percent of its actual attorney's fees which were necessarily incurred. The actual fees shall include fees for legal work customarily performed by an attorney but which was delegated to and performed by an investigator, paralegal or law clerk.[1]

The purpose of Civil Rule 82 is to partially compensate a prevailing party for the expense of litigation. *City of Valdez v. Valdez Development Co.*, 523 P.2d 177, 184 (Alaska 1974).

Although the Attorney General, as counsel for the state, bills client agencies at a rate far below the market rate of attorneys in private practice, it is well settled that when the state is the prevailing party, it may request reimbursement of attorney's fees at a reasonable market rate. The Attorney General is not limited to

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[1] Alaska Rule Civ. Proc. 82(b)(2).

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DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

recovering fees based on the Department of Law's inter-agency billing rate.[2] There is clear authority for awarding attorney's fees under Civil Rule 82 based on market rates instead of the department's overhead rate. *Atlantic Richfield Co. v. State*, 723 P.2d 1249, 1251-52 (Alaska 1996) (Alaska Supreme Court ruled it appropriate to use average of hourly billing rates charged by private attorneys to calculate fee award for legal work performed by assistant attorneys general); *Amfac Hotels v. State, Dept. of Transportation*, 659 P.2d 1189, 1194 (Alaska 1983) (approved fee award based on "the average private billing rate"—$75 per hour, 25 years ago); *Morrison-Knudsen Co., Inc. v. State,* 519 P.2d 834, 844 (Alaska 1974) (argument rejected that state could not recover attorney's fees at a rate higher than hourly salary of highest paid assistant attorney general who worked on case).

The Attorney General has worked to identify a uniform reasonable market rate upon which to base attorney fee requests that will more fairly reimburse the State of Alaska and state represented officials for their fees as a prevailing party. *See* Affidavit of Counsel. This was necessary because the department's historic rate formulae and the newer universal blended rate formula all produce figures far below the

---

[2] The Department of Law has formulated a blended attorney "overhead rate" for any assistant attorney general (regardless of years of practice), which has been $121.98 during this calendar year. The previous blended rate was $116.50. This is a uniform rate used to bill client agencies for legal services, regardless of the experience level or salary range of the individual assistant attorney general who actually handled the legal matter.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

market rate and value of the services rendered, and because Civil Rule 82 provides for only partial reimbursement of actual fees.

Based on the recommendations of a working group tasked with assessing the Department of Law's policy on attorney fee requests, the Attorney General established in 1997 a policy to request $150 per hour as the market rate for journey level attorneys (Attorneys III and above). *Id.* This decision was based on the working group's review of attorney billing rates statewide, a similar policy in the U.S. Attorney's Office, and the fact that the average rate (typically reflecting a discount for the state) that the Department pays experienced private practitioners to provide legal services to the state under contract exceeds $150 per hour. *Id.* The rate of $125 per hour was approved for less experienced attorneys. *Id.* The courts have awarded the state fees based on these rates for over a decade.

As the prevailing party, the Department is entitled to recover 20 percent of its attorney's fees. A copy of the billing printout detailing the work done and time spent relative to this case is attached as Exhibit A. The Department therefore requests a Civil Rule 82(b)(2) fee award as calculated in section II.

II. Calculation of Total Fees Requested

The defense counsel of record in this case, Stacie Kraly, holds an Attorney VI position, and has been practicing law for almost 15 years. Co-counsel of record, Elizabeth Bakalar, holds an Attorney III position and has been practicing law

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

for almost three years. Other Assistant Attorneys General who assisted on this case, Kelly Henriksen and Nevhiz Calik, also hold Attorney III positions and have been practicing law for approximately 15 and three years respectively. The attorney hours expended in defending this action total 129.2 hours.[3] Using the market rate of $150, total fees came to $19,380.00, 20% of which is $3,876.00.[4]

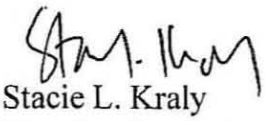
CONCLUSION

Based on the foregoing, the Department respectfully requests that the court award total attorney's fees in the amount of $3,876.00.

DATED this 22nd day of June, 2009.

DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: 
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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[3] Exhibit A.

[4] *Id.*

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
Elizabeth M. Bakalar	9/18/08	2.5	$304.95	Began researching and drafting a motion to dismiss.
	9/30/08	1.5	$182.97	Reviewed first amended complaint/drafted answer to same.
	10/7/08	0.5	$60.99	Discussed case with Tammy Sandoval.
	10/8/08	3.5	$426.93	Revieed documents from Dave Campana and continued drafting pleadings.
	10/9/08	1.5	$182.97	Revised and Reviewed answer.
	10/20/08	1.0	$121.98	File review, talked to Jim Gottstein, drafted pretrial order.
	10/23/08	1.5	$182.97	Continued working on Rule 26 disclosures.
	10/27/08	2.5	$304.95	Worked on discovery, spoke to Dave Campana.
	10/28/08	0.5	$60.99	File review and scheduling.
	10/29/08	0.5	$60.99	Finalized disclosures for Ms. Kraly's review.
	11/4/08	1.0	$121.98	Extensive revisisons to pretrial disclosures.
	11/12/08	1.0	$121.98	Met with client to discuss case.
	11/12/08	0.5	$60.99	Worked on Rule 26 Disclosures.
	11/13/08	0.5	$60.99	Added to pretrial disclosures.
	11/18/08	0.5	$60.99	Email with Jim Gottstein; clients; discuss issues w/Ms. Kraly; attempts to schedule ADR.
	11/20/08	0.5	$60.99	Reviewed final Rule 26 and strategized discovery issues w/client.
	12/9/08	0.3	$36.59	Reviewed motion to amend complaint.
	12/10/08	0.3	$36.59	Read motion to amend complaint; drafted response.
	12/24/08	0.3	$36.59	Pretrial scheduling conference.
	12/29/08	1.0	$121.98	Read Medicaid/Foster Care/Psychotropics materials from Oregon in anticpation of upcoming settlement meeting.
	1/7/09	3.0	$365.94	Reviewed file for upcoming meeting with Jim Gottstein; drafted lengthy case assessment email to clients.
	1/8/09	1.0	$121.98	Continued file review, emails with clients, document review, etc. in anticipation of settlement meeting tomorrow.
	1/9/09	1.7	$207.37	Met with Jim Gottstein and principals for initial settlement talks.
	1/14/09	3.0	$365.94	Continued review of case file (pleadings and documentation); emailed pertinent information to Ms. Raymond; reviewed additional information and materials from principals.
	1/15/09	1.6	$195.17	Continued file review, case strategizing.
	1/20/09	0.5	$60.99	Reviewed additional materials from Jim Gottstein.
	1/23/09	0.4	$48.79	Reviewed new materials from Jim Gottstein; reviewed with client (Brita Bishop, et al) parameters for Bring the Kids Home meeting and possible issues related to plaintiff's presence at same.
	1/29/09	0.3	$36.59	Corresponded with Jim Gottstein and client re: participation in upcoming mental health teleconference.
	2/4/09	0.5	$60.99	Finalized notice and motion for protective order, and proposed protective order.
	2/4/09	1.0	$121.98	Reviewed plaintiff's Motion for Protective Order; drafted Limited Opposition; discussed with Ms. Kraly; finalized for filing.
	2/5/09	0.5	$60.99	Drafted letter re: impact of public relations on settlement to Jim Gottstein.
	2/6/09	0.4	$48.79	Continued working on email/settlement info to Jim Gottstein/Stacie Kraly.
	2/9/09	1.5	$182.97	Reviewed file; Met with Richard Nault/Karen Forrest re: "gold standard" for psych meds.
	2/11/09	0.6	$73.19	Corresponded w/Jim Gottstein re: depositions.
	2/17/09	0.6	$73.19	Coordinated and strategized issues related to pending depositions.
	2/19/09	0.3	$36.59	Continued coordinating discovery in psych rights matter.
	2/20/09	1.5	$182.97	Continued to work on discovery and deposition prep.
	2/23/09	5.6	$683.09	Continued to research and draft motion for judgment on pleadings.
	2/24/09	3.1	$378.14	Continued to draft Motion for Judgment on Pleadings.
	2/26/09	4.9	$597.70	Began research and drafting on motion to dismiss/judgment on pleadings; worked on motion to quash deposition; strategized same with Stacie Kraly.
	2/26/09	1.0	$121.98	Deposition prep with Dave Campana and discussion with Ed Sniffen.
	3/4/09	0.8	$97.58	Worked on motion for judgment on pleadings and motion to stay discovery.
	3/5/09	1.3	$158.57	Continued working on 12(c) motion; incorporated some of Ed Sniffen's suggested edits.
	3/9/09	6.0	$731.88	Worked on motion for judgment on pleadings/motion to stay discovery.
	3/10/09	4.7	$573.31	Continued working on 12c and discovery motions.

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
	3/11/09	3.4	$414.73	Continued to work on motino for judgment on pleadings.
	3/12/09	0.8	$97.58	Finalized dispositive motion and motion to stay discovery for filing.
	3/17/09	0.6	$73.19	Reviewed response to motion for expedited consideration of motion to stay discovery/strategized with Ms. Kraly.s
	3/18/09	1.3	$158.57	Reviewed pending discovery and worked on reply to opposition to motion for EC.
	4/1/09	2.5	$304.95	Reviewed plaintiffs' opposition to motion for judgment on pleadings; began formulating reply; strategized with Ms. Kraly re: website postings on plaintiffs' website and necessary action.
	4/2/09	2.5	$304.95	Worked on reply to opposition to motion for judgment on pleadings.
	4/3/09	2.4	$292.75	Worked on reply to opposition.
	4/6/09	4.0	$487.92	Continued working on reply to opposition to motion for summary judgment and limited opposition to motion for leave to amend.
	4/8/09	1.3	$158.57	Worked on finalizing reply to opposition to motion for judgment on pleadings and conditional non-opposition to motion for leave to amend.
	4/9/09	2.1	$256.16	Finalized reply brief (to op to mot for judgment on pleadings).
	4/30/09	0.4	$48.79	Reviewed materials and read articles on psych rights web page re: pending litigation.
Elizabeth M. Bakalar		**88.5**	**$10,795.20**	
Nevhiz E. Calik	3/27/09	1.0	$121.98	Edited and filed for Libby Bakalar and Stacie Kraly.
Nevhiz E. Calik		**1.0**	**$121.98**	
Kelly E. Henriksen	3/11/09	2.2	$268.36	Review and edit motion for judgment on the pleadings.
	3/16/09	0.4	$48.79	Conference iwth Bakalar re strategy re M/expedited consideration.
	3/17/09	0.2	$24.40	Conference wth Libby re procedural question.
	3/24/09	0.4	$48.79	Review and respond to Kraly re opposition to motion to stay discovery.
	3/25/09	0.2	$24.40	Conference with Kraly re motion to stay discovery.
	3/26/09	1.7	$207.37	Review and edit Reply to Motion to Stay per Kraly.
	4/9/09	0.5	$60.99	Review reply per Kraly.
Kelly E. Henriksen		**5.6**	**$683.10**	
Stacie L. Kraly	9/18/08	0.6	$73.19	Discuss answer and motion to dismsis issue with Ms. Bakalar.
	9/29/08	0.5	$60.99	Work on complaint, pretrial order with Ms. Bakalar and Mr. Gottstein.
	10/8/08	0.4	$48.79	Work on Answer.
	10/9/08	1.5	$182.97	Continue to work on answer.
	10/27/08	0.3	$36.59	Discuss options re meeting with Mr. Gottstien with Ms. Bakalar.
	10/29/08	0.5	$60.99	Review draft initial disclosures.
	11/6/08	0.4	$48.79	Work on initial disclosures.
	11/12/08	0.8	$97.58	Attend Meeting with senior staff at DHSS related to settlement and initial dislcosures.□ □
	11/20/08	0.7	$85.39	Work on initial disclosures; discuss data collection with DJJ.
	1/7/09	1.0	$121.98	Staff case with Ms. Bakalar, review email re same.
	1/8/09	0.3	$36.59	Prepare for meeting tomorrow.
	1/9/09	2.0	$243.96	Prepare for and attend settlement conference with Mr. Gottstien, Commisisoenr Hogan, Ms. Sandavol, Mr. McComb and Ms. Bakalar.
	1/14/09	0.8	$97.58	Review data from OCS and DJJ, update Ms. Raymond.
	2/2/09	0.3	$36.59	Work on discovery isuses with Ms. Bakalar.
	2/6/09	0.5	$60.99	Work on email/repsosne to Mr. Gottstein re public vetting of liigation issues.
	2/10/09	0.8	$97.58	Work with Ms. Bakalar on discovery strategy.
	2/17/09	0.6	$73.19	Work on deposition issues.
	2/24/09	1.0	$121.98	Work on deposition issues, discuss motion practice re same.
	3/4/09	0.5	$60.99	Work on motion to dismiss re standing.
	3/5/09	0.4	$48.79	Work on motion to dismiss.
	3/9/09	0.7	$85.39	Work on dispositive motions with Ms. Bakalar.

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
	3/10/09	2.0	$243.96	Work on motions with Ms. Bakalar.
	3/11/09	0.5	$60.99	Discussion with Mr. Jesse (mental health trust) re options and isuses in litigation.
	3/11/09	1.5	$182.97	Work on Motion to Dismiss with Ms. Bakalar.
	3/17/09	0.5	$60.99	Discuss reply strategy re motion for expedited consideration with Ms. Bakalar.
	3/24/09	0.7	$85.39	Review opposition to motion to stay.
	3/25/09	4.2	$512.32	Work on reply brief.
	3/26/09	3.0	$365.94	Work on reply brief.
	3/27/09	1.5	$182.97	Work on reply brief.
	4/2/09	0.5	$60.99	Work on reply to motion for judgment on the pleadings.
	4/3/09	0.6	$73.19	Work on reply brief; review motion to amend.
	4/6/09	1.0	$121.98	Work on reply brief.
	4/7/09	2.0	$243.96	Work on reply brief.
	4/9/09	1.5	$182.97	Work on reply brief.
Stacie L. Kraly		34.1	$4,159.51	
Total Fees		129.2	$15,759.79	

Costs	Date	Amount	Description
	3/18/09	$113.50	#23353895 STACIE L KRALY
	3/18/09	$19.00	#01411513 US TRAVEL, LLC
	3/18/09	$99.00	#01411516 HICKEL INVESTMENT CO
	3/18/09	$495.00	#01411510 ALASKA AIRLINES INC.
	4/9/09	$62.00	#01428019 ALASKA AIRLINES INC.
	4/9/09	$100.00	#01428024 ALASKA AIRLINES INC.
	4/9/09	$19.00	#01428027 US TRAVEL, LLC
Total Costs		$907.50	
Total Fees and Costs		$16,667.29	

Exhibit A page 3 of 3

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

Case No. 3AN-08-10115 CI

AFFIDAVIT OF COUNSEL

STATE OF ALASKA)
) ss.
FIRST JUDICIAL DISTRICT)

I, Elizabeth M. Bakalar, having been duly sworn, hereby state as follows:

1. I am an Assistant Attorney General employed by the Department of Law and one of the attorneys of record in the above-captioned case on behalf of the

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

State of Alaska. I submit this affidavit in support of the Motion for Attorney's Fees on behalf of the State as the prevailing party.

2. Attorney's fees in the amount of $15,759.79 were incurred on behalf of the Department in defending this litigation. This includes 88.5 hours of work performed by me personally, at an hourly rate of $121.98. Exhibit A, attached, contains an itemized listing of the dates, descriptions of work accomplished, and the time expended. I have reviewed this report for accuracy and applicability.

3. I have determined both that the information presented in Exhibit A is correct, and that the time listed was necessarily spent in defending this matter. I do not believe that any of the work performed in this case was unnecessary or duplicative. I believe the total amount of time and money expended on behalf of the Department is reasonable.

4. Although the state bills client agencies at a rate far below the market rate of attorneys in private practice, in 1997 the Attorney General established a policy that would more fairly reimburse the state for its fees as a prevailing party. To that end, the Attorney General approved the hourly rate of $150 as the market rate for journey level attorneys (Attorneys III and above). This rate was based on the recommendations of a working group tasked with assessing the Department of Law's policy on attorney fee requests. After reviewing attorney billing rates statewide, the policy in place at the U.S. Attorney's Office, and the fees paid by the state to experienced private practitioners who provide legal services to the state, the working

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group determined that $150 per hour was a reasonable rate that would more fairly reimburse the state for its legal services. The rate of $125 per hour was approved for less experienced attorneys.

5. I have been practicing law in the State of Alaska for almost three years and am an Attorney III. Based on the foregoing, a request for reimbursement for the time spent on this case by me at a rate of $150 per hour is reasonable.

6. The actual, reasonable attorney's fees that were necessarily incurred in this matter amount to a total of $19,380.00.

DATED this 22nd day of June, 2009.

Elizabeth M. Bakalar
Alaska Bar No. 0606036

SUBSCRIBED AND SWORN TO before me this 22ND day of June, 2009.

STATE OF ALASKA
OFFICIAL SEAL
HEIDI HAFFNER
NOTARY PUBLIC
My Commission Expires With Office

Notary Public, State of Alaska
My commission expires with office

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

OPPOSITION TO
MOTION FOR AWARD OF ATTORNEY'S FEES

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®) opposes the defendants' Motion for Award of Attorney's Fees. Civil Rule 82(3)(I) provides:

> (3) The court may vary an attorney's fee award calculated under subparagraph (b)(1) or (2) of this rule if, upon consideration of the factors listed below, the court determines a variation is warranted:
>
> (I) the extent to which a given fee award may be so onerous to the non-prevailing party that it would deter similarly situated litigants from the voluntary use of the courts;

Any award is likely to deter litigants from the voluntary use of the courts. This was raised in §II.B., of PsychRights Opposition to Motion for Judgment on the Pleadings and is incorporated herein by reference.

DATED: January 30, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUL 10 2009

Case No. 3AN-08-10115 CI

DEFENDANTS' REPLY TO OPPOSITION TO MOTION FOR AWARD OF ATTORNEY'S FEES

The State of Alaska and the remaining above-named defendants (hereinafter "the Department") reply as follows to plaintiff's Opposition to Motion for Award of Attorney's Fees.

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DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
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In its Motion, the Department requested $3,876.00 in attorney's fees as a prevailing party under Civil Rule 82. Plaintiff in opposition asks the court to deviate from the standard prevailing party fee schedule and vary the fee award because the requested fees would "be so onerous to the non-prevailing party, that it would deter similarly situated litigants from the voluntary use of the courts."[1]

Plaintiff then refers the court to §II.B of its Opposition to Motion for Judgment on the Pleadings, in which plaintiff: (1) asserts without explanation that it is "reluctant" to add individual plaintiffs to achieve interest-injury standing; (2) claims it has citizen-taxpayer standing even though it contradicts this claim by stating individual plaintiffs could be substituted for plaintiff's law firm; and (3) makes unsubstantiated (and factually incorrect) allegations against the Attorney General's Office purported policy to "always" seek attorney's fees "against people on welfare" and other non-prevailing parties, "even if they can't afford them."[2]

Plaintiff—a law firm, albeit a non-profit one—makes no averments as to why the requested fee award would be onerous. Furthermore, litigants similarly situated to this plaintiff arguably *should* be deterred from the voluntary use of the courts. The reason for dismissal of this action and the Department's ensuing status as a prevailing party is that the plaintiff—who is a law firm and not a "person on

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[1] Civil Rule 82(b)(3)(I).

[2] Plaintiff's Opposition to Motion for Judgment on the Pleadings, p. 23-24.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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welfare"—lacked both interest-injury and citizen taxpayer standing to sue.[3] A law firm without standing should not be permitted to squander judicial resources forcing defendants to prove the point.

In short, plaintiff gives the court no reason to vary the fee award from the standard Rule 82 fee schedule. The court should grant the Department's Motion for Award of Attorney's Fees as requested.

Dated this 8th day of July, 2009.

DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

Certificate of Service
I hereby certify that on this day of July 8, 2009, true and correct copies of the foregoing REPLY was served via U.S. mail, first class, postage prepaid to the following attorney of record:

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, AK 99501

_____
H. Raven Haffner, Law Office Assistant II

[3] Court's Order on Record, May 27, 2009.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUL 30 2009

Case No. 3AN-08-10115 CI

JUN 24 2009

ORDER GRANTING DEFENDANT'S MOTION FOR ATTORNEY'S FEES

THE COURT, having considered the Department's Motion for Attorney's Fees, any opposition and any responses thereto, and being fully advised,

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

HEREBY ORDERS that the motion is GRANTED. The defendant is entitled to a total fee award under Civil Rule 82(b)(2) of $3,876.00. This amount shall be entered in the final judgment with post-judgment interest to run from

16 June 2009

DATED: 7-28-09

Jack W. Smith
Superior Court Judge

I certify that on 7-29-09 a copy of the above was mailed to each of the following at their address of record. Sattstun, Kraly, Bakalar

Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600