



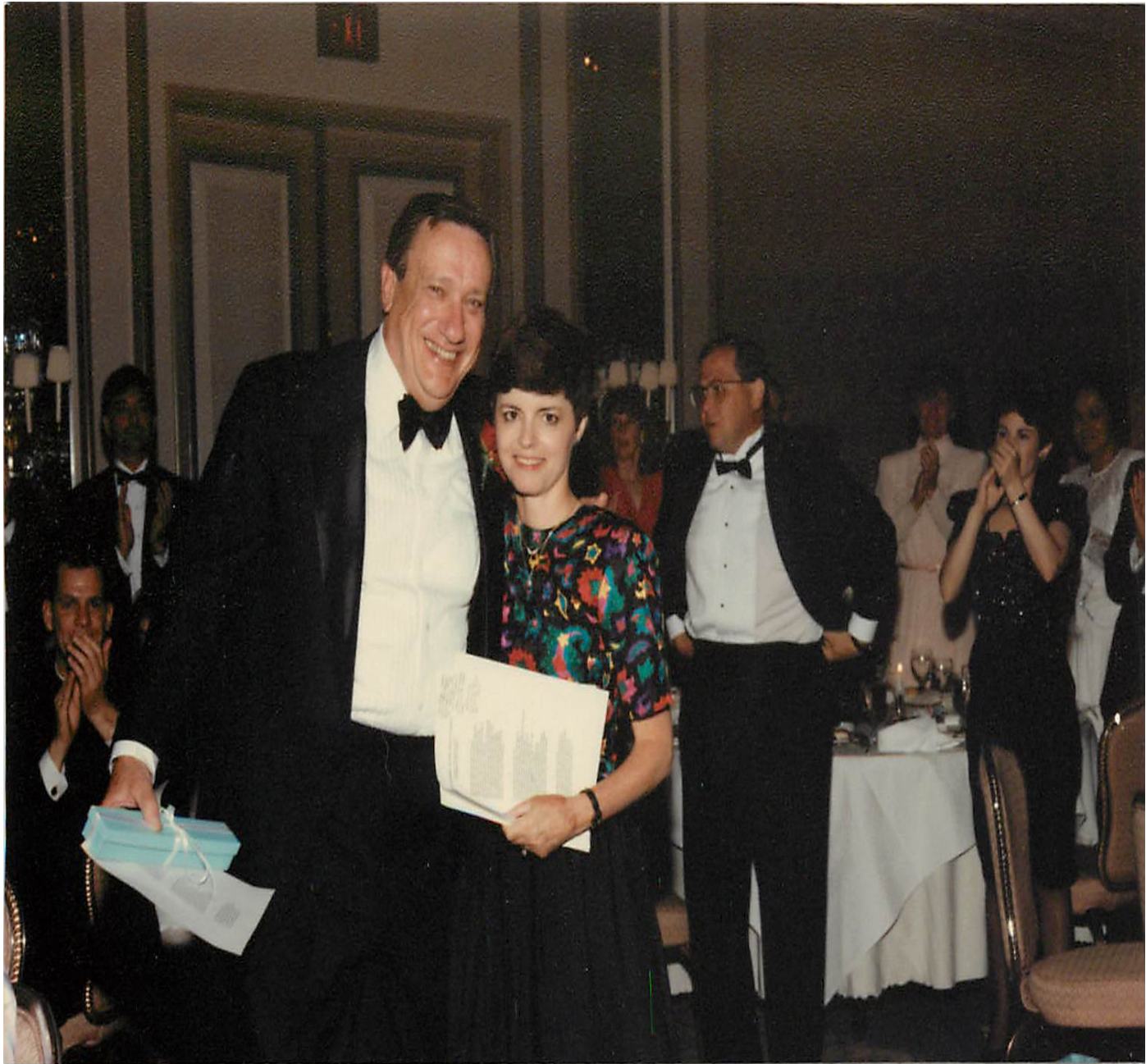
SILENT ADVOCACY: PRACTICAL POINTS FOR THE TRIAL ATTORNEY

**Chilton Davis Varner
King & Spalding LLP
Atlanta, Georgia**

**IADC Trial Academy
July 29, 2018**







THE LAVIN METHOD

“The method will not be suitable for those lawyers

- (a) whose knowledge of the subject matter of the litigation is less than comprehensive;
- (b) whose mastery of the technical aspects of the case is shallow;
- (c) Whose willingness to work very hard and prepare meticulously has any limits; or
- (d) Whose confidence in their ability to deal authoritatively with *whatever* the witness may offer is not profound.

In all respects, the Lavin system is the precise opposite of the much more prevalent shoot from the hip style of trial lawyering.”

- Litvin & McHugh, §24.9



SILENT ADVOCACY

- Appearance



SILENT ADVOCACY

- Appearance
- Demeanor



SILENT ADVOCACY

- Appearance
- Demeanor
- Professional preparation



SILENT ADVOCACY

- Appearance
- Demeanor
- Professional preparation
- Helpfulness




SILENT ADVOCACY

A jury consists of twelve persons chosen to decide who has the better lawyer.



JURORS' QUESTIONS

- ❑ Do we trust these people before us?
- ❑ Do we even like these people?
- ❑ Are these people prepared, so they don't waste our time?
- ❑ Are these people knowledgeable?
- ❑ Are these people helping us do our jobs?
- ❑ Are these people trying to see that justice is done?



*Optimus est enim orator qui
dicendo animos audientum et docet
et delectate et permovet.*

-Cicero



CICERO'S THREE GOALS

- To teach
- To charm
- To move



OPENING STATEMENT

- Check local rules and practice – in advance



OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?



OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?

OPENING STATEMENT

- ❑ Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- ❑ Do not throw away the Golden Moment

OPENING STATEMENT

- ❑ Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- ❑ Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”
 - “There are two sides to any story. . . .”

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”
 - “There are two sides to any story. . . .”
 - First impressions matter.

OPENING STATEMENT

- Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”
 - “There are two sides to any story. . . .”
 - First impressions matter.
 - Know what you are going to say.

OPENING STATEMENT

- ❑ Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- ❑ Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”
 - “There are two sides to any story. . . .”
 - First impressions matter.
 - Know what you are going to say.
- ❑ Never make a promise you cannot keep.

OPENING STATEMENT

- ❑ Check local rules and practice – in advance
 - Can you show actual evidence?
 - Can you label your slides?
 - Can you use an easel?
 - Where can you stand/walk?
 - What are the rules for entering the “well”?
- ❑ Do not throw away the Golden Moment
 - “What I say is not evidence. . . .”
 - “The purpose of an opening is to preview what we think the evidence will be. . . .”
 - “There are two sides to any story. . . .”
 - First impressions matter.
 - Know what you are going to say.
- ❑ Never make a promise you cannot keep.
- ❑ Use signal phases to help jurors move from one subject to another.

SIGNAL CHANGES FROM ONE TOPIC TO ANOTHER

- We will hear
- You will learn
- I expect you will find
- You will come to know
- You will soon realize
- The evidence will show
- You will not hear
- Make sure you pay careful attention
- Now don't miss this



DIRECT EXAMINATION

- Initial planning



DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration

DIRECT EXAMINATION

□ Initial planning

- The theme(s): who can best present it?
- Witness order: first and last are most important, particularly for the defendant.
- Substance: an offer of proof.

□ Preparation of witnesses

- Prior testimony
- Effect of Rule of Sequestration
- Outlines?

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- Presentation of witnesses

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- Presentation of witnesses
 - Goal: clear and understandable presentation of the facts

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- Presentation of witnesses
 - Goal: clear and understandable presentation of the facts
- Are experts different?

DIRECT EXAMINATION

- Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- Presentation of witnesses
 - Goal: clear and understandable presentation of the facts
- Are experts different?
 - Believability/credibility are key.

DIRECT EXAMINATION

- ❑ Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- ❑ Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- ❑ Presentation of witnesses
 - Goal: clear and understandable presentation of the facts
- ❑ Are experts different?
 - Believability/credibility are key.
 - CV

DIRECT EXAMINATION

- ❑ Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- ❑ Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- ❑ Presentation of witnesses
 - Goal: clear and understandable presentation of the facts
- ❑ Are experts different?
 - Believability/credibility are key.
 - CV
 - Prior testimony, including *Daubert* challenges

DIRECT EXAMINATION

- ❑ Initial planning
 - The theme(s): who can best present it?
 - Witness order: first and last are most important, particularly for the defendant.
 - Substance: an offer of proof.
- ❑ Preparation of witnesses
 - Prior testimony
 - Effect of Rule of Sequestration
 - Outlines
 - Prepare for cross-examination
- ❑ Presentation of witnesses
 - Goal: clear and understandable presentation of the facts
- ❑ Are experts different?
 - Believability/credibility are key.
 - CV
 - Prior testimony, including *Daubert* challenges
 - Trial testimony

Dr. Fiona Scott Morton

Employment:

- 2006-present Senior Associate Dean for Faculty Development, Yale School of Management
- 2002-present Professor of Economics, Yale School of Management
- 2005-2006 Adam Smith Visiting Fellow in Economics, University of Edinburgh, Scotland
- 2000-2002 James L. Frank '32 Associate Professor of Private Enterprise and Management, Yale School of Management
- 1999-2000 Associate Professor of Economics and Strategy, Yale School of Management
- 1997-1999 Assistant Professor of Strategic Management, Graduate School of Business, University of Chicago
- 1994-1997 Assistant Professor of Strategic Management, Graduate School of Business, Stanford University
- 1991-1992 Instructor for Economics 10, Prof. Martin Feldstein, Harvard University

Education:

- 1994 Massachusetts Institute of Technology, PhD. Economics
- 1989 Yale University, B.A. Economics, *magna cum laude*

Fiona M. Scott Morton

School of Management
Yale University
P.O. Box 338208
New Haven, CT 06526-8208

+1.203.432.5589 voice
+1.203.432.6174 fax
fsmorton@yale.edu

Employment:

2006-present Senior Associate Dean for Faculty Development, Yale School of Management
2002-present Professor of Economics, Yale School of Management
2005-2006 Adam Smith Visiting Fellow in Economics, University of Edinburgh, Scotland
2000-2002 James L. Frank '32 Associate Professor of Private Enterprise and Management, Yale School of Management
1999-2000 Associate Professor of Economics and Strategy, Yale School of Management
1997-1999 Assistant Professor of Strategic Management, Graduate School of Business, University of Chicago
1994-1997 Assistant Professor of Strategic Management, Graduate School of Business, Stanford University
1991-1992 Instructor for Economics 10, Prof. Martin Feldstein, Harvard University

Education:

1994 Massachusetts Institute of Technology, PhD. Economics
1989 Yale University, B.A. Economics, *magna cum laude*

Peer-reviewed Articles:

"Entry and Exit in British Shipping Canals, 1876-1929"
Journal of Economic & Management Studies 34:679-724, 1997
"The Strategic Response by Pharmaceutical Firms to the Hospital Shift From Outpatient to Inpatient Care"
The RAND Journal of Economics 28:269-293, 1997
"The Interaction Between a Monopolistically Competitive Firm and Price Dispersion: An Empirical Examination of the Medicaid Rebate Policy of 1997"
Journal of Economic & Management Studies 34:1133-1158, 1997
"Misplaced Fear of the Dependent Variable in a Dynamic Response Surface"
NBER Working Paper No. 6600, MIT and John Hopkins, University of Chicago
Journal of Econometrics 87:235-249, 1998
"Social Status, Entry, and Predation: The Case of British Shipping Canals, 1876-1929"
Johns Hopkins Press, Yale 2001
The Journal of Political Economy 109:1450-1497, 2001
"Business to Business, Market Advertising, and Growth Entry in the US Pharmaceutical Industry"
International Journal of Industrial Organization 18:1180-1199, 2000
"Entry Decisions in the Generic Pharmaceutical Industry"
The RAND Journal of Economics 14:3:423-440, 1999
"Lost or Money? The Effect of Incentive Schemes in the California Wine Industry"

EXHIBIT

1093

Dr. Fiona Scott Morton Awards

Fiona M. Scott Morton

Joint with Mark Duggan, University of Maryland
 "The Impact of Loss Aversion in Auto Transactions"
 Joint with Shantanu Dutta, Yale SOM
 "The Influence of Social Capitalism on the Role of Agency"
 Joint with Gary K. Hui, University of California
 "Buying for a Discount"
 Joint with Andy Coughlan, Yale SOM, and David Harrell, Kenan College

Other Publications

"My Economics Instructors Failed the Market"
Financial Times, March 20, 2009
 "Strategic Commitments and Substitutes"
Journal of Marketing Research, 4 Nov 1999
 "The Economics of Price Controls"
Public Choice, Spring 2001
 "Consumer Benefit from Use of the Internet"
AACSB International Policy and the Economics, 2002

Awards:

2007	Yale School of Management Alumni Association Teaching Award, the only teaching prize awarded at Yale SOM in the academic year 2006-7
2007	Green Award, <i>Journal of Marketing Research</i> , for the paper "How the Internet Lowers Prices: Evidence from Matched Survey and Automobile Transaction Data"
2005-2008	National Science Foundation Research Grant 0518858 "The Effect of Government Procurement of Pharmaceuticals"
2001-2003	National Science Foundation Research Grant 0111885 "The Effect of Internet Car Shopping on Prices and Discrimination"
1998-2002	National Science Foundation Research Grant 9810178 "Studies of Competition"
1995	Distinguished Teaching Commendation by Stanford MBA students for excellence in teaching during the academic year 1994-1995
1993-1994	Program on the Pharmaceutical Industry, MIT, grant for full tuition and stipend

Teaching:

Competitive Strategy: Stanford MBA course covering topics in I/O, such as price and quality competition, entry, exit, and exit, as well as strategy concepts such as industry analysis, competitive advantage, and sustainability.

Economic Strategy: Executive MBA course applying microeconomic principles to understand the sources of profit in information technology-based industries.

Awards:

2007

Yale School of Management Alumni Association Teaching Award: the only teaching prize awarded at Yale School of Management for the academic year 2006-7

2007

Green Award, *Journal of Marketing Research*, for the paper "How the Internet Lowers Prices: Evidence from Matched Survey and Automobile Transaction Data"

2005-2008

National Science Foundation Research Grant 0518858 "The Effect of Government Procurement of Pharmaceuticals"

2001-2003

Joint with Mark Duggan, University of Maryland
 National Science Foundation Research Grant 0111885 "The Effect of Internet Car Shopping on Prices and Discrimination"
 Joint with Florian Zettelmeyer, UC Berkeley

1998-2002

National Science Foundation Research Grant 9810178 "Studies of Competition"

1995

Distinguished Teaching Commendation by Stanford MBA students for excellence in teaching during the academic year 1994-1995

1993-1994

Program on the Pharmaceutical Industry, MIT, grant for full tuition and stipend

EXHIBIT
1093

Dr. H. Scott Baldwin – Education and Training

- M.D. University of Virginia School of Medicine
- Residency, Pediatrics, Strong Memorial Hospital, University of Rochester
- Sr. Chief Resident, Pediatrics, Strong Memorial Hospital, University of Rochester
- Research Fellow, Pediatric Cardiology, University of Iowa
- Post Doctoral Research Scientist, Dept. of Biology, University of Iowa
- Board Certified Pediatric Cardiologist with Active Clinical Practice

Dr. H. Scott Baldwin – Organizations

- American College of Cardiology
- American Heart Association
 - Council on Cardiovascular Disease in the Young
 - President of the Board of Directors, Nashville Affiliate, 2004-2005
 - Currently a Member of the National Research Committee
- Member, Scientific Board of the Stanley Sarnoff Foundation for Cardiovascular Research, 2004-present
- Society for Pediatric Research

Expertise in Cardiac Development

- Published 56 Peer Reviewed Articles and 28 Book Chapters or Editorial Reviews on the Cardiac Development
- Director of Research Laboratory - NIH/AHA/March of Dimes Funding on Cardiac Development Research (20+ years)
- Invited Presentations Both Nationally and Internationally
- Peer-Reviewer for Over 18 Journals (New England Journal of Medicine, Cell, Science, Nature)
- Editorial Board of the Journal, Developmental Dynamics
- Organized National and International Meetings on Cardiac Development

Dr. Anthony Scialli

- ▶ Obstetrician / Gynecologist
- ▶ Reproductive Toxicologist
- ▶ Teratologist
- ▶ Professor / Teacher
- ▶ Health & Environmental Consultant
- ▶ Senior Scientific Advisor
- ▶ Advisor to Government Agencies
- ▶ Member of Professional Organizations
- ▶ Editor of Medical Literature
- ▶ Author of Medical Publications
- ▶ Consultant & Lecturer to FDA

Overview of Assignment

- Describe how prescription drugs are priced and distributed.
- Examine the way Alabama Medicaid pays pharmacies for prescription drugs, including what information Alabama Medicaid had about prices and when.



KEYS TO A SUCCESSFUL CROSS-EXAMINATION

1. Preparation
2. Control
3. Permission



HOW TO LOSE THE CROSS-EXAMINATION BATTLE: THREE STEREOTYPES

1. The Barger



HOW TO LOSE THE CROSS-EXAMINATION BATTLE: THREE STEREOTYPES

1. The Barger
2. The Borer



HOW TO LOSE THE CROSS-EXAMINATION BATTLE: THREE STEREOTYPES

1. The Barger
2. The Borer
3. The Buffoon



HOW TO WIN THE CROSS-EXAMINATION BATTLE: FIVE CATEGORIES

1. Peripheral

Dr. Schwartz's Report

Page 2 of 10

II. Summary of Opinions

I have been asked by attorneys for Plaintiffs in Paxil Birth Defect litigation to review the company-sponsored animal studies for Paxil and, where appropriate, recommend upon additional animal testing that could have been performed by the company prior to 2005 to investigate Paxil teratogenicity.

My opinions are as follows:

- 1) The early Paxil animal studies demonstrated significant embryonic death as well as death post-partum. This significant death (called "resorption" in pregnant female animals) was never investigated by then-available techniques called "histology" to determine whether the dead suffered from teratologies.
- 2) Higher-dose neural studies could have been performed as far back as the 1980s, yet were not done by the company. Such a study would have revealed teratogenicity.

III. Review of Early Paxil Studies

... believed that the mammalian embryo developed in the impervious uterus of the mother, protected from all extrinsic factors. However, after the thalidomide disaster of the 1960s, it became apparent and more accepted that the developing embryo could be highly vulnerable to certain environmental agents that have negligible or non-toxic effects to adult individuals.

Dr. Schwartz's Report, Pg. 2

Comparison - Language Is Identical

In humans and other mammals

Teratogenesis

Birth defects are known to occur in 3-5% of all newborns.^[1] They are the leading cause of infant mortality in the United States, accounting for more than 20% of all infant deaths. Seven to ten percent of all children will require extensive medical care to diagnose or treat a birth defect.^[1] And although significant progress has been made in identifying the etiology of some birth defects, approximately 65% have no known or identifiable cause.^[1]

It was previously believed that the mammalian embryo developed in the impervious uterus of the mother, protected from all extrinsic factors. However, after the thalidomide disaster of the 1960s, it became apparent and more accepted that the developing embryo could be highly vulnerable to certain environmental agents that have negligible or non-toxic effects to adult individuals.

A review published in 2010 identified 6 main teratogenic mechanisms associated with medication use: folate antagonism, neural crest cell disruption, endocrine disruption, oxidative stress, vascular disruption and specific receptor- or enzyme-mediated teratogenesis.^[2]

Wilson's & netoloides

... believed that the mammalian embryo developed in the impervious uterus of the mother, protected from all extrinsic factors. However, after the thalidomide disaster of the 1960s, it became apparent and more accepted that the developing embryo could be ... vulnerable to certain environmental agents that have negligible or non-toxic effects to adult individuals.

Teratology - Wikipedia
<http://en.wikipedia.org/wiki/Teratology>

II. Summary of Opinions

I have been asked by attorneys for Plaintiffs in Paxil Birth Defect Litigation to review the company-sponsored animal studies for Paxil and, where appropriate, comment upon additional animal testing that could have been performed by the company prior to 2003 to investigate Paxil teratogenicity.

My opinions are as follows:

- 1) The early Paxil animal studies demonstrated significant embryonic death as well as death post-partum. This significant death (called "resorptions" in pregnant female animals) was never investigated by then-available techniques called "histology" to determine whether the dead suffered from teratologies.
- 2) Higher-dose aviral studies could have been performed as far back as the 1980s, yet were not done by the company. Such a study would have revealed teratogenicity.

III. Review of Early Paxil Studies

... believed that the mammalian embryo developed in the impervious uterus of the mother, protected from all extrinsic factors. However, after the thalidomide disaster of the 1960s, it became apparent and more accepted that the developing embryo could be ... vulnerable to certain environmental agents that have negligible or non-toxic effects to adult individuals.

Dr. Schwartz's Report, Pg. 2

Dr. Schwartz's Report

Along with this new awareness of the in utero vulnerability of the developing mammalian embryo came the development and refinement of The Six Principles of Teratology which are still applied today. ... Jim Wilson in 1959 and in his monograph *Environment and Birth Defects*. [5] These principles guide the study and understanding of teratogenic agents and their effects on developing organisms:

1. Susceptibility to teratogenesis depends on the genotype of the conceptus and the manner in which this interacts with adverse environmental factors.
2. Susceptibility to teratogenesis varies with the developmental stage at the time of exposure to an adverse influence. There are critical periods of susceptibility to agents and organ systems affected by these agents.
3. Teratogenic agents act in specific ways on developing cells and tissues to initiate sequences of abnormal developmental events.
4. The access of adverse influences to developing tissues depends on the nature of the influence. Several factors affect the ability of a teratogen to contact a developing conceptus, such as the nature of the agent itself, route and degree of maternal exposure, rate of placental transfer and systemic absorption, and composition of the maternal and embryonic/fetal genotypes.
5. There are four manifestations of deviant development (Death, Malformation, Growth Retardation and Functional Defect).
6. Manifestations of deviant development increase in frequency and degree as dosage increases from the No Observable Adverse Effect Level (NOAEL) to a dose producing 100% Lethality (LD100).

embryonic/fetal genotypes.
5. There are four manifestations of deviant development: (Death, Malformations, Growth Retardation and Functional Defect).
6. Manifestations of deviant development increase in frequency and degree as dosage increases from the No Observable Adverse Effect Level (NOAEL) to a dose producing 100% Lethality (LD100).

Dr. Schwartz's Report, Pp. 2-3

Comparison - Language Is Identical

Along with this new awareness of the in utero vulnerability of the developing mammalian embryo came the development and refinement of The Six Principles of Teratology which are still applied today. ... Jim Wilson in 1959 and in his monograph Environment and Birth Defects.[5] These principles guide the study and understanding of teratogenic agents and their effects on developing organisms:

1. Susceptibility to teratogenesis depends on the genotype of the conceptus and the manner in which this interacts with adverse environmental factors.
2. Susceptibility to teratogenesis varies with the developmental stage at the time of exposure to an adverse influence. There are critical periods of susceptibility to agents and organ systems affected by these agents.
3. Teratogenic agents act in specific ways on developing cells and tissues to initiate sequences of abnormal developmental events.
4. The access of adverse influences to developing tissues depends on the nature of the influence. Several factors affect the ability of a teratogen to contact a developing conceptus, such as the nature of the agent itself, route and degree of maternal exposure, rate of placental transfer and systemic absorption, and composition of the maternal and embryonic/fetal genotypes.
5. There are four manifestations of deviant development (Death, Malformation, Growth Retardation and Functional Defect).
6. Manifestations of deviant development increase in frequency and degree as dosage increases from the No Observable Adverse Effect Level (NOAEL) to a dose producing 100% Lethality (LD100).

Teratology - Wikipedia

<http://en.wikipedia.org/wiki/Teratology>

Along with this new awareness of the in utero vulnerability of the developing mammalian embryo came the development and refinement of The Six Principles of Teratology which are still applied today. ... Jim Wilson in 1959 and in his monograph Environment and Birth Defects.[5] These principles guide the study and understanding of teratogenic agents and their effects on developing organisms:

1. Susceptibility to teratogenesis depends on the genotype of the conceptus and the manner in which this interacts with adverse environmental factors.
2. Susceptibility to teratogenesis varies with the developmental stage at the time of exposure to an adverse influence. There are critical periods of susceptibility to agents and organ systems affected by these agents.
3. Teratogenic agents act in specific ways on developing cells and tissues to initiate sequences of abnormal developmental events.
4. The access of adverse influences to developing tissues depends on the nature of the influence. Several factors affect the ability of a teratogen to contact a developing conceptus, such as the nature of the agent itself, route and degree of maternal exposure, rate of placental transfer and systemic absorption, and composition of the maternal and embryonic/fetal genotypes.
5. There are four manifestations of deviant development (Death, Malformation, Growth Retardation and Functional Defect).
6. Manifestations of deviant development increase in frequency and degree as dosage increases from the No Observable Adverse Effect Level (NOAEL) to a dose producing 100% Lethality (LD100).

embryonic/fetal genotypes.
5. There are four manifestations of deviant development (Death, Malformation, Growth Retardation and Functional Defect).
6. Manifestations of deviant development increase in frequency and degree as dosage increases from the No Observable Adverse Effect Level (NOAEL) to a dose producing 100% Lethality (LD100).

Dr. Schwartz's Report, Pp. 2-3

Comparison - Language Is Identical

Teratogens are those chemicals that lead to structural and/or functional birth defects. The effects of teratogenic compounds are time dependent ... dose dependent. Time dependency is a function of the differences in development of particular organs and systems during pregnancy. The original definition of teratogens was narrow and referred to those chemicals, drugs, and diseases that led to structural and functional abnormalities observed in early life. The classic therapeutic human teratogen is thalidomide. This drug, a sedative developed in the late 1950s and early 1960s, induced serious birth defects in babies whose mothers had taken the drug during the critical period of organogenesis of the limbs (second trimester of pregnancy). The babies were born with several defects, including missing or stumped limbs (phocomelia), cleft palate and lip, and other defects. This abnormality affected over 10,000 babies worldwide and led to the testing of all new drugs (and eventually some pesticides and commodity chemicals) for teratogenic potential.

1843441 - Glossary/Dictionary - Medical Dictionary

Veterinary Dictionary: teratogen

An agent or influence that causes physical defects in the developing embryo.

Teratogenic substances

MICHAEL GALLO

Copyrights:

OXFORD
UNIVERSITY PRESS
GALE
eLibrary Learning

Answers.com

<http://www.answers.com/topic/teratogen>

Teratogens are those chemicals that lead to structural and/or functional birth defects. The effects of teratogenic compounds are time dependent ... dose dependent. Time dependency is a function of the differences in development of particular organs and systems during pregnancy. The original definition of teratogens was narrow and referred to those chemicals, drugs, and diseases that led to structural and functional abnormalities observed in early life. The classic therapeutic human teratogen is thalidomide. This drug, a sedative developed in the late 1950s and early 1960s, induced serious birth defects in babies whose mothers had taken the drug during the critical period of organogenesis of the limbs (second trimester of pregnancy). The babies were born with several defects, including missing or stumped limbs (phocomelia), cleft palate and lip, and other defects. This abnormality affected over 10,000 babies worldwide and led to the testing of all new drugs (and eventually some pesticides and commodity chemicals) for teratogenic potential.

... that time that minimal drug-testing standards could not be established, they made certain recommendations including the suggestion that drug screening programs be expanded beyond the conventional tests with rodents. In 1966 the FDA issued the Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use.¹ The recommended tests were more comprehensive than earlier ones; they specifically included testing during the sensitive-susceptible stages of development. This regulation required that a new drug not be administered to women capable of becoming pregnant until studies have been performed in animals and reasonable evidence of the drug's safety and effectiveness has been demonstrated. Until 1991, these guidelines remained the standard in this country for testing the drug effects on reproduction. The 1992 ICH Guidelines² brought together developmental and reproductive testing in the United States, Europe and Japan. It is a three-study design: the original US segment II study was retained.³

The safe level as used in the context of testing was defined as the no observable effect level (NOEL) as it is called, which represents concentrations of drugs that do not induce recognizable effect level above "normal" or background limits and are a prime criterion of testing. In contrast, the so-called threshold level (LOEL) is the lowest dosage above the no-effect level that elicits a

¹ Public Law 87-781, 21 USC 355.

² Odenstedt, E.I. Drug Review Branch, Division of Toxicological Evaluations, Bureau of Science, FDA, March 1996.

³ Federal Register 43 (143): 377336-37469, Aug 22, 1978.

⁴ ICH Harmonized Tripartite Guidelines on Detection of Toxicity to Reproduction for Medicinal Products.

Dr. Schwartz's Report, Pg. 3



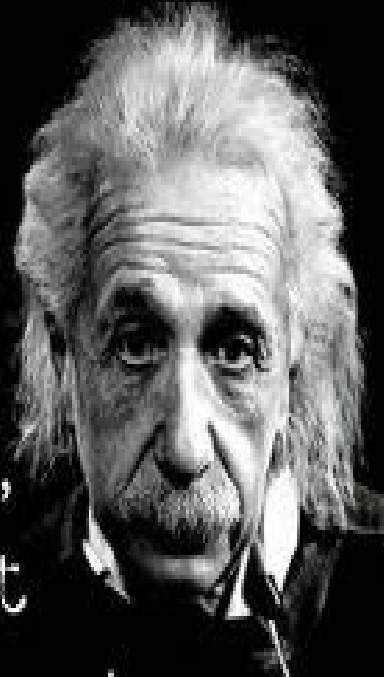
HOW TO WIN THE CROSS-EXAMINATION BATTLE: FIVE CATEGORIES

1. Peripheral
2. Fence

UniqueTeachingResources.com

"If you
can't
explain
it simply,
you don't
understand
it well enough."

~ Albert Einstein





HOW TO WIN THE CROSS-EXAMINATION BATTLE: FIVE CATEGORIES

1. Peripheral
2. Fence
3. Agree



HOW TO WIN THE CROSS-EXAMINATION BATTLE: FIVE CATEGORIES

1. Peripheral
2. Fence
3. Agree
4. Attack



HOW TO WIN THE CROSS-EXAMINATION BATTLE: FIVE CATEGORIES

1. Peripheral
2. Fence
3. Agree
4. Attack
5. Home Run

LASSOING THE EVASIVE EXPERT

1. True or false?
2. This is one of those simple questions.
3. Then your answer to my question is [yes] [no]?
4. Is that another way of saying yes?
5. Does that answer mean yes?
6. Are you having trouble understanding my questions?
7. Didn't that question call for a 'yes' or 'no'?
8. [TO THE COURT REPORTER]: Would you kindly read that question to the witness; maybe he doesn't understand me.
9. I didn't ask why you didn't do it; I asked you whether you did it.
10. Do you understand the difference between 'why' and 'whether'?
11. Are you refusing to answer my question?

LASSOING THE EVASIVE EXPERT

(cont'd)

12. That does not answer my question. Let me try it again.
13. “Your Honor, I move to strike everything after [yes] [no] as non-responsive.” [Again, you must have full and repeated permission before saying this.]
14. That’s a long way of saying ‘yes’?
15. I understand what you’re saying, but I would prefer that you answer my question.
16. With all due respect, you have not answered my question. Will you please answer my question.
17. I appreciate your [opinion] [answer], but that was not my question.
18. I understand that, [sir], but all I was asking you was [...]
19. I understand all that, but can you answer my question?
20. Here. I’ll write YES and NO on this board. [Do so]. Now, which one should I circle? [Remember that you will need the jury’s permission for this one.]



CLOSING ARGUMENT

1. Primacy: your case, not the rebuttal of your opponent




CLOSING ARGUMENT

1. Primacy: your case, not the rebuttal of your opponent
2. Did the opponent fail to deliver on any promises?



CLOSING ARGUMENT

1. Primacy: your case, not the rebuttal of your opponent
2. Did the opponent fail to deliver on any promises?
3. Review from opening the fact issues the jury must decide

- 
-
1. Was Fosamax Appropriate for Ms. Glynn?
 2. Did Merck Appropriately Test and Investigate Fosamax Before It Sold It?
 3. Did Merck Monitor Fosamax Once FDA Approved It and Merck Began To Sell It?
 4. Does Fosamax “Cause” Atypical Femur Fractures?
 5. Did Merck Fail to Provide Adequate Warnings To Doctors About a Risk of Atypical Femur Fracture?



CLOSING ARGUMENT

1. Primacy: your case, not the rebuttal of your opponent
2. Did the opponent fail to deliver on any promises?
3. Review from opening the fact issues the jury must decide
4. Cover *legal* issues, carefully following the judge's instructions to the jury

CLOSING ARGUMENT

1. Primacy: your case, not the rebuttal of your opponent
2. Did the opponent fail to deliver on any promises?
3. Review from opening the fact issues the jury must decide
4. Cover *legal* issues, carefully following the judge's instructions to the jury
5. Be brief