

# **An Inconvenient Parent: How a Father Fought the FDA and Won**

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International Society for Ethical Psychology & Psychiatry (ISEPP)

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# Driving Force: Therapeutic Jurisprudence

## PSYCHOLOGY IN FAMILY LAW, aka CHILD CUSTODY, INC.

- ◆ Court-Appointed Child Psychologist
- ◆ Court-Appointed Parenting Coordinator
- ◆ Court-Appointed Guardian ad Litem
- ◆ Court-Appointed Child Custody Evaluator
- ◆ Court-Appointed Forensic Evaluator
- ◆ Family Court Judge
- ◆ Child Protective Services

# Driving Force: Therapeutic Jurisprudence (Cont'd)

## Court-Appointed Child Psychologist

- ♦ Kathryn Kuehnle, Ph.D.
- ♦ [Sued for Wrongful Death, Negligence, Loss of Consortium](#)
- ♦ Local Court Granted Summary Judgment in Favor of Dr. Kuehnle
- ♦ Overturned by District Court of Appeals - see [Estate of Rotell v. Kuehnle](#), 2010 WL 2178581 (Fla. Dist. Ct. App. June 2, 2010) and [Mental and Physical Disability Law Reporter](#) Vol. 34, No. 4 (July August 2010), pp. 550-554

Recommended physical and blanket restraint of my 5-year old child (In addition to recommending my child be restrained on the floor, Dr. Kuehnle instructed the other parent to “wrap a blanket around [the child], as you would a baby, and hold [the child] until [the child] can calm down”--other experts likened the blanket restraint to a rudimentary form of mechanical restraint and crude straightjacket)

- ♦ A Board Certified Behavioral Analyst, and Psychologist Jean Mercer, Ph.D., who filed amicus brief in [People v. Watkins](#) (Candace Newmaker case), experts issued opinions opposing restraint
- ♦ Dr. Kuehnle withdrew as my child’s psychologist
- ♦ Court granted my motion to prohibit physical restraint

# Driving Force: Therapeutic Jurisprudence (Cont'd)

## Court-Appointed Guardian ad Litem (GAL)

- ♦ James R. Flens, Psy.D.
- ♦ Dr. Kuehnle referenced 21 times in Dr. Flens curriculum vitae (incidentally also references S. Greenberg)
- ♦ *Keesee v. Keesee*, 675 So. 2d 655 - FLA: Dist. Court of Appeal, 5th Dist. 1996

There also is an unseemly pattern emerging in some of these cases of conduct that amounts to a conflict of interest, or, at the very least, a failure of disclosure. This is especially common in "court appointed expert" cases, where unbeknownst to one side or the other, the "independent" or "court" psychologist has a former or current professional or business relationship with one of the lawyers or with the psychologist for one of the contestants. It is very dangerous for counsel to agree to an "independent" expert in these cases unless he or she can be sure the psychologist truly is independent of the opposing side.

- ♦ Omitted from Dr. Flens' C.V.

Records indicate: Flens arrested, charged, got probation for Aggravated Battery (*Florida v. Flens*, Hillsborough, Case No. 79-546MM-A-43); subject of Restraining Order (*Flens v. Flens*, Hillsborough, Case No. 90-DR-019865); found liable for Civil Theft after failing to refund remainder of custody evaluation retainer - *McCormack v. Flens*, 27 So. 3d 179 (Fla. 2d DCA 2010) appeals court reinstated jury verdict in *McCormack v. Flens*, Hillsborough, Case No. 07-CA-2419.

- ♦ Ironically, Dr. Flens claimed on his website to be an expert in "intimate partner violence"
- ♦ Front-page, above-the-fold [Tampa Bay Times story](#): "[Court expert, life of turmoil](#)"
- ♦ After Motion to Disqualify GAL, article published, Dr. Flens no longer GAL of my child

# Driving Force: Therapeutic Jurisprudence (Cont'd)

## Court-Appointed Parenting Coordinator

- ◆ Mark E. Prange, Ph.D.
- ◆ Dr. Flens' curriculum vitae references Dr. Prange; Dr. Prange in turn refers other parent to Prange's personal attorney, who handled his divorce and his mother's probate. *Keese v. Keese*, 675 So. 2d 655 - FLA: Dist. Court of Appeal, 5th Dist. 1996 (re: conflicts of interest)
- ◆ Florida Department of Health [administrative complaint](#) against Dr. Prange alleged he *drank wine with a female client*, he *kissed his female client*, he wrote his female client personal and *intimate correspondence*, he exchanged gifts with his female client, he *met his female client in places other than his office*, he engaged in "reparenting" exercises with his female client whereby *the two would put their head in each other's lap*, and his conduct exceeded the boundaries of a psychologist-client relationship. The DOH complaint also alleged he *divulged confidential information* to his female client about her husband, which he learned from a colleague treating the husband.

# Driving Force: Therapeutic Jurisprudence (Cont'd)

## Living Rent-Free Inside a Psychologist's Mind

- Though Dr. Prange is cognizant numerous details don't match my family's case, he clings to the delusion that I'm behind multiple negative reviews of him. (I'm not)



-John D in Tampa, FL | Jan 21, 2016

Continued waste of my time and he clearly had sided with my ex wife on the parental coordinating. He allowed her to control the situation and isolated me from my children for about 10 months. Now that I have seen his previous charges of drinking wine at lunch with a female client( that he had her... [more](#)

Flag this  Was this helpful?



Response on behalf of Dr. Prange:

*Submitted on May 25, 2017*

“ This review is from the current host of multiple websites attacking psychologists, psychiatrists, and the pharmaceutical industry. This individual was a brief Parent Coordination client who continues to retaliate against my practice and other psychologists. This individual has made it a goal to write review after negative review, changing story details, to discredit me. None of these malicious allegations made are true. ”

Flag this 

# Driving Force: Therapeutic Jurisprudence (Cont'd)

“Happy Birthday, Peggy. I feel that I know the song that reflects the real you and I want to sing it so that you can see your beauty. Your soul is a tribute to love in spite of what was done to you as a child. I only hope and pray that you can let love come back to you. You deserve it. Love, Mark”

- Correspondence from Dr. Mark Prange to his female client M.C.

The [final order](#) relating to the administrative complaint against Dr. Prange accepting a proposed settlement agreement with respect to the DOH administrative complaint against Dr. Mark Prange, issuing a letter of concern to Dr. Prange, imposing an administrative fine on Dr. Prange in the amount of \$5,000, requiring Dr. Prange to reimburse additional costs in the amount of \$5,461.37, and ordering Dr. Prange to complete continuing education in the areas of ethics and boundaries.

On May 22, 2018, the Florida Department of Health filed another [administrative complaint](#) against Dr. Mark Prange. This time, DoH accused Dr. Prange of not turning over patient answers to the MMPI-2, relating to a Court-appointed parenting plan evaluation.

# Driving Force: Therapeutic Jurisprudence (Cont'd)

“I’m a member of the National Alliance on Mental Illness, many people know it as NAMI.” - Kim Campbell, Judge, Florida 6<sup>th</sup> Circuit



*Enjoying the NAMI Pinellas annual picnic in May are, left to right, Sgt. Ryan Buckley, CIT officer with the Sheriff's Office and his wife Kim Campbell, President of the Clearwater Bar Association and a candidate for the Circuit Judge in Pinellas/Pasco; Martha Lenderman, NAMI Advisory Board; Joanne Jones, NAMI Board of Directors; Barbara Daire, CEO of Suncoast Center; Dr. Karl Jones, Medical Director for our Community Partner Windmoor Healthcare; and Rep. Darryl Rouson, Florida House of Representatives.*

# Driving Force: Therapeutic Jurisprudence (Cont'd)

- Many people know the National Alliance on Mental Illness as disease-mongering astroturf, masquerading as a grassroots patient advocacy group.

## [Senator Grassley Seeks Financial Details From Medical Groups](#)

*New York Times*, December 2, 2009

“Mr. Grassley sent a similar letter to the National Alliance on Mental Illness. In response, the group told the senator that more than two-thirds of its donations come from the pharmaceutical industry. In response to the disclosure, Dr. H. Richard Lamb, a board member for the alliance, resigned. Dr. Lamb joined the board of the organization in 2005, when he was ‘shocked to learn that approximately half of NAMI’s income comes from the large pharmaceutical companies,’ he wrote in a resignation letter that Mr. Grassley made public.”

Bedfellows: (now) Senator Roulson--pictured with (now) Judge Campbell--has accepted contributions from Abbott Labs, PHRMA, Novartis, Psychiatric Society, American Pharmacy Cooperative, Inc., Florida Family Medicine PAC, etc.

Judge Campbell: parent unable to question a psychologist about a diagnosis that was “*already handed down.*” (as if a diagnosis is some sort of monarchical edict)

# Driving Force: Therapeutic Jurisprudence (Cont'd)

Dr. Eric Tridas, allowed by Judge Campbell to conduct an evaluation, diagnosed my child with ADHD, recommended Concerta (manufactured by his benefactor Janssen/J&J), despite multiple known contraindications. After Tridas' pharma ties were exposed, a psychiatrist's subsequent evaluation concluded "teacher scores did not screen [child] as having ADHD."



According to reports, Dr. Tridas' son was [arrested](#) under suspicion of [trafficking in amphetamine 28 to 200 grams](#).<sup>\*</sup> Dr. Tridas has received payments totaling tens of thousands of dollars from ADHD drug manufacturers, including...

\*Innocent until proven guilty

# Driving Force: Therapeutic Jurisprudence (Cont'd)

“Beginning in fiscal year 1999-2000, the sheriffs of Pasco County, Manatee County, Broward County, and Pinellas County have the responsibility to provide all child protective investigations in their respective counties.” Florida Statute 39.3065



[Bridget Nocco](#), Pasco County Sheriff Chris Nocco's wife, is a consultant for lobbyists Ballard Partners.

Ballard Partners clients include:



Mallinckrodt

AstraZeneca 

*Walgreens*

Note: Parkland in Broward. CPS had multiple contacts with Cruz. DCF report indicates Cruz took medication for ADHD.



# Therapeutic Jurisprudence: Parents Galvanized

“Our position is the answers to life’s problems are not found in the bottom of prescription-drug bottle,” said Andrew Thibault, a New Port Richey resident and one of the protest organizers.



[Parents protest psychiatric meds for children](#)

*Tampa Tribune*, February 6, 2014

## **PART II**

# **Taking On the FDA**

# FDA Adverse Event Reporting System (AERS)

## Say What???

```
|primaryid$caseid$caseversion$i_f_code$event_dt$mfr_dt$init_fda_dt$fda_dt$rept_cod$mfr_num$mfr_sndr$age$age_cod$gi  
100033001$10003300$1$I$$20131015$20140306$20140306$PER$1289378$GENENTECH$77$YR$F$N$$$20140124$N$CN$US$  
100033011$10003301$1$I$$20130729$20140228$20140228$PER$US - JNJFOC - 20130719067$JANSSEN$$$F$N$$$20140109$N$CN$US$  
100033021$10003302$1$I$$20140307$20140312$20140312$PER$US - PFIZER INC - 2014068976$PFIZER$$$M$Y$$$20140311$N$CN$US$  
100033051$10003305$1$I$$20140307$20140312$20140312$PER$US - PFIZER INC - 2014069067$PFIZER$48$YR$F$Y$$$20140312$N$MD:  
100033061$10003306$1$I$$20120731$20140312$20140312$EXP$US - GILEAD - 2012 - 0059171$GILEAD$$$F$Y$$$20140312$N$CN$US$US  
100033072$10003307$2$F$$20120719$20140312$20140312$EXP$US - GILEAD - 2012 - 0058057$GILEAD$$$F$Y$$$20140312$N$MD$US$US  
100033082$10003308$2$F$$20130516$20140312$20140312$EXP$US - GILEAD - 2012 - 0063316$GILEAD$$$F$Y$$$20140312$N$MD$US$US  
100033092$10003309$2$F$$20120726$20140312$20140312$EXP$US - GILEAD - 2012 - 0057858$GILEAD$$$M$Y$$$20140312$N$CN$US$US  
100033102$10003310$2$F$$20130531$20140312$20140312$EXP$US - GILEAD - 2012 - 0063271$GILEAD$$$F$Y$$$20140312$N$CN$US$US  
100033112$10003311$2$F$$20120601$20121106$20140312$20140312$EXP$US - GILEAD - 2012 - 0058241$GILEAD$76.394$YR$F$Y$$$201.  
100033132$10003313$2$F$$20130221$20140312$20140312$EXP$US - GILEAD - 2012 - 0057186$GILEAD$$$F$Y$$$20140312$N$MD$US$US  
100033141$10003314$1$I$$20120726$20140312$20140312$EXP$US - GILEAD - 2012 - 0058848$GILEAD$$$M$Y$$$20140312$N$CN$US$US  
100033151$10003315$1$I$$20140305$20140312$20140312$EXP$US - GILEAD - 2014 - 0096363$GILEAD$$$M$Y$$$20140312$N$CN$US$US  
100033162$10003316$2$F$$20130221$20140312$20140312$EXP$US - GILEAD - 2012 - 0057916$GILEAD$$$F$Y$$$20140312$N$CN$US$US  
100033171$10003317$1$I$$20121209$20140115$20140312$20140312$EXP$US - GLAXOSMITHKLINE - A1057101A$GLAXOSMITHKLINE$46$YI  
100033202$10003320$2$F$$20121214$20140312$20140312$EXP$US - GILEAD - 2012 - 0056834$GILEAD$$$M$Y$$$20140312$N$CN$US$US  
100033212$10003321$2$F$$20131126$20140320$20140312$20140327$EXP$JP - GLAXOSMITHKLINE - B0975691A$GLAXOSMITHKLINE$71.7:  
100033222$10003322$2$F$$20121112$20140312$20140312$EXP$US - GILEAD - 2012 - 0057218$GILEAD$$$F$Y$$$20140312$N$MD$US$US  
100033231$10003323$1$I$$201402$20140303$20140312$20140312$PER$US - B. I. PHARMACEUTICALS, INC. / RIDGEFIELD - 2014 - BI - 095:  
100033242$10003324$2$F$$20121016$20140312$20140312$EXP$US - GILEAD - 2012 - 0058151$GILEAD$$$F$Y$$$20140312$N$MD$US$US  
100033251$10003325$1$I$$20120730$20120731$20140312$20140312$EXP$US - GILEAD - 2012 - 0059125$GILEAD$68.214$YR$F$Y$$$201.
```

# Deciphering AERS: Pediatric Stimulant Fatalities

```
SET MAX_JOIN_SIZE = 10000000000;  
CREATE TABLE drug_deaths  
SELECT information.CASE, information.ISR, information.AGE, information.AGE_COD,  
information.GNDR_COD, information.DEATH_DT, outcomes.outc_cod  
FROM information  
JOIN outcomes  
ON information.ISR = outcomes.isr  
WHERE ( ( information.AGE_COD = 'DY' AND information.AGE !=" AND information.AGE  
>=0 AND information.AGE <=6569 ) OR ( information.AGE_COD = 'MO' AND  
information.AGE !=" AND information.AGE >=0 AND information.AGE <=215 ) OR  
( information.AGE_COD = 'YR' AND information.AGE !=" AND information.AGE >=0 AND  
informations.AGE <18 ) ) AND outcomes.outc_cod = 'DE'  
LIMIT 0 , 10000000000;
```

```
SELECT * FROM `drug_deaths` WHERE `drugname` LIKE 'Adderall%' OR `drugname`  
LIKE 'Amphetamine%' OR `drugname` LIKE 'Atomoxetine%' OR `drugname` LIKE  
'Clonidine%' OR `drugname` LIKE 'Concerta%' OR `drugname` LIKE 'Daytrana%' OR  
`drugname` LIKE 'Desoxyn%' OR `drugname` LIKE 'Dexedrine%' OR `drugname` LIKE  
'Dexmethylphenidate%' OR `drugname` LIKE 'Equasym%' OR `drugname` LIKE 'Focalin%'
```

# AERS: Pediatric Stimulant Fatalities (287)

CASE	DRUGNAME	OUTCOME	AGE	GENDER
6091101	ADDERALL 10	DEATH	3	M
7668780	CONCERTA	DEATH	3	M
8304189	FOCALIN	DEATH	4	M
7290573	AMPHETAMINE SULFATE	DEATH	5	M
8068592	AMPHETAMINE SULFATE	DEATH	5	M
5838311	ADDERALL XR 15, DEXTROAMPHETAMINE, FOCALIN	DEATH	6	M
7146812	CONCERTA	DEATH	6	
7933064	VYVANSE	DEATH	6	F

# FDA: Estimated Pediatric Vyvanse Use

**Table 2.2.3**

**Diagnoses associated with the use of lisdexamfetamine as reported by U.S. office-based physician surveys, stratified by patient age, from July 2012 through June 2015, cumulative**

	July 2012-June 2015		
	Uses N	Share %	95% Confidence Interval
<b>Total Uses</b>	<b>13,650,000</b>	<b>100.0%</b>	<b>13,051,000 - 14,248,000</b>
<b>0-5 years</b>	140,000	1.0%	79,000 - 200,000
3140 ATTENTION DEFICIT DIS	135,000	96.4%	75,000 - 194,000
2967 BIPOLAR AFFECTIVE NOS	5,000	3.6%	<500 - 16,000
<b>6-11 years</b>	3,550,000	26.0%	3,244,000 - 3,855,000
3140 ATTENTION DEFICIT DIS	3,512,000	98.9%	3,208,000 - 3,816,000
2999 EARLY CHLD PSYCHOSIS NOS	14,000	0.4%	<500 -32,000
3138 OTH EMOTIONAL DIS CHILD	7,000	0.2%	<500-21,000
3129 CONDUCT DISTURBANCE NOS	7,000	0.2%	<500-21,000
2969 AFFECT PSYCHOSES NEC/NOS	5,000	0.1%	<500-17,000
2967 BIPOLAR AFFECTIVE NOS	5,000	0.1%	<500-16,000
<b>12-16 years</b>	3,727,000	27.3%	3,414,000 - 4,039,000
3140 ATTENTION DEFICIT DIS	3,678,000	98.7%	3,368,000 - 3,989,000
3138 OTH EMOTIONAL DIS CHILD	22,000	0.6%	<500-46,000
2999 EARLY CHLD PSYCHOSIS NOS	9,000	0.3%	<500-25,000
V623 EDUCATIONAL CIRCUMSTANCE	8,000	0.2%	<500-22,000
2780 OBESITY	5,000	0.1%	<500-17,000
2998 EARLY CHLD PSYCHOSES NEC	4,000	0.1%	<500-15,000
<b>17+ years and older</b>	5,635,000	41.3%	5,250,000 - 6,019,000
<b>Unspecified Age</b>	599,000	4.4%	474,000 - 725,000

# Media Outrage: Toddler Stimulant Use

More than 10,000 American toddlers 2 or 3 years old are being medicated for attention deficit hyperactivity disorder outside established pediatric guidelines, according to data presented on Friday by an official at the Centers for Disease Control and Prevention.

Alan Schwarz, *New York Times*, May 16, 2014

'That's nuts': 10,000 toddlers get drugs for ADHD

A. Pawlowski, *Today*, May 19, 2014

Shocking Study: Toddlers Given ADHD Meds Despite Pediatric Guidelines

Fox & Friends, *Fox News*, May 20, 2014

The Overmedication of Our Kids Is Worse Than We Thought

Ben Collins, *Esquire*, May 22, 2014

10,000 Toddlers Are on Stimulant Drugs for ADHD

Allen Frances, M.D., *Huffington Post*, July 17, 2014

# AERS: Pediatric Psychotropic Fatalities (~1,889)

count	case	isr	drugname	ro	or	dose_vbm	dechal	rech	age	ag	gn
1	3042917	5096101	RITALIN 10 MG TID (METHYLPHENIDATE HYDRO	C	DE				13 YR		F
2	3124297	7890158	CLONAZEPAM	C	DE	NA			7 YR		M
2	3124297	7890158	CARBAMAZEPINE	C	DE	NA			7 YR		M
1	3221831	4307567	ZOLOFT	PS	DE	50 MG (DAILY), OR	D	D	13 YR		M
2	3783841	5088962	PROZAC	PS	DE	TRANSPLACENTAL	D	D	1 DY		
2	3783841	5088962	XANAX	C	DE				1 DY		
2	3783841	5113814	PROZAC	PS	DE	20 MG, DAILY (1/D)	D	D	1 DY		F
2	3783841	5113814	XANAX	C	DE				1 DY		F
1	3859464	4353104	MIDAZOLAM HCL	C	DE				8 YR		F
2	3867525	4600342	FLUOXETINE	SS	DE		U	U	3 YR		
2	3867525	4600342	OLANZAPINE	SS	DE		U	U	3 YR		
1	3881254	4596189	XANAX	SS	DE	MG	D	D	17 YR		M
1	3886529	5500774	PAXIL	PS	DE				14 YR		F
3	3942303	4292232	PAXIL	PS	DE	10MG PER DAY			12 YR		F
3	3942303	4292232	ZYPREXA	C	DE	2.5MG AT NIGHT			12 YR		F
3	3942303	4292232	CONCERTA	C	DE	18MG PER DAY			12 YR		F
3	3942303	4305067	PAXIL	PS	DE	10MG PER DAY			12 YR		F
3	3942303	4305067	ZYPREXA	C	DE	2.5MG AT NIGHT			12 YR		F
3	3942303	4305067	CONCERTA	C	DE	18MG PER DAY			12 YR		F
3	3943163	4288926	CELEXA	PS	DE	SEE IMAGE	D	D	16 YR		F
3	3943163	4288926	VALPROIC ACID	C	DE				16 YR		F
3	3943163	4288926	SEROQUEL	C	DE				16 YR		F
1	3945374	4269453	DESIPRAMINE HCL	C	DE	INITIALLY 10 MG BID, INCREASED TO 1			15 YR		M
1	3945374	4345220	DESIPRAMINE HCL	C	DE	INITIALLY 10 MG BID, INCREASED TO 1			15 YR		M
1	3945374	4350776	DESIPRAMINE HCL	C	DE	INITIALLY 10 MG BID, INCREASED TO 1			15 YR		M
1	3945374	4523523	DESIPRAMINE HCL	C	DE	INITIALLY 10 MG BID, INCREASED TO 1			15 YR		M
1	3959270	4310793	CLOBAZAM	C	DE				6 YR		F
2	3970831	4501064	STRATTERA	PS	DE	80 MG/DAY	D	D	16 YR		M

# AERS: HHS estimated ADE incidence

**FDA's current postmarketing data collection systems for approved drugs are intended to compensate for the limitations of information from clinical trials by detecting the existence of previously unidentified ADEs. However, because FDA's Adverse Event Reporting System (AERS) relies on voluntary reports from physicians, pharmacists, patients, and others, it can uncover instances of problems but it cannot determine their true incidence. The same intrinsic limitation applies to the incident reporting systems that many hospitals have established to monitor adverse events, including ADEs. All such systems based on spontaneous reporting detect only a fraction of the total number of adverse events. **Experts believe that FDA's system includes an estimated 1 to 10 percent of adverse reactions****

## **ADVERSE DRUG EVENTS: Substantial Problem but Magnitude Uncertain**

Testimony Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate, Statement of Janet Heinrich, Associate Director, Health Financing and Public Health Issues, Health and Human Services Division, February 1, 2000

# FDA FOIA Lawsuit: Timeline

- First Freedom of Information Act (FOIA) request submitted on October 2, 2014
- FDA must produce responsive non-exempt records or deny the request in writing within 20 business days. 5 U.S.C. § 552(a)(6)(A)-(B) and 21 C.F.R. § 20.41(b)
- After the FDA failed to respond and/or produce the requested public records, the FOIA lawsuit was filed on August 4, 2015.
- FDA produced heavily redacted and completely redacted (hundreds of pages) AERs on Oct. 8, 2015.
- Appeal letter sent to Acting Commissioner Stephen Ostroff on November 9, 2015.
- FDA supplemental production of less redacted AERs on Dec. 8, 2015. Agency still withheld entire case narratives of 46 cases.
- Amended complaint filed on March 8, 2016 challenging the FDA's redactions.
- FDA produces unredacted/lesser redacted narratives of 23 of the 46 cases by Oct. 13, 2016.

# FDA FOIA Lawsuit Disposition

- Obtained 3,200+ pages of previously withheld AERs linking psychotropics to homicides.
- Obtained hundreds of pages of unredacted or lesser redacted AERs that had previously been produced either completely or heavily redacted.
- 72 filings (complaints, responses, declarations, memoranda of law, etc.)
- U.S. District Court ordered the FDA to pay Plaintiff's court costs on Aug. 25, 2017, citing 5 U.S.C. § 552(a)(4)(E)(i), when "the complainant has substantially prevailed"; and citing *Warren v. Colvin*, "finding a plaintiff entitled to costs where he filed a FOIA suit after a series of unsuccessful requests and the defendant voluntarily released the documents after the plaintiff initiated the suit."
- "Plaintiff contends that the FDA improperly withheld information from the public about the increased risk of **suicidality** associated with antidepressant medication in youth, adolescents and young adults." (e.g. David Carmichael, David Crespi)

Honorable Cynthia Edwards Honeywell, U.S. District Judge  
*Thibault v. U.S. Food and Drug Administration*, Doc. 69, p. 12

# It's Not the Crime, But the Cover Up

- “The Food and Drug Administration will make the fullest possible disclosure of records to the public...” 21 C.F.R. § 20.20(a)
- When the FDA finally produced the first batches of responsive AERs--only after the FOIA lawsuit was filed--hundreds of pages were completely redacted and others were heavily redacted. An amended complaint was filed, alleging the agency inappropriately redacted information (e.g. causality assessments, number of victims, etc.) contained in the AERs.
- Sample AERs supporting the allegations were attached as exhibits to the complaint. DoJ letter, a thinly veiled threat, demanded destruction of produced AERs. (see MIA) AERs clearly showed FDA redacted to cover up causality, not for privacy reasons.
- Go Fish (their word) – FOIA only litigation where plaintiff/judge blindfolded from the evidence. Subpoena served to depose an FDA employee, quashed by a magistrate.
- In a shocking twist, just when it seemed the truth would not come out--and intended to justify the agency's inappropriate redactions--the FDA *volunteered* startling revelations...

# FDA: AERS Cases Pertain to School Shootings

“DIDP also carefully reviews redactions to responsive AERs that describe sensational events. Sensational events are those where the individuals involved, or the method of death or injury described, is unique. For example, a unique event might be a ***school shooting*** in a particular location or ***an uncommon method of committing murder.***”

Declaration of Nancy B. Sager

Director of the Division of Information Disclosure Policy, FDA

*Thibault v. U.S. Food and Drug Administration*

Doc. 33-2, ¶ 61

# FDA: AERS Cases Pertain to Notorious Murders

“CDER uses the term ‘sensational event’ to refer to events where the individuals involved, or the method of death or injury described is unique. For example, a sensational event might be a school shooting in a particular location or ***a murder that received extensive press coverage.***”

Declaration of Nancy B. Sager

Director of the Division of Information Disclosure Policy, FDA

*Thibault v. U.S. Food and Drug Administration*

Doc. 33-2, Exhibit 9, p. 1

# Headline: FDA Admits Rx-School Shooting Link

Extra, Extra, Read All About it...

## **FDA Admits Drug Reports Linked to School Shootings and Notorious Murders**

Kooky conspiracy theory, instead we get real science...

## **On the Trail of a Secret Pentagon U.F.O. Program**

*New York Times*, Dec. 18, 2017

## **People Are Seeing U.F.O.s Everywhere, and This Book Proves It**

*New York Times*, April 24, 2017

# Headlines: Fiction as Fact

**No links between Ritalin and school shootings, as NRA's Oliver North claimed, *Politifact*, May 22, 2018**

“Nowhere does it claim that no (zero) school shooters were on Ritalin or other drugs.” Angie Holan, Editor

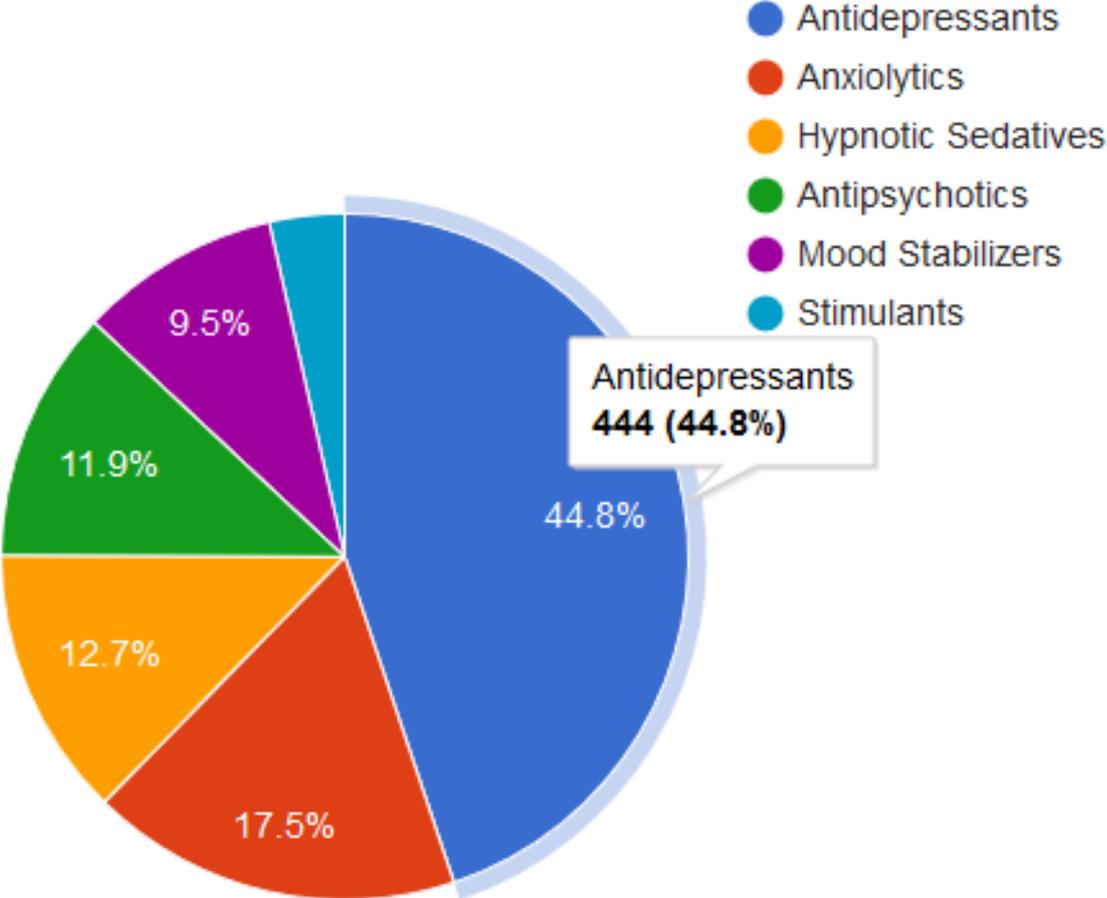
**A Psychiatrist is Slain, and a Sad Debate Deepens**

*New York Times*, Sept. 19, 2006 “An Otsuka employee reported that a 19-year-old male patient became agitated and committed murder while on aripiprazole.” ([AERS 6138537](#))

**Man accused in killing at Perkins found competent for trial, *Baltimore Sun*, Feb. 9, 2012 ([ANZ study](#), [EA](#))**

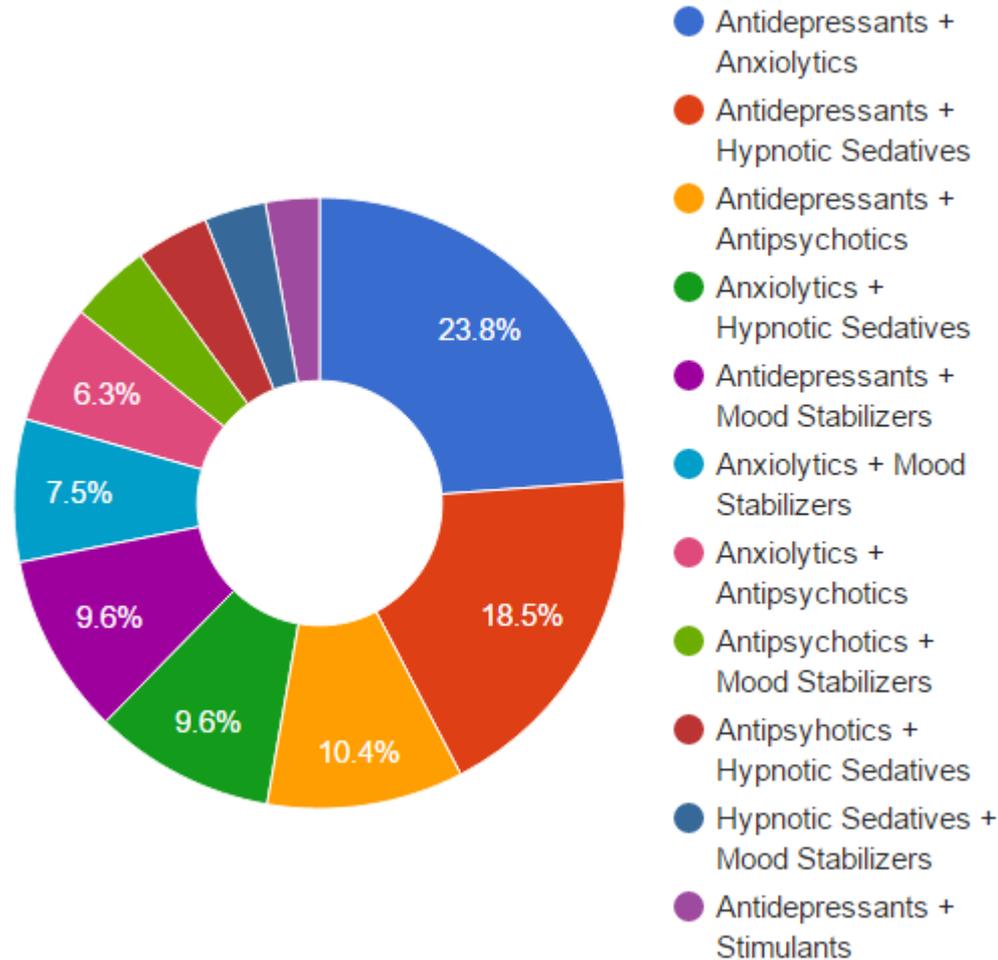
# AERS Homicide Reports by Drug Class

FDA Adverse Event Reporting System Homicide Reports



# AERS Homicide Reports by Drug Cocktail

Top 10 Homicidal Drug Cocktails



# Stoneman Douglas Public Safety Commission



Florida Senator Lauren Book, Democratic Leader Pro Tempore. Lobbyist father Ron Book counts Teva among his clients. Sen. Book's 2018 campaign contributors include:

