

### **National Autism Conference**



PROGRESS THROUGH PARTNERSHIP

#### Jon S. Bailey, PhD, BCBA-D Florida State University

August 4, 2014

# ABA on Trial:

A true tale of deception, denial and redemption as told by an expert witness

### Jon S. Bailey, PhD, BCBA-D

Professor Emeritus Florida State University

### FLORIDA FIFTH CIRCUIT COURT



Elizabeth Dudek Secretary Florida Agency for Health Care Administration



V. Dudek

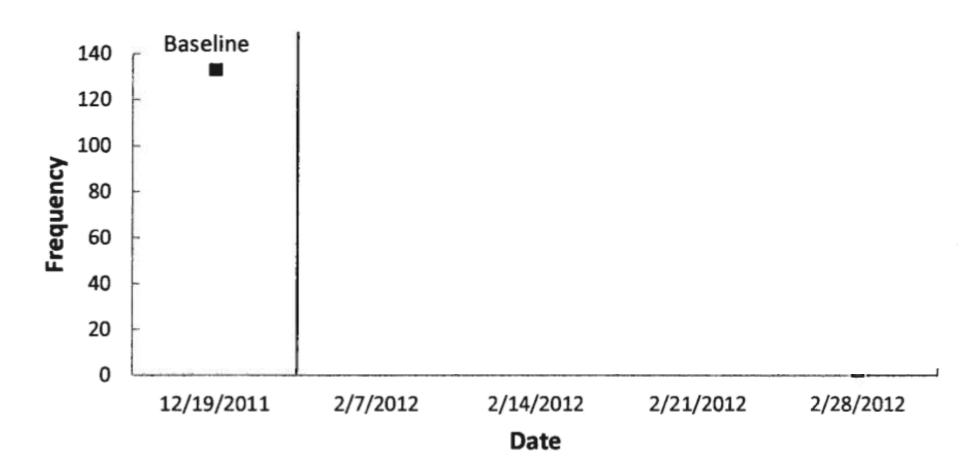


STATES DISTRICT COLLER

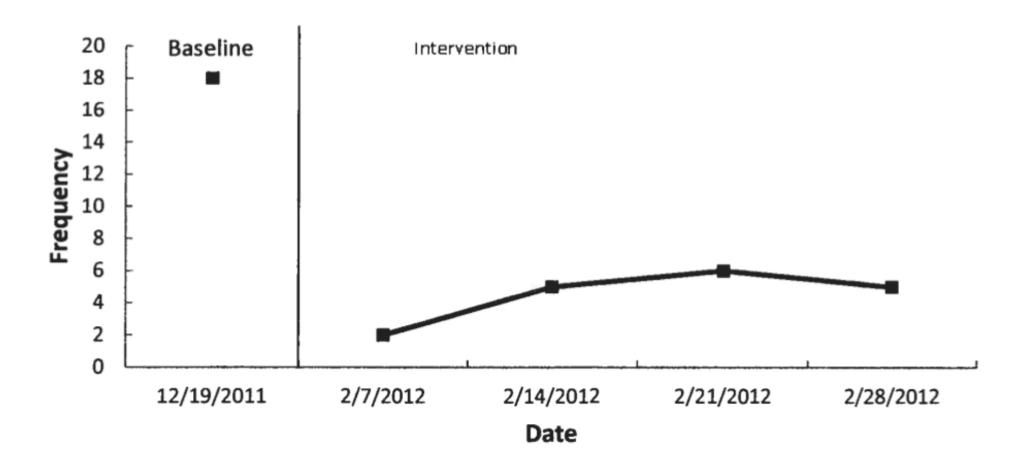
FOR THE SOUTHERN DISTRICT OF FLORIDA

Federal Judge Joan Lenard

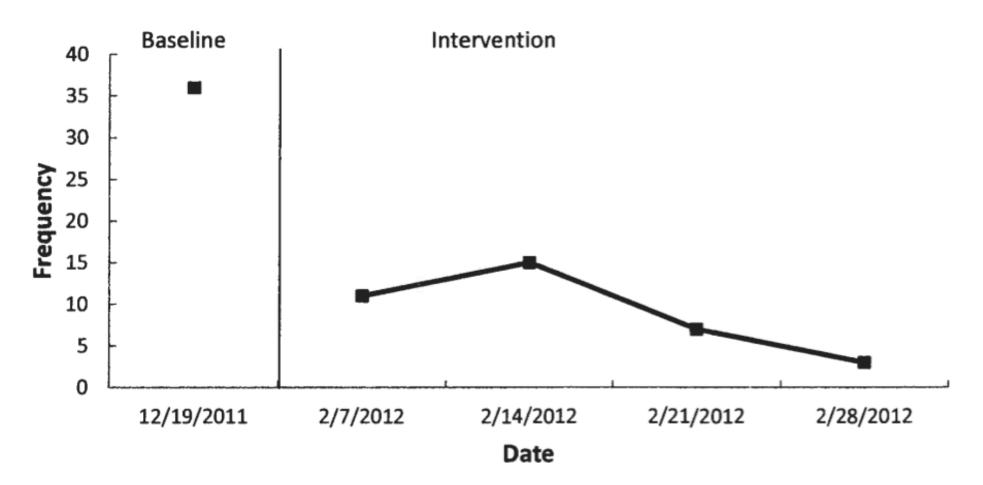
#### **Physical Aggression**

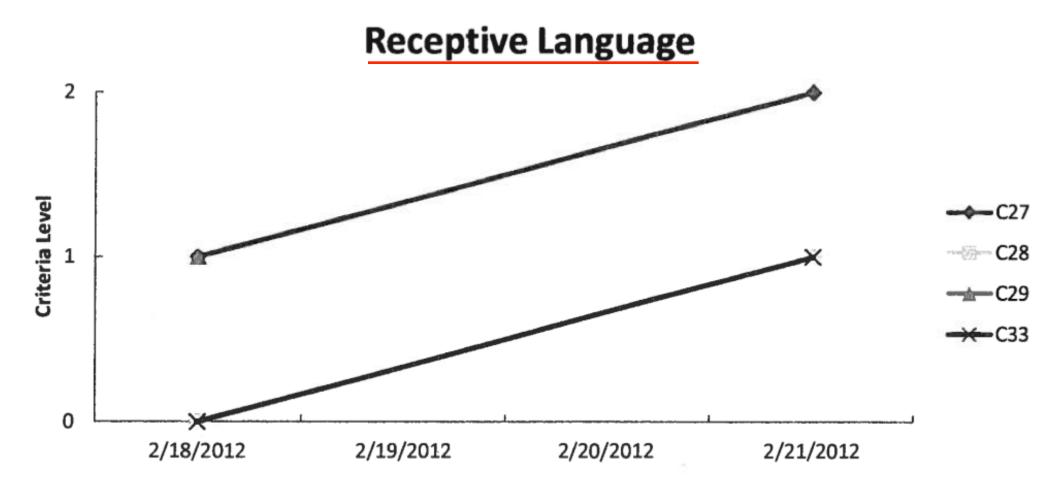


#### **Arm Biting - SIB1**



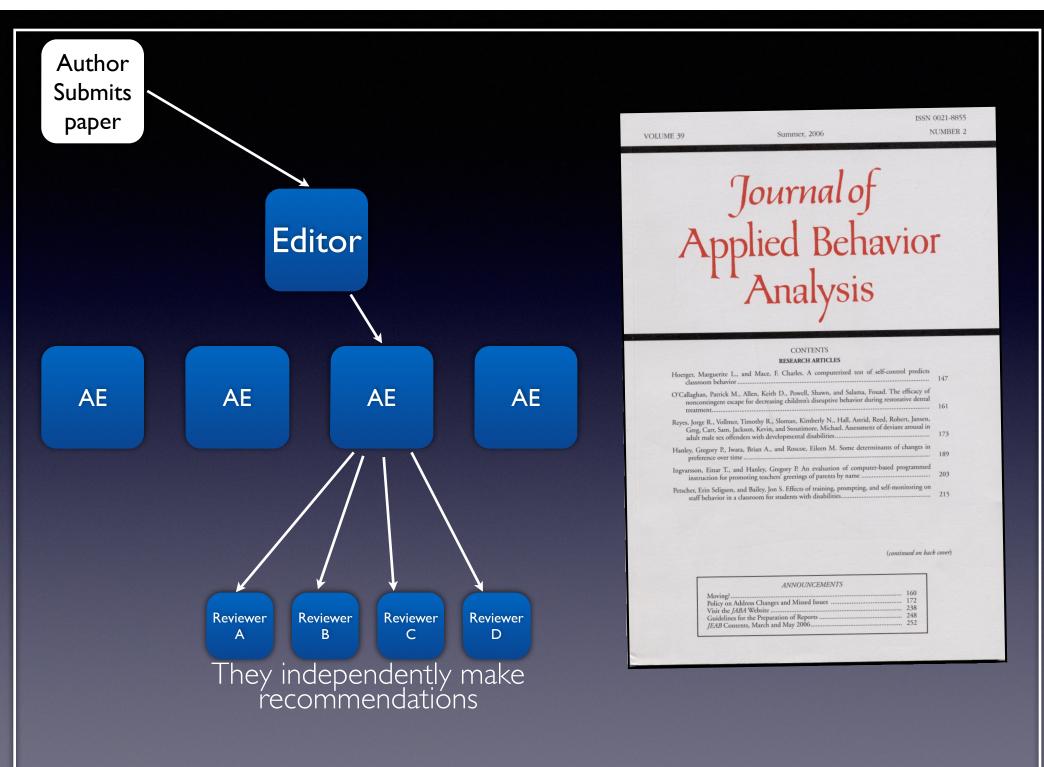
#### Head Hitting - SIB3

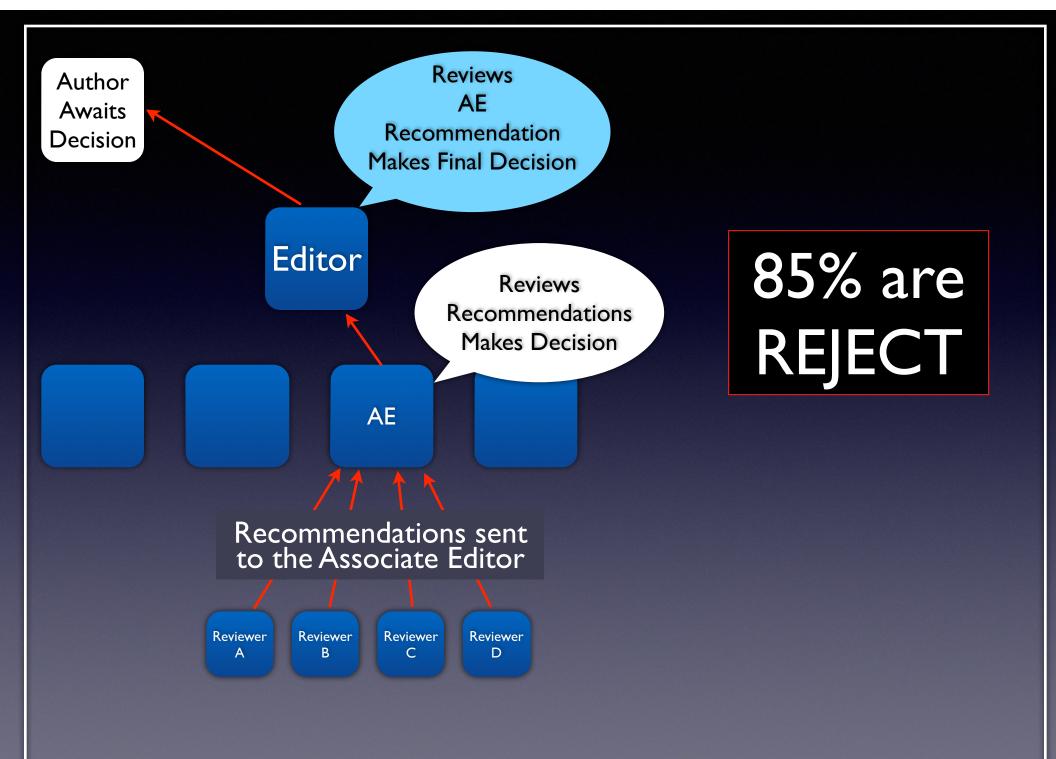




Building the foundation for the science of behavior:

Q. Can you describe the journal peer-review process?

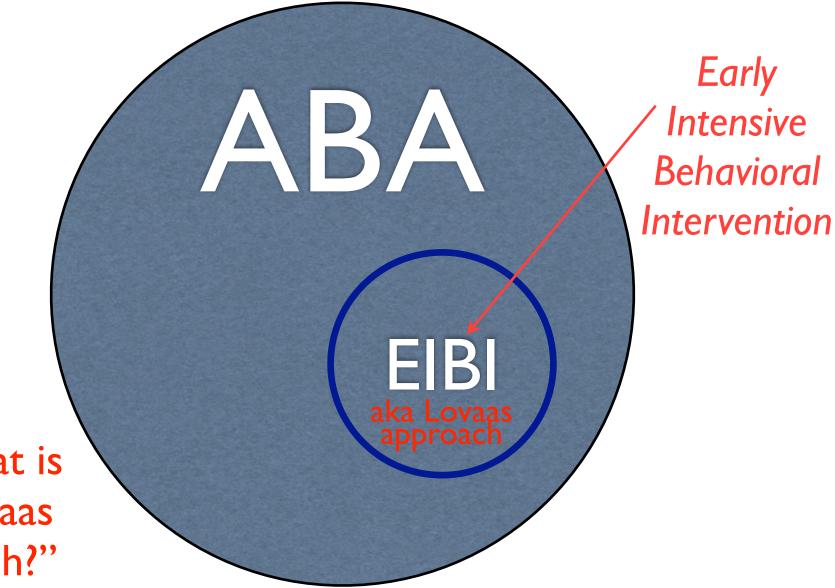




#### The Witness:

"Ultimately the peer review process establishes the quality level of research at that moment in time."

### Q."What is the difference between ABA & EIBI?"



Q."What is the Lovaas approach?"

# The Hayes Directory

# Hayes directory

#### Intensive Behavioral Intervention Therapy for Autism

October 25, 2010

Hayes, Inc. 157 S. Broad Street, Suite 200 Lansdale, PA 19446 215.855.0615 Fax 215.855.5218 www.hayesinc.com

#### "may promote gains in cognitive function, language skills, and adaptive behavior."

Fa

...although almost all studies suggested improvements in ac nt children treated with IBI compared with other treatments...'

"...most studies had major limitations in S. Br Lan design and methodology...'

"Although the initial work by Lovaas suggested that some high-functioning autistic children who undergo IBI therapy can achieve normal school performance and behavior, these findings have not been replicated by other investigators."

**Conclusions:** There behavioral intervention promote gains in cognit suggested improvemen limitations in design an lack of blinded assessn some high-functioning behavior, these finding **Hayes Rating** of C is a

"Based on the available evidence, a Hayes Rating of C is assigned to the use of IBI therapy for the treatment of autism in children."

children with intensive is (ABA) therapy, may ough almost all studies nost studies had major all sample sizes, and a Lovaas suggested that shool performance and available evidence, a ildren. **Q**. I'll be asking you several questions about the Hayes Directory. What will your testimony be regarding?

A. This regards my reaction to the Hayes report...and my concerns over what I consider (their) *disingenuous* analysis of the studies they covered.

# Rebuttal of Testimony of Alison Little, MD (expert witness for the state)



Q. Dr. Little posits that systematic reviews are at the top of the hierarchy. As regards ABA, would you agree with her? A. No, I would say that we've moved beyond simple reviews of the literature and moved into meta analysis, sometimes called systematic meta analysis.

# TRADITIONAL REVIEW OF THE LITERATURE

Only prospective comparative or controlled studies that included at least 10 patients and assessed programs specifically based on intensive behavioral intervention (IBI) therapy were selected for review. Studies in which IBI was one of several components of a treatment program were not included for review, e.g., Dawson et al. (2010).

Literature Review: A total of 14 prospective comparative or control indentified in the liter

on IBI therapy consists of a prospective controlled study with a subsequent long-term follow-up study comparing outcomes in young autistic children who underwent intensive therapy with outcomes in children who received minimal treatment (Lovaas, 1987; McEachin et al., 1993).

#### Hayes directory

Intensive Behavioral Intervention Therapy for Autism

October 25, 2010

Hayes, Inc. 157 S. Broad Street, Suite 200 Lansdale, PA 19446 215,855.0615 Fax 215,855.5218 www.hayesinc.com

### 14 STUDIES (REVIEW OF THE LITERATURE)

# WHAT THEY MEASURED

#### Table 1. Instruments Used to Assess Outcomes Following IBI Therapy in the Reviewed Studies

	Outcome/Domain Assessed	Name of Instrument(s) Utilized	
	Intelligence/ Cognitive Skills	Bayley Scales of Infant Development (BSID) Cattell Infant Intelligence Scale (CIIS) Stanford-Binet (S-B) Peabody Picture Vocabulary Test (verbal intelligence) Wechsler Intelligence Scale for Children (WISC) Wechsler Preschool and Primary Scale of Intelligence (WPPSI)	
	Other Cognitive Tests	Differential Abilities Scale (DAS) Mullen Scales of Early Learning (MSEL)	
	Visual-Spatial/Nonverbal Skills	Leiter International Performance Scale (nonverbal intelligence) Merrill-Palmer Scale of Mental Tests (visual-spatial skills/nonverbal intelligence)	
	Development	Developmental Assessment of Young Children (DAYC) Developmental Checklist Developmental Profile II (DP-II) Gesell Infant Development Scale Psychoeducational Profile – Revised (PEP-R)	
	Language Skills	British Picture Vocabulary Scale II (BPVS II) Clinical Evaluation of Language Fundamentals – Third Edition (CELF-III) Expressive One-Word Picture Vocabulary Test-Revised Reynell Developmental Language Scales (RDLS)	
	Adaptive Behavior	Vineland Adaptive Behavior Scale (VABS)	
	Academic Achievement	Wechsler Individualized Achievement Test (WIAT) Woodcock-Johnson III Tests of Achievement	
	Social/Emotional Functioning	Achenbach Child Behavior Checklist and Teacher Report Form Personality Inventory for Children (PIC)	
	Play	Symbolic Play Test – Second Edition (SPT-II) Test of Pretend Play	
	Functional Skills	Hung Functional Behavior Checklist	
	Social Communication	Early Social Communication Scales	
ſ	Child Behavior	Developmental Behavior Checklist	

Authors/Study Design	Study Population	Treatment	Results	Conclusions/Comments/ Limitations
Lovaas (1987)* UCLA, Los Angeles, CA	n=59 children w/ autism (mean age 38 mos; 27 boys, 11 girls) assigned to either an intensive or minimal to	Children were assigned to intensive or minimal tx grps for 2-6 yrs based on the availability of therapists.	Assessments performed at BL indicated that intensive and minimal tx grps had no statistically significant differences.	Results suggest that EIBI can lead to recovery for some autistic children.
Nonrandomized comparative study to evaluate the effect of EIBI	grp Intensive tx grp: n≃19 Minimal tx grp: n=19	Intensive tx grp: >40 hrs of 1:1 behavioral tx/wk w/ negative reinforcement, including contingent physical aversives, and ongoing		<i>Limitations:</i> Very small sample size; no power analysis; no randomization; mean age and
F/u: See McEachin et al. (1993)	Control grp: n≃21	tx by parents. Tx was reduced to ≤10 hrs/	children passed 1st grade in aphasia classes, and 2 (10%) remained profoundly developmentally delayed and were placed in classes for autistic	sex of children in control grp NR; details regarding specific autism subset classification of children not available; intensive tx grp had 31%
Time frame: NI ('Resu	ults suggest th	nat EIBI recial education	children.	fewer boys than minimal bx grp; no outcome measures beyond school

"Results suggest that EIBI can lead to recovery for some autistic children."

"Limitations:Very small sample; no randomization; mean age and sex of children in control group NR..."

### The Litany of "*Limitations*"

• Small sample size • No power analysis • Wide age range No randomization • Examiners independent but not blinded • Integrity of interventions not evaluated • Relatively short follow up • No non-EIBI group.

# Meta Analysis What is this?

Meta-analysis refers to... the statistical analysis of a large collection of ... results from individual studies for the purpose of integrating the findings. (Glass, 1976, p. 3)

## Understanding The New Statistics

Effect Sizes, Confidence Intervals, and Meta-Analysis



**Geoff Cumming** 

In a meta-analysis, research studies are collected, coded, and interpreted using statistical methods similar to those used in primary data analysis. The result is an integrated review of findings that is more objective and exact than a narrative review.

Six Were Included in the Hayes Directory



"The conclusions of the metaanalyses were conflicting and appeared to vary depending on the types of studies included."

# Six Were Included

<u>Weak/Inadequate</u> Ospina et al., 2008 Spreckley & Boyd, 2009

### **Beneficial**

Reichow & Wolery, 2009 Eldevik et al., 2009 Eldevik et al., 2010 Virues-Ortega, 2010



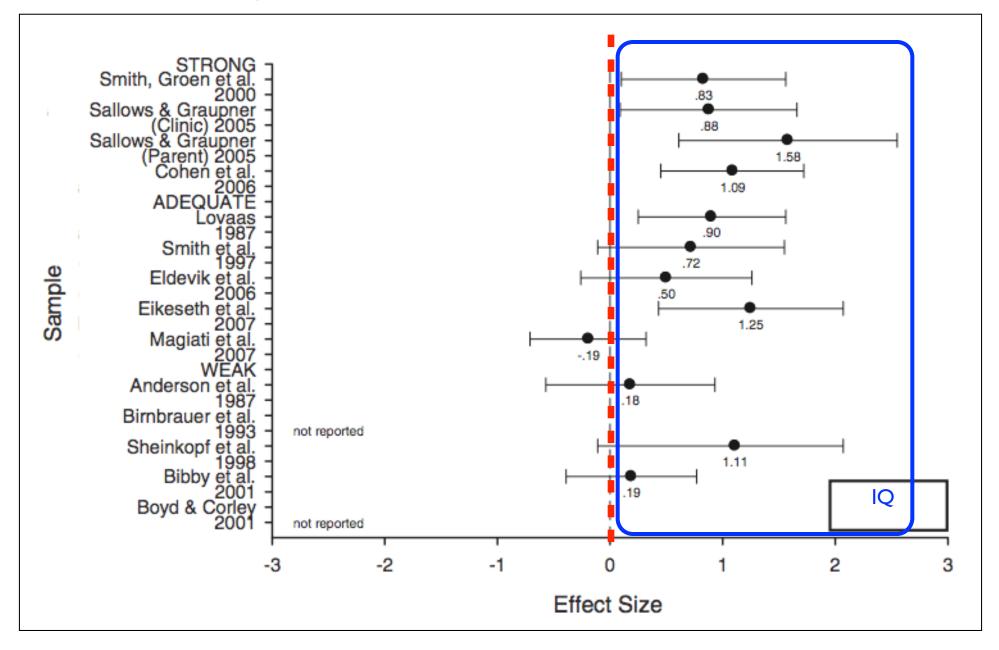
Reichow & Wolery, 2009 (14 studies, n=172)

Comprehensive Synthesis of Early Intensive Behavioral Interventions for Young Children with Autism Based on the UCLA Young Autism Project Model,

J Autism Dev Discord 39

"Finally, the data analyzed for this synthesis demonstrated EIBI has been shown as an intervention capable of producing strong effects, suggesting EIBI can be an effective intervention for some children with autism. However, the intervention has not worked for all children."

#### Reichow & Wolery, 2009 (14 studies, n=172)



# NORWAY

#### Eldevik et al. 2009 (34 studies, n=297)

Meta-Analysis of Early Intensive Behavioral Intervention for Children with Autism J. of Clinical Child & Adolescent Psychology

Study name	Туре	Outcome	
			Hedges's g
(Smith, et al, 2000)	Contr	ABC	0,13
(Birnbrauer & Leach, 1993)	Contr	ABC	0,14
(Remington et al, 2007)	Contr	ABC	0,31
(Howard, et al, 2005)	Contr	ABC	0,96
(Cohen, et al, 2006)	Contr	ABC	1,22
(Eikeseth, et al, 2002)	Comp	ABC	0,89
(Eldevik, et al, 2006)	Comp	ABC	0,64
(Howard, et al, 2005)	Comp	ABC	0,71
			0,66

#### Adaptive Behavior Composite

"EIBI produces large to moderate effect sizes for changes in IQ and adaptive behavior composite scores for children with ASD when compared to no intervention controls and eclectic provision. These results support the clinical implication that **EIBI at** present should be an intervention of choice for children with ASD."

Eldevik et al. 2010 (16 studies, n=309)

Meta Analy

Using Participant Data to Extend the Evidence Base for Intensive Behavioral Intervention for children with Autism, *American Journal on Intellectual and Developmental Disabilities* 



BASED

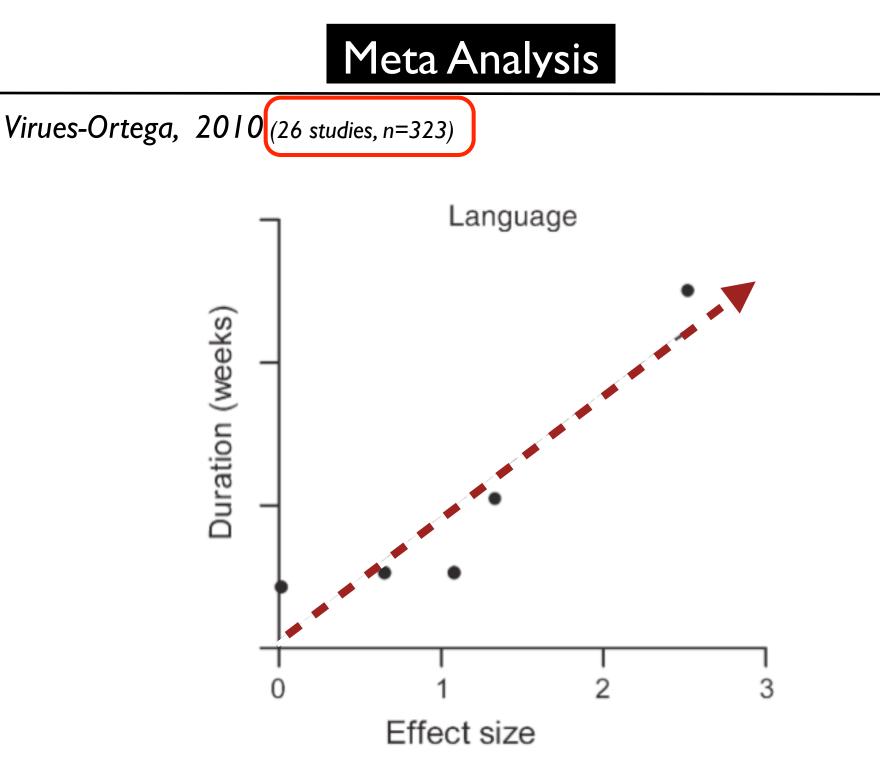


"The present analysis provides evidence that intensive behavioral intervention is an evidence-based intervention for children with autism ... According to the criteria developed by the **Oxford Centre for** (2009), the evidence for intensive behavioral intervention for young children with autism is at Level Ib."

Virues-Ortega, 2010 (26 studies, n=323) Applied behavior analytic intervention for autism in early childhood: Meta-analysis metaregression and dose-response meta-analysis of multiple outcomes.

Clinical Psychology Review

"Results suggested that long-term, comprehensive ABA intervention leads to (positive) medium to large effects in terms of intellectual functioning, language development, acquisition of daily living skills and social functioning in children with autism."



#### Virues-Ortega, 2010 (26 studies, n=323)

#### Meta Analysis

Study, year Clinic-based intervention	Sample size	
Ben-Itzchak 2007	25	0.98 (0.56, 1.40)
Ben-Itzchak 2008	39/37	2.23 (1.74, 2.73)
Birnbrauer 1993	9	1.60 (0.53, 2.66)
Cohen 2006	21/21	0.73 (0.23, 1.23)
Eikeseth 2002*	13/12	1.34 (0.60, 2.08)
Eldevik 2006	13/15	0.72 (0.11, 1.34)
Harris 1991	8/9	1.42 (0.48, 2.35)
Harris 2000	27	0.63 (0.29, 0.96)
Howard 2005	26/16	1.36 (0.78, 1.93)
Lovaas 1987	19	1.04 (0.53, 1.54)
Magiati 2007	28/16	
Matos 2005	4	1.56 (-0.97, 4.07)
Remington 2007	23/21	0.85 (0.35, 1.34)
Sallows 2005a	13	1.97 (0.99, 2.95)
Smith 2000	15/13	1.32 (0.63, 2.01)
Smith 1997	11/10	2.11 (1.13, 3.09)
Subgroup		1.23 (0.95, 1.51)
Parent-managed intervention		
Anderson 1987	13	0.92 (0.33, 1.52)
Bibby 2001	22	0.32 (-0.02, 0.66)
Sallows 2005b	10	2.80 (1.22, 4.38)
Sheinkoff 1998	9/10	
Subgroup		1.02 (0.12, 1.93)
Overall		1.19 (0.91, 1.47)

IQ

THE COURT: In your opinion, the meta analyses should be given more weight than just the review of studies?

THE WITNESS: I believe so. Sure.

THE COURT: Thank you.



**THE COURT:** Doctor were you ever contacted by the Florida Agency for Health Care Administration in regard to the treatment of ASD?

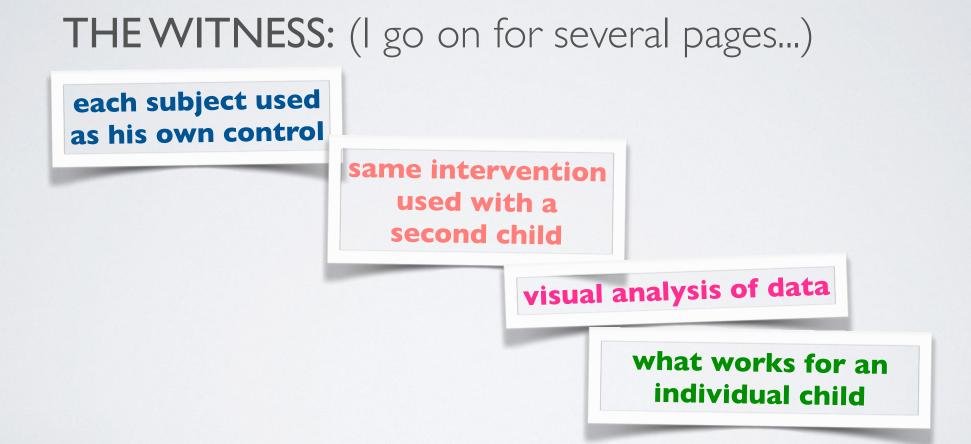
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRAT

THE WITNESS: No.

Q: And would you say that these findings were accurately brought into the overall conclusion made by Hayes with the C rating?

A: No.

# **THE COURT:** What does that mean, single-subject design?



Then:

"...in meta analysis they can go back and use the change rates for individual subjects and make some sense of the size of effect. That's really sort of the genius of meta analysis. That's why I give it such a higher rating."



THE WITNESS continues:

"A large effect is considered b be a .6. In many of these studies, the effect size will range from .8 to 1.5.

So it is more than twice as big as what would be considered a large effect."



**Q:** How long has that kind of small n case trials that you're discussing been going on?

A: This has been going on since the early '60s, the first study was actually published in 1964.

The witness continues: "The Hayes report looks like a **proprietary**--not-in-the-public-domain--document. It certainly doesn't represent what professionals, researchers, pediatricians, and general practice physicians recognize as what's considered the standard acceptable model of treatment in autism."

**Q**: And if you just looked only at the Hayes grading system, would you say that was an accurate reflection of these reports and the content that they reviewed?

A: I would say certainly not. If a grade of "C" was given to a study it would never even be published. I mean that's *ridiculous*.



**Q**: And if you read all of those tables and all of those findings in the Hayes report showing how ABA is effective, as you did, could you--would it still be reasonable--to determine ABA is **experimental**?



A: I just don't see how. When you have five, ten, fifteen replications from all over the world, I just don't see how you could say it's experimental. Not any more.

**Q:** Doctor Bailey, are you aware of any study finding ABA to be ineffective?

A: No I am not.

**Q**. Are you aware of any study finding ABA to be experimental?

A. No. It's a well-established, proven procedure.

#### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA

CASE NO. 11-20684-CIV-LENARD/O'SULLIVAN

K.G., by and through his next friend, ILIANA GARRIDO, I.D., by and through his next friend, NILDA RIVERA, and C.C., by and through his next friend, RACHELLE CRAWFORD,

Plaintiffs,

v.

ELIZABETH DUDEK, in her official capacity as Secretary, Florida Agency for Health Care Administration,

Defendant.

# PERMANENT INJUNCTION

THIS CAUSE is before the Court following a four-day bench trial. Plaintiffs K.G., I.D., and C.C., by and through their next friends, Iliana Garrido, Nilda Rivera, and Rachelle Crawford, respectively, brought suit against Defendant Elizabeth Dudek, in her official capacity as Secretary, Florida Agency for Health Care Administration ("AHCA" or "the Does the Treatment Meet the Definition of Proof? AS DEFINED BY THE FIFTH CIRCUIT (FEDERAL)

**"HAS THE SERVICE** COME TO BE **GENERALLY ACCEPTED** BY THE PROFESSIONAL MEDICAL COMMUNITY **AS AN EFFECTIVE AND PROVEN TREATMENT** FOR THE CONDITION FOR WHICH IT IS BEING USED?"



# THE FEDERAL JUDGE'S ORDER

"ABA *is* 'medically necessary' and is **not** '*experimental*' as defined under Florida administrative law and federal law."



## Judge Lenard's Order



"Based on the testimony and exhibits at trial, the Court finds that the determination by AHCA that ABA is experimental was arbitrary, capricious, and unreasonable both in its process and its conclusion."

#### THE FEDERAL JUDGE'S ORDER CONT.

"Plaintiffs have established through their expert witnesses that there exists in the medical and scientific literature a plethora of peer-reviewed meta analyses, studies, and articles that clearly establish ABA is an effective and significant treatment to prevent disability and restore developmental skills to children with autism and ASD."



# THE FEDERAL JUDGE'S ORDER

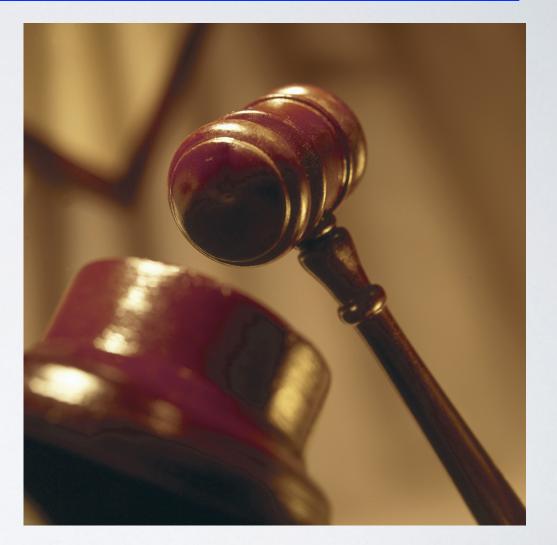
"As of 10:34 a.m. on March 26, 2012, the State of Florida is hereby ordered to provide, fund, and authorize Applied Behavioral Analysis treatment to



Plaintiffs K.G., I.D., and C.C., as well as all Medicaideligible persons under the age of 21 in Florida who have been diagnosed with autism or Autism Spectrum Disorder, as prescribed by a physician or other licensed practitioner."

# THE FEDERAL JUDGE'S ORDER

"Defendant shall take whatever additional steps are necessary for the *immediate* and orderly administration of ABA treatment..."



# ABA MON!

# The ball is rolling now...



**Washington**--Children with autism spectrum disorders insured by the state's Apple Health program, including those on Medicaid, will be covered for Applied Behavior Analysis (ABA) therapy under a lawsuit settlement approved by U.S. District Court Judge Richard A. Jones.

**Utah-**-During the 2012 legislative session, Utah lawmakers approved a bill to create three pilot programs to provide autism services, with administrators tracking the cost and effectiveness of the treatments and reporting results by next November. The Medicaid pilot, will provide up to 250 children with 20 hours a week of applied behavior analysis therapy in their homes, along with respite care, through June 2014. The total cost per child is \$30,020 per year.



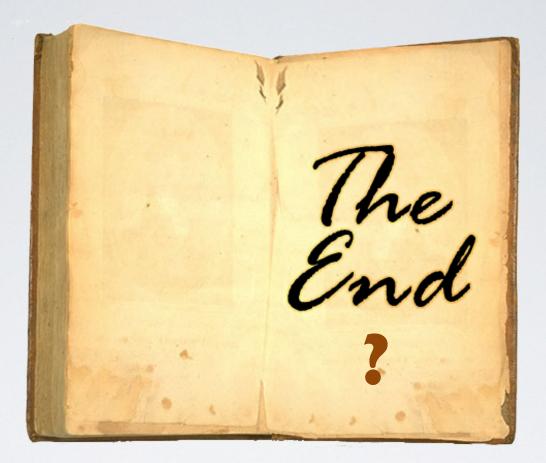


#### Federal Court Strikes Down Blue Cross of Michigan's Denial of Applied Behavior Analysis Therapy to Children with Autism

**DETROIT**, April 1, 2013 /PRNewswire/ -- The federal district court in Detroit held, on March 30, 2013, that Blue Cross Blue Shield of Michigan acted illegally in denying Applied Behavior Analysis ("ABA") therapy to children with autism spectrum disorder. This ruling is expected to benefit over 500 children with autism spectrum disorder, and will result in over \$5 million in ABA therapy benefits being

paid to class members. In his ruling, Hon. Stephen J. Murphy, III held that Blue Cross's characterization of ABA therapy as "experimental"

was not supported by its own Medical Policy.



### But, the decision was appealed.



#### Order Directing Florida Medicaid to Cover ABA Upheld on Appeal MIAMI (September 23, 2) September 23, 2013 la to cover applied

behavior analysis

**±** AUTISM SPE

RESOURCE

ENTER

In a strongly word

LEGAL

Upheld!

victory by the e plaintiffs, alth Care . The plaintiffs ge on the basis

e to cover ABA.

asking, "How many I I th Circuit U.S. Court of Appeals "This case will have national impact because, while most states mandate that private insurance companies must cover ABA, most Medicaid programs do not provide coverage," said Miriam Harmatz of Florida Legal Services, lead

counsel for the plaintiffs. The children's treating physicians explained the extreme disparity between the prognosis of privately insured children with autism, who receive ABA, and those on Medicaid, who do not, she said.





By MICHELLE DIAMENT July 17, 2014

Medicaid programs nationwide must offer "medically necessary diagnostic and treatment services" to kids with autism, the Centers for Medicare and Medicaid Services told states in a bulletin this month.



#### **National Autism Conference**





# Thank You For Inviting Me

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