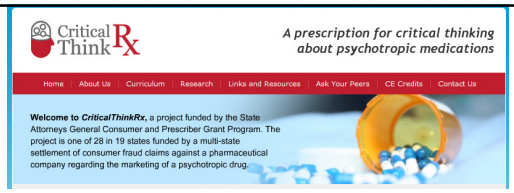


A Critical Curriculum on Psychotropic Medications

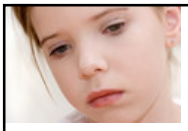
Critical Think Rx

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)

11

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

21

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.

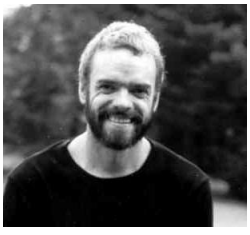
- M.S.W. with a background in journalism and corporate communication
- Clinician focused on holistic approaches to the treatment of trauma-related mood and behavioral problems

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.

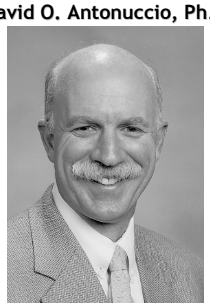
- Professor, Director of the Ph.D. Program, and Associate Dean for Strategic Initiatives in Social Work at Virginia Commonwealth University, where she has taught since 1989
- Author, *The Social Worker & Psychotropic Medication* (3rd ed., 2006) (with Joseph Walsh)
- Editor, *Psychiatric Medication Issues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



26

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*

27

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

29

30

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

32

CBS NEWS Oct. 1, 2007 12:10pm

CBS EVENING NEWS | THE EARLY SHOW | 48 HOURS MYSTERY | 60 MINUTES

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

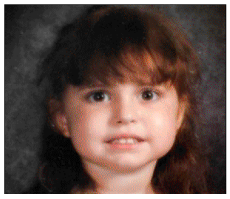
AP Associated Press

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.



33

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

35

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

36

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)

37

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)

38

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.

39

… 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

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40

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

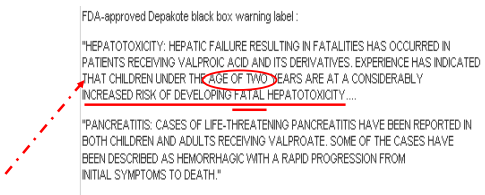
By Lawrence Diller | June 19, 2007

"… 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.*

46

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."

47

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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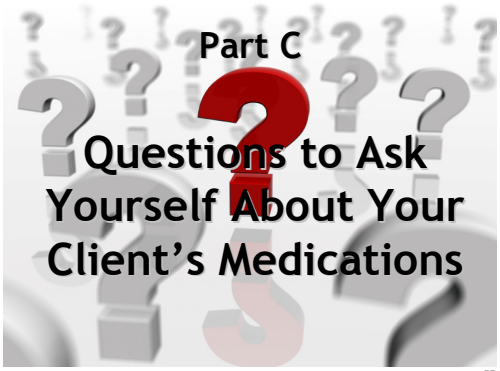

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56

- 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

62

- 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?

79

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

80

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Module 1

The End

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81