

ELECTRONIC FETAL MONITORING: A BRIDGE TOO FAR

Thomas P. Sartwelle, LL.B., B.B.A.

ABSTRACT

Electronic fetal monitoring in labor is ubiquitous throughout the industrialized world and has been for 40 years. It is used in 85% of births in the United States. Yet EFM's scientific basis is not only weak, it is almost nonexistent. Its interpretation has been proven to be significantly inconsistent even among so called experts. Its false positive rate is more than 99%. EFM was in part responsible for a five-fold increase in C-sections, with the attendant morbidity and mortality associated with that major abdominal operation. Overall, EFM may have harmed more mothers and babies than it helped. Despite advances in medical technology, birth is still a dangerous journey. And EFM does not help.

Additionally, EFM is the most significant accelerant to the current international birth injury malpractice crisis and is the centerpiece of rapidly increasing birth injury trials and settlements not only in the United States but around the world. Yet, EFM is and always has been junk science.

This article explores the questions of why so feeble a medical modality became the standard of care not only clinically but in the world's courtrooms. The answer is multifactorial but partially lies in the belief in myth, not only by physicians but by the public and trial lawyers. It also explores the question why ACOG and other professional societies have remained mute allowing an inferior medical modality to become a *deus ex machina* not only in labor rooms but courtrooms as well. Finally, a suggested solution is offered for overcoming the still persistent myth that physicians are in control of the birth process and that asphyxia is the sole cause of cerebral palsy and other neurologic birth injuries.

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INTRODUCTION

The most common obstetrical procedure in the United States is electronic fetal monitoring (EFM) during labor.² Approximately 85% of the 4,000,000 annual births are EFM monitored.³ EFM is the standard of care in virtually every community. Hospitals have invested multiple millions of dollars in electronic fetal monitoring since its acceptance into clinical practice in the late 1960s. Hospitals and physicians have billed and been paid many millions of dollars for EFM use.⁴

Despite its ubiquity and acceptance in daily clinical obstetrical practice, there are and always have been some important, esoteric EFM secrets: its scientific foundation is feeble; inter-observer/intra-observer reliability is poor; the false-positive prediction of fetal distress rate is greater than 99%; it has substantially increased the cesarean section rate with attendant mortality and morbidity; and it failed completely in its initial stated promise—reducing by

¹Thomas P. Sartwelle is a partner with the law firm of Beime, Maynard & Parsons, L.L.P. in Houston, Texas. Correspondence may be addressed to Mr. Sartwelle at 1300 Post Oak Blvd., Suite 2500, Houston, Texas 77056 or via e-mail at tsartwelle@bmpllp.com. “A Bridge Too Far” is an idiom meaning an act of overreaching, inspired by “Operation Market Garden,” the failed WWII Allied parachute armored assault on German-occupied Holland in September 1944. The epic battle was chronicled by famed war correspondent Cornelius Ryan (1920–1974) in a 1974 book by the same name and made into the 1977 movie starring a cornucopia of famous actors. Ryan’s book title and the idiom were inspired by British Lt. Gen. Frederick Browning, Allied Airborne Deputy Commander, who told Field Marshall Bernard Montgomery before the battle: “I think we may be going a bridge too far.” He was prescient. The Allies fell short of capturing the last bridge, the Rhine River bridge at Arnhem. See, e.g., CORNELIUS RYAN, *A BRIDGE TOO FAR* (1974).

² Thomas P. Sartwelle, *Defending a Neurologic Birth Injury: Asphyxia Neonatorum Redux*, 30 J. LEGAL MED. 181, 213 (2009).

³ E.g., Am. Coll. Obstetricians & Gynecologists, *Practice Bulletin, No. 106, Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles*, 192 (July 2009) [hereinafter *ACOG Practice Bulletin 106*].

⁴ Cf. Leonard J. Nelson, III et al., *Medical Liability and Health Care Reform*, 21 HEALTH MATRIX 443, 482 (2011).

half the incidence of cerebral palsy (CP), mental retardation (MR), and perinatal mortality.⁵ Any other medical procedure with such an abysmal pedigree would have gone the way of bleeding by medieval barbers. But rather than abandon EFM, medicine elevated it to rockstar status. And in the last four decades more babies and mothers have probably suffered harm from EFM than have been helped.

Electronic fetal monitoring was also used as a courtroom truncheon by self-designated EFM “experts” across the United States as they assaulted their supposedly less intelligent colleagues in cerebral palsy and other neurologic birth injury trials. These experts delivered courtroom babies with perfect results, branding their unenlightened colleagues negligent because they failed to recognize the alleged EFM evidence that a child was being asphyxiated in labor. Thus the negligent miscreants sentenced the child to a lifetime of cerebral palsy or other neurologic devastation. The experts made millions of dollars kibitzing as it were. The trial lawyers sponsoring the experts made even more millions of dollars convincing juries that physicians, nurses, and hospitals caused cerebral palsy. It was, and is, junk science. But it continues unabated even today. Strangely, organized medicine stood mute to these assaults, and still does today, allowing EFM to masquerade as science. This strange litigation–junk science dance is even more confusing considering that EFM had its origins in the most important and recognized symbol of medicine’s reliance on science—the stethoscope.

This article examines EFM’s beginning, its history, its rise to ubiquity, and its use today, as well as EFM’s intimate connection to cerebral palsy and other birth-related brain maladies. It also examines EFM’s use and abuse in birth injury litigation and the international malpractice crisis that EFM spawned. The article explores the reasons why physicians and the public believe in EFM technology in spite of its known flaws, defects, and shortcomings, and why the American Congress of Obstetricians and Gynecologists (ACOG) and related worldwide professional organizations have not only failed to curtail EFM use but have actually allowed it to be elevated to the status of *deus ex machina*.⁶

⁵ See Sartwelle, *Defending*, *supra* note 2, at 213 (2009).

⁶ Michael F. Greene, *Obstetricians Still Await a Deus ex Machina*, 355 NEW ENG. J. MED. 2247, 2247 (2006). *Deus ex Machina*, god out of the machine, “a person or thing that appears or is introduced (as into a story) suddenly and unexpectedly and provides an artificial or contrived solution to an apparently insoluble difficulty.” WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 617 (1981). Greene opined about studies attempting to use continuous fetal oxygen saturation measurements (similar to pulse oximetry) in conjunction with electronic fetal heart rate monitoring to assess fetal well-being during labor. Greene, *supra*, at 2247. Fetal oximetry failed to alter neonatal outcomes, just as electronic fetal monitoring failed to alter outcomes. *Id.* Greene’s point is that oximetry, unlike EFM, was appropriately tested, and not simply disseminated. *Id.* Regardless of EFM’s noble purpose, Greene writes, we are now forced to find a new technology to undo the unintended and undesirable consequences of a technological innovation without appropriate scientific testing. *Id.* at 2248.

I. EFM HISTORY: A SHORT STORY

A. In the Beginning

A French physician, Marsac, is thought to be the first to have heard the fetal heart tones sometime in the seventeenth century.⁷ His observations languished, however, until in 1821 Kergaradec—using Laennec's 1806 invention, the stethoscope—listened to the fetal heart and wondered if variations in the fetal heart rate revealed the fetus's state of health.⁸ In 1833, Kennedy published the first book suggesting that there was great value in listening to the fetal heart and proposing that fetal heart rate changes were indicative of fetal distress, urging physician intervention in labor with forceps.⁹ In 1893, Van Winckel published fetal distress criteria that physicians used unquestioned for almost a century to justify intervention: heart rate greater than 160 bpm, less than 100 bpm, meconium passage, "and gross alteration of fetal movement."¹⁰ Few thought to question Van Winckel's suppositions,¹¹ and his fetal distress (fetal asphyxia) theories became dogma.¹²

Similar thoughts about fetal distress had occurred to London orthopedist William John Little, the first to study what we now know as cerebral palsy.¹³ In 1843, he published a series of lectures speculating that the clinical problems he observed with crippled children had their genesis in asphyxia.

⁷ ROGER K. FREEMAN ET AL., *FETAL HEART RATE MONITORING* 1 (3d ed. 2003); see Raymond G. Kennedy, *Electronic Fetal Heart Rate Monitoring: Retrospective Reflections on a Twentieth-Century Technology*, 91 J. ROYAL SOC'Y MED. 244 (1998) (history of the development and implementation of EFM technology and how it came to be introduced widely and rapidly into British obstetric practice).

⁸ Dermot MacDonald, *Cerebral Palsy and Intrapartum Fetal Monitoring*, 334 NEW ENG. J. MED. 659, 659 (1996).

⁹ R.K. FREEMAN ET AL., *supra* note 7, at 1.

¹⁰ *Id.*

¹¹ *Id.*

¹² The term fetal distress is synonymous with fetal asphyxia. BARRY S. SCHIFRIN, *The Diagnosis and Treatment of Fetal Distress*, in *FETAL NEUROLOGY* 143 (Alan Hill & Joseph J. Volpe eds., 1989). Fetal asphyxia over the years became synonymous with physician negligence. The term fetal distress became so pejorative that the ACOG attempted to replace it with "nonreassuring fetal heart rate tracing." *Fetal Heart Rate Patterns: Monitoring, Interpretation, and Management*, ACOG Technical Bulletin No. 207 (1995). The effort was largely unsuccessful. Considerable controversy exists today concerning the definition such that "fetal distress remains mostly in the eye of the beholder." Jeffrey P. Phelan, *What Constitutes Fetal Distress*, *OBGYN.NET* (May 23, 2012, 5:04 PM), at <http://hcp.obgyn.net/ultrasound/content/article/1760982/1898406>; see Sartwelle, *Defending*, *supra* note 2 (discussion of the defense of a physician accused of causing cerebral palsy and the relationship between fetal distress, asphyxia, and related concepts and CP and EFM).

¹³ The condition now called cerebral palsy was known for many years as "Little's Disease," after London orthopedic surgeon William John Little. CYRIL B. COURVILLE, *CEREBRAL PALSY* 6 (1954). Forty years later, Sir William Osler published a monograph on the subject entitled *The Cerebral Palsies*. VIOLA E. CARDWELL, *CEREBRAL PALSY* 3 (1956). Since then, varied terminology has been used to include a variety of descriptive terms encompassing both disability and causation: infantile cerebral palsy; congenital spastic diplegia; hemorrhagic encephalopathy; disseminated encephalomyelitis; cerebral spastic; and

neonatorium—difficult, traumatic, or slow birth causing “improper aeration of the blood.”¹⁴ In other words, oxygen deprivation resulting from fetal distress during birth injured the fetal brain. The clinical manifestations of these brain injuries—cerebral palsy—were permanent, abnormal movements of arms or legs, or both, sometimes accompanied by cognitive and other neurologic deficits.

Little’s nineteenth-century speculation along with Van Winckel’s fetal distress criteria were uncritically accepted by subsequent generations of physicians, who, in turn, taught this same speculation as gospel well past the middle of the twentieth century.¹⁵ Perinatal neurologic brain injury was reduced to a simple if/then syllogism that was not only simple, but also seemed to make common sense: if the fetal heart decelerated during labor or delivery, the fetus was experiencing asphyxia. If the infant later developed CP, cognitive deficits, epilepsy, or any combination, then the cause was asphyxia. The obvious cure was a quick delivery as soon as fetal distress was detected.¹⁶

cerebral paralytic. Dr. Winthrop M. Phelps is credited with selecting “cerebral palsy” to denote this group of signs and symptoms. *Id.* at 3; COURVILLE, *supra* note 13, at 6; FRANK R. FORD, DISEASES OF THE NERVOUS SYSTEM 1041-46 (1944).

¹⁴ COURVILLE, *supra* note 13, at 7 (quoting from Little’s lectures originally published in 1843 in *Lancet* and 10 years later as a monograph).

¹⁵ Nat’l Inst. of Child Health and Hum. Dev., Nat’l Inst. Neurological and Communicative Disorders and Stroke, U.S. Dep’t of Health and Human Servs., *Prenatal and Perinatal Factors Associated with Brain Disorders* 1 (John M. Freeman ed., 1985) [hereinafter *Collaborative Perinatal Study*]; Stuart L. Weinstein & Barry R. Tharp, *Etiology and Timing of Static Encephalopathies of Childhood (Cerebral Palsy)*, in FETAL AND NEONATAL BRAIN INJURY 221, 222 (David K. Stevenson & Phillip Sunshine eds., 1989); Ronald S. Illingworth, *Why Blame the Obstetrician? A Review*, 1 BRIT. MED. J. 797 (1979). In describing historical evidence that crippling neurologic birth conditions have been with us from ancient times, Weinstein & Tharp note that Freud disagreed with Little’s proposal that the origins of CP were difficult labors and mechanical injuries to a baby’s head and neck during assisted birth. Freud thought CP’s genesis was an accidental combination of etiologic factors, including ischemic disturbances primarily during gestation. Weinstein & Tharp, *supra* note 15, at 222.

¹⁶ Reduced to simplicity, Little’s hypothesis is one that every person on earth accepts as true—oxygen deprivation causes brain injury. Sartwelle, *Defending*, *supra* note 2, at 183. It does not matter that 40 years of research has repeatedly proven that asphyxia causes only a small fraction of CP cases and that CP because of asphyxia is, except in rare cases, unpreventable. *Id.* at 183-84. The public, trial lawyers, and a surprisingly substantial number of physicians still believe the oxygen deprivation is the major cause of perinatal brain damage myth. E. Rebecca Pschirrer & Edward Yeomans, *Does Asphyxia Cause Cerebral Palsy?*, 24 SEMINARS IN PERINATOLOGY 215, 215 (2000). As to physicians in general, the public, and trial lawyers, see AM. ACAD. PED. & AM. COLL. OBSTET. & GYNECOL., GUIDELINES FOR PERINATAL CARE 221 (3d ed. 1992) (“In the past the causes of cerebral palsy, mental retardation, and epilepsy were unknown; and they were widely assumed to be due to ‘brain damage’ originating during parturition. This misperception is still held by many physicians, patients, and attorneys”); Jeffrey P. Phelan et al., *Birth Asphyxia and Cerebral Palsy*, 32 CLINICS IN PERINATOLOGY 61 (2005); Susan N. Ramin, *New Concepts in Cerebral Palsy—Introduction*, 24 SEMINARS IN PERINATOLOGY 195 (Susan N. Ramin guest ed., 2000); Pschirrer & Yeomans, *supra* note 16; John M. Freeman & Al D. Freeman, *Cerebral Palsy and the “Bad Baby” Malpractice Crisis: New York State Shines Light Toward the End of the Tunnel*, 146 AM. J. DISEASES CHILDREN 725 (1992). As to obstetricians in particular, see Maria A. Morgan et al., *Neonatal Encephalopathy and Cerebral Palsy Revisited: The Current State of Knowledge and the Impact of American College of Obstetricians and Gynecologists’ Task Force*

Little's and Van Winckel's untested medical speculation turned into inviolate maxims. Along the way were added markers that, according to conventional wisdom, reliably identified the asphyxiated fetus during labor, delivery, or shortly thereafter: meconium-stained amniotic fluid, low APGARs, and acidosis at birth. All proved to be red herrings when finally tested.¹⁷

Throughout the nineteenth and to the middle of the twentieth century the labor and delivery standard of care was intermittent fetal heart rate auscultation to discern if Van Winckel's parameters were exceeded. If exceeded, intervention to rescue the fetus occurred; first with forceps and, subsequently, as anesthesia improved, by cesarean section. Missing from this equation was any medical proof that early intervention was efficacious or that the theories about fetal distress, fetal asphyxia, cerebral palsy's causes, or any of the other dogma were anything other than myth.

B. The Rise of Technology

It was inevitable that as medical technology advanced, attention was focused not on proving the labor and delivery dogma but on devices to better hear the fetal heartbeat so intervention could occur quickly. After the stethoscope came the fetoscope in the early twentieth century. Also known as the De Lee-Hillis stethoscope, its invention is itself a story of considerable intrigue.¹⁸ The fetoscope was designed to allow accurate fetal heartbeat counting. But in the 1950s questions arose as to a human being's ability to accurately count fetal heartbeats by simply listening with the fetoscope.¹⁹ Counting was critical to the application of the fetal distress criteria. Studies revealed wide divergence in counting accuracy.²⁰ Thus, as the world became increasingly beguiled by computers, the space race, and technological advances in consumer products,

Report, 25 J. PERINATOLOGY 519 (2005); Gary Hankins et al., *Neonatal Encephalopathy and Cerebral Palsy: A Knowledge Survey of Fellows of the American College of Obstetricians and Gynecologists*, 101 OBSTETRICS & GYNECOLOGY 11 (2003); John C. Morrison, *Fetal/Neonatal Neurologic Injury and "ACOG Technical Bulletin 163": A Light at the End of the Tunnel*, 16 J. PERINATOLOGY 421 (1996).

¹⁷ Am. Coll. Obstet. & Gynecol. & Am. Acad. Peds., *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology* 2 (2003) [hereinafter ACOG-AAP]; Karin B. Nelson, Can We Prevent Cerebral Palsy? 349 NEW ENG. J. MED. 1765, 1767 (2003); Alastair MacLennan, *A Template for Defining a Causal Relation Between Acute Intrapartum Events and Cerebral Palsy: International Consensus Statement*, 319 BRIT. MED. J. 1054 (1999) [hereinafter Int'l Cerebral Palsy Task Force].

¹⁸ R.K. FREEMAN ET AL., *supra* note 7, at 1.

¹⁹ Sartwelle, *Defending*, *supra* note 2, at 206-07.

²⁰ R.K. FREEMAN ET AL., *supra* note 7, at 2; see Edward Hon, *The Electronic Evaluation of the Fetal Heart Rate*, 75 AM. J. OBSTETRICS & GYNECOLOGY 1215 (1958) (wide divergence in obstetricians' ability to accurately count fetal heart rate). A review of 24,863 deliveries concluded that fetal heart rate is an unreliable indicator of fetal distress except in extreme ranges. R.C. Benson et al., *Fetal Heart Rate as a Predictor of Fetal Distress: A Report from the Collaborative Project*, 32 OBSTETRICS & GYNECOLOGY 259, 259, 262-63 (1968).

medicine led the way with technological innovations. It is little wonder that labor and delivery also succumbed to technology's infallibility charms.

An electronic device was used in 1906 to record a fetal heart rate.²¹ However, it remained limited to diagnosing the presence of fetal life only until 1957, when it was suggested that this electronic monitor and the changes it revealed in fetal heartbeats might correlate with fetal distress.²² A year later, Yale University's Dr. Edward Hon began reporting on his proposal to use continuous electronic monitoring to count fetal heartbeats and more accurately diagnose fetal bradycardia and fetal distress.²³ Hon subsequently coupled his more accurate electronic fetal heart rate counting with a simultaneous electronic assessment of uterine activity.²⁴ Hon compared the continuous recordings with fetal outcomes using APGAR scores and the fetus's biochemical status.²⁵ Hon defined what he believed to be normal and abnormal EFM patterns. He published his results in 1963.²⁶ Hon's work was universally accepted.²⁷

Hon's core, but unproven, belief was that a lack of oxygen in labor caused fetal distress and fetal brain damage. In 1958, this belief received what was thought to be substantiation by no less an authority than Virginia Apgar, who famously proposed the APGAR score, which by then was in wide use. Apgar's 1958 acidosis and asphyxia study, with no controls and no follow-up, and ignoring studies showing that infants can take up to two or three hours after birth to reach adult oxygen saturation levels, concluded that active oxygenation was required immediately after birth for asphyxiated infants to avoid brain damage.²⁸ This study paved the way for oxygen in delivery rooms. The belief that brain damage was caused solely by a lack of oxygen was now even more firmly established, even as EFM was working its way from theory to reality.

Hon was not the only physician making observations and comparing outcomes. Physicians around the world were also reporting on similar fetal heart and contraction patterns and defining what they thought was fetal distress. These researchers were all using different machines, different recording speeds, and different nomenclature. International conferences helped adopt some common language and procedures, although much of the hardware remained individualized.²⁹

²¹ R.K. FREEMAN ET AL., *supra* note 7, at 2.

²² *Id.*

²³ *Id.*; H.M.L. Jenkins, *Thirty Years of Electronic Intrapartum Fetal Heart Rate Monitoring: Discussion Paper*, 82 J. ROYAL SOC'Y MED. 210, 210 (1989).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ Michael Obladen, *Lame from Birth: Early Concepts of Cerebral Palsy*, 26 J. CHILD. NEUROL. 248 (2011).

²⁹ R.K. FREEMAN ET AL., *supra* note 7, at 3.

Despite the alluring façade of scientific trappings, pseudo-empirical data, and a machine's seeming infallibility, electronic fetal monitoring's entire foundation still stood upon the syllogistic sand³⁰ of unverified nineteenth-century speculation about the meaning of variations in fetal heartbeats, speculation rarely challenged by contemporary science, much less more sophisticated twentieth-century physicians. It apparently never occurred to the EFM advocates that using a machine to continually count fetal heartbeats was not providing new data. It simply supplied more of the old data, which was being interpreted with Little's untested speculation now turned dogma and the researchers' untested theories of what the patterns on the tracing paper must mean to the fetus's well-being.

C. Technology Invades the Labor and Delivery Suite

The first commercially available fetal monitor was introduced into clinical use in 1968.³¹ By 1978, electronic fetal monitoring was in routine use in over half of all California deliveries.³² But not even one randomized, controlled clinical trial had been performed to prove EFM's promises.³³ Rather, an entire generation of obstetricians, nurses, and midwives accepted the promise of experts that EFM placed them in control of the birth process and the baby's neurologic viability and future. It was so simple: monitor, interpret the pattern, and quickly do a C-section or instrumented delivery on any baby experiencing an "abnormal" pattern as defined by the experts. The experts published books and articles illustrating the abnormal fetal heart rate and contraction patterns, as well as opining confidently about the intrauterine causes for the patterns and when such patterns dictated quick C-section delivery to rescue the fetus.³⁴

³⁰ Matthew 7:26 (King James).

Therefore whosoever heareth these sayings of mine and doeth them, I will liken him unto a wise man, which built his house upon a rock:

And the rain descended and the floods came, and the wind blew, and beat upon that house; and it fell not: for it was founded upon a rock.

And everyone that heareth these sayings of mine, and doeth them not, shall be likened unto a foolish man, which built his house upon the sand:

And the rain descended, and the floods came, and the winds blew, and beat upon that house; and it fell: and great was the fall of it.

Matthew 7:24-27 (King James).

³¹ R. K. FREEMAN ET AL., *supra* note 7, at 3.

³² *Id.* at 4 (citing R.L. Williams & W.E. Hawes, *Cesarean Section, Fetal Monitoring and Perinatal Mortality in California*, 69 AM. J. PUBLIC HEALTH 864, 866 (1979)).

³³ Greene, *supra* note 6; MacDonald, *supra* note 8, at 659; Roger K. Freeman, *Intrapartum Fetal Monitoring—A Disappointing Story*, 322 NEW ENG. J. MED. 624, 625 (1990).

³⁴ E.g., Barry S. Schiffrin & Laureen Dame, *Fetal Heart Rate Patterns: Prediction of APGAR Score*, 219 J.A.M.A. 1322 (1972); EDWARD H. HON, AN ATLAS OF FETAL HEART RATE PATTERNS (1968).

Experts begat experts, and more and more definitive pattern interpretations and causation theories were published.³⁵

D. Gadgets and Simple Cures

In 1975, a year before the first EFM controlled trial was even reported, two leading EFM experts predicted that EFM alone would reduce by half intrapartum deaths, mental retardation, and CP.³⁶ These experts cited several medical “facts” demonstrating EFM’s solid, sturdy, scientific foundation justifying their optimism that EFM would be CP’s nemesis. In these facts is reflected perfectly that era’s secure assurance that the birth process secrets are known and man’s ability to intervene and alter unwanted outcomes is being consummated. These facts also reflect perfectly the true scientific knowledge dearth about the human fetus’s physiologic parameters in utero as well as the pseudoscience underlying birth process intervention based solely on fetal heart rate changes and contraction patterns. According to the two experts, EFM’s rationale was based on these facts: the stress of labor could cause fetal death and it was therefore reasonable to assume that it also caused brain damage; a study of institutionalized, severely retarded individuals revealed that half had experienced events attributable to delivery; and insight into how acute human fetal hypoxia and stress due to maternal hypertension, placental separation, or excessive uterine activity possibly resulted in cerebral palsy could be derived from asphyxia in primates, which produced a brain pathology identical to that seen in humans with CP.³⁷

Thus, medicine once again embraced Little’s hypothesis—oxygen deprivation in labor and delivery causes CP, MR, and seizures—and monitoring the fetal heart was the key to the prevention of brain damage. This 1975 article also illustrates that medicine—supposedly a bastion of strict scientific proof and the scientific method—was as easily hypnotized by the lure of gadgets, quick fixes, and simple cures to complex problems as was the rest of American society.³⁸ The hypnotic spell, however, was about to be abruptly, unpleasantly, and rudely broken.

³⁵ E.g., Barry S. Schiffrin et al., *Fetal Heart Rate Patterns and the Timing of Fetal Injury*, 14 J. PERINATOLOGY 174(1994); John R. Shields & Barry S. Schiffrin, *Perinatal Antecedents of Cerebral Palsy*, 71 OBSTETRICS & GYNECOLOGY 899 (1988); Kirk Keegan et al., *Obstetric Characteristics and Fetal Heart Rate Patterns of Infants Who Convulse During the Newborn Period*, 153 AM. J. OBSTETRICS & GYNECOLOGY 732(1985).

³⁶ Edward J. Quilligan & Richard H. Paul, *Fetal Monitoring: Is It Worth It?*, 45 OBSTETRICS & GYNECOLOGY 96, 98 (1975).

³⁷ *Id.* at 97.

³⁸ *Id.*; see also Stephen B. Thacker, *The Impact of Technology Assessment and Medical Malpractice on the Diffusion of Medical Technologies: The Case of Electronic Fetal Monitoring*, Comm. Study Med. Prof’l Liab. & Delivery Obstetrical Care, Inst. Med., Div. Health Promotion & Disease Prevention, 2 MED. PROF. LIABILITY & DELIVERY OB. CARE 9-11 (Victoria P. Rostow & Roger J. Bulger eds., 1989); see PETER W. HUBER, *GALILEO’S REVENGE: JUNK SCIENCE IN THE COURTROOM* (1983). In Chapter 5, entitled “Gadgets and Knives—Cashing in on Magical Cures,” Huber emphasizes how medicine’s fascination

E. The Perfect Storm³⁹

In the 1950s and 1960s, Hon and others worked to overcome mechanical, nomenclature, and other practical electronic monitoring problems and document what they imagined were fetal distress patterns. At the same time, Virginia Apgar's study reconfirmed the old belief that brain damage was caused solely by a lack of oxygen. None of these participants could possibly have known that the medical world was on the cusp of a perfect litigation storm—a storm made up of various influences including massive court-made expansion of tort law liability, a fundamental change in societal attitudes toward injury responsibility, a sea change in the organized Bar's century-old lawyer advertising restrictions, and the death of medical paternalism. At the epicenter of the coming exponential increase in medical malpractice liability was the electronic fetal monitor. EFM would present and preserve the evidence that would lead to CP jury verdicts undreamed of by the most optimistic trial lawyer.

II. THE LITIGATION GAMES BEGIN

Medical malpractice law traces its roots to English common law and the development of the general law of personal injury negligence. Healthcare providers were not exempt from negligence, although different rules were developed about experts, schools of practice, and a few other details. In America, medical malpractice suits were rare compared to other life experiences but certainly common enough that a substantial body of law developed.⁴⁰

In the late 1960s, the frequency of claims per physician and claim severity suddenly, and mysteriously, began to accelerate rapidly.⁴¹ Claims reached unprecedented levels, precipitating the medical malpractice insurance crisis of the mid-1970s.⁴² In response, virtually every state legislature

with gadgets (EFM) and knives (scalpels and Cesarean sections) propels them into plaintiffs' attorneys' crosshairs.

³⁹ *The Perfect Storm* is the title of Sebastian Junger's book about the 1991 Halloween nor'easter storm. It describes the confluence of three different weather phenomena that combined to create what a Boston meteorologist described as the perfect situation to generate a monster storm. SEBASTIAN JUNGER, *THE PERFECT STORM: A TRUE STORY OF MEN AGAINST THE SEA* 150 (1997). The phrase has become a metaphor for any confluence of conditions that combine to create a negative situation. Cf. Carol McCrehan Parker, *The Perfect Storm, the Perfect Culprit: How a Metaphor of Fate Figures in Judicial Opinions*, 43 McGEORGE L. REV. 323, 324 (2012).

⁴⁰ KENNETH ALLEN DeVILLE, *MEDICAL MALPRACTICE IN NINETEENTH CENTURY AMERICA, ORIGINS AND LEGACY* (1992); see Kim Price, *Towards a History of Medical Negligence*, 375 LANCET 192 (2010) (a short commentary on the social influences driving medical malpractice suits in the nineteenth century and the differences between the American and British experience).

⁴¹ Patricia M. Danzon, *The Frequency and Severity of Medical Malpractice Claims: New Evidence*, 49 LAW & CONTEMP. PROBS. 57 (1986).

⁴² E.g., *id.*; see also PATRICIA M. DANZON, *MEDICAL MALPRACTICE: THEORY, EVIDENCE AND PUBLIC POLICY* 97 (1985); SYLVIA LAW & STEVEN POLAN, *PAIN AND PROFIT: THE POLITICS OF MALPRACTICE* (1978). For

enacted tort reforms to assure medical malpractice insurance availability. The reforms momentarily slowed the upward trend, but only momentarily.⁴³ The reasons for the surge in frequency and severity were many and varied. Chief among the supposed causes were urbanization, concomitant deterioration of patient–physician relationships, increasing numbers of lawyers and, in 1977, a United States Supreme Court decision allowing lawyer advertising that would eventually open lawyer advertising floodgates in every available media.⁴⁴

Into this milieu, EFM was introduced. Noble in purpose no doubt, but with almost no proven scientific foundation, EFM delivered (no pun intended) CP litigation’s crown jewel to a bevy of eager trial lawyers: a permanent computer tracing that became the primary instrument of blame in the high-stakes CP litigation lottery.⁴⁵ This instrument of blame would be wielded not so much by lawyers as by the self-proclaimed EFM experts. These experts’ skills lie not in the delivery room but in the courtroom. They would verify the defendant physician’s negligence by reexamining the EFM strip and pointing to the exact moment the child experienced the asphyxia that led to brain damage and lifelong neurologic devastation.

a more contemporary and much briefer look at malpractice, see John J. Fraser, Jr. et al., *Technical Report: Alternative Dispute Resolution in Medical Malpractice*, 107 PEDIATRICS 602 (2001) (although this Technical Report was retired in 2011, the brief history is still accurate); *Policy Statement—AAP Publications Reaffirmed and Retired*, 127 PEDIATRICS 857, 857 (2011). *Contra* REED N. OLSEN, *THE EFFICIENCY OF MEDICAL MALPRACTICE LAW: THEORY AND EMPIRICAL EVIDENCE* (2000), available at <http://courses.missouristate.edu/ReedOlsen/medmal%20claims.pdf> (last visited May 24, 2012); Reed N. Olsen, *The Reform of Medical Malpractice Law, Historical Perspectives*, 55 AM. J. ECON. & SOCIOLOGY, 257 (July 1996) (arguing that there is not now and never has been a medical malpractice crisis).

⁴³ *Id.*

⁴⁴ *Id.* Until 1977 lawyer advertising was prohibited by virtually all bar associations. With the Supreme Court’s opinion in *Bates v. State Bar of Arizona*, lawyer advertising was on its way to becoming ubiquitous. *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977); see also Thomas P. Sartwelle, *Your Doctor Is Board Certified: Is Your Lawyer?*, 20 PROFESSIONAL LAWYER 1 (2011) (exploring the interface between lawyer board certification, lawyer advertising, Super Lawyers-Best Lawyers, and the lawyer standard of care for specialists); J. GORDON HYLTON, *PROFESSIONAL VALUES AND INDIVIDUAL AUTONOMY, THE UNITED STATES SUPREME COURT AND LAWYER ADVERTISING* (1998) (Professor Hylton provides a readable and detailed account of lawyer advertising from the nineteenth century to the 1990s).

⁴⁵ The litigation lottery and similar metaphors have been used many times: *E.g.*, Maxwell J. Mehlman, *Bad “Bad Baby” Bills*, 20 AM. J.L. & MED. 129, 130 (1984) (quoting a memorandum supporting no-fault legislation from then New York Governor Mario Cuomo’s office); see also HASTINGS CTR., *ACCOUNTABILITY: PATIENT SAFETY AND POLICY REFORM* 16-18 (Virginia A. Sharp ed., 2004) (arguing that present systems of accountability contribute to medical errors and unjust compensation). The random nature of this bias is described by one observer as “the epitome of injustice.” Peter W. Huber, *How Lawyers Have Invaded the Delivery Room*, 69 MED. ECON. 149, 157 (1992). In a similar vein, Professor Alastair MacLennan observed: “There are no proven obstetrical interventions that prevent cerebral palsy at term and, therefore, using the litigation system to blame doctors and nurses for failing to prevent CP is nothing more than using health care providers as a ‘de facto’ social welfare insurance scheme for children with cerebral palsy.” *Int’l Cerebral Palsy Task Force*, *supra* note 17. MacLennan argued for a limited, speedy, no-fault system as well as re-education of the public and “some pediatricians” to recognize that the “neuropsychology of cerebral palsy is established in the large majority of cases antenatally.” Mark Silvert, *Claim That Events Before Birth Caused Cerebral Palsy Is Disputed*, 320 BRIT. MED. J. 1626 (2000).

Over the intervening years these experts would deliver countless thousands of children a second time in courtrooms across the United States. Each time, the babies were delivered with unblemished health and, of course, were neurologically perfect. The defendant physician, nurse, or midwife could have accomplished this perfect delivery if only she had been better educated or more alert and more attentive to the EFM tracing. Verdicts multiplied along with huge damages. Each year perinatal brain injury cases consistently were among the highest verdicts and settlements in the country, with some reaching above \$200 million, verdicts on a par with business litigation cases.⁴⁶

In 1968, when EFM entered clinical practice, the litigation blame game was almost totally new to physicians, nurses, and midwives. They knew Little's syllogism was true. They knew that fetal distress-asphyxia caused CP and brain damage. But to the medical mind the thought that asphyxia could be used to place blame on them was a complete non-sequitur. For decades birth asphyxia was the medical explanation used to console parents as physicians explained why their child was born with CP or had experienced a brain injury. Physicians never dreamed that they would be asked to explain to lawyers and juries why they did not prevent the asphyxia.⁴⁷ More important, before EFM a fetus was intermittently monitored with stethoscopes and fetoscopes. If a child later developed CP, MR, seizures, or a similar condition, no amount of speculation about fetal distress could overcome the obstetrician's recollections that the intermittent auscultation revealed no evidence of fetal distress. Thus, there had been no reason to intervene.⁴⁸ EFM changed everything. Like Jonah, the age of medical innocence sailed into the perfect storm.⁴⁹

A. The EFM Age: 1968–2012

In hindsight, the EFM age is merely a microcosm of dozens of sociological influences on the changing American psyche—influences ranging from the retreat from medical paternalism to the rise of instant but untrained inter-net experts, as well as litigation's exponential expansion to compensate real

* David R. Lucchese, *Defending the Perinatal Brain Injury Lawsuit*, FOR THE DEFENSE, Nov. 2007, at 65, 65. Attorney websites showcase big verdicts and settlements. Search "cerebral palsy" in Google, and the results are primarily attorney web sites listing big CP verdicts and settlements. E.g., KLINE & SPECTER, <http://www.KlineSpecter.com/cerebral-palsy-lawyer.html> (last visited Aug. 2, 2011). The U.S. Department of Health and Human Services studied the medical liability system in 2002. In its report it found the system broken, unpredictable, costly, and unjust. Part of the problem, the report noted, was the ever-increasing mega verdicts, which in turn drive up settlement payments. As an example, it was noted that in Mississippi before 1995 the largest verdict was \$9 million. Since then Mississippi jury verdicts between \$15 million and \$100 million have not been unusual. U.S. DEPT OF HEALTH & HUMAN SERVS., OFF. OF THE ASST. SEC. PLAN AND EVAL., CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM (2002), available at <http://aspe.hhs.gov/daltcp/reports/litrefin.pdf> [hereinafter *Healthcare Crisis 2002*].

* Cf. *Collaborative Perinatal Study*, *supra* note 15, at 3.

* Huber, *supra* note 38, at 78-79.

* Jonah 1:4-17; see Parker, *supra* note 39.

and perceived bodily or psychic injuries, lawyer advertising, class action lawsuits, drug and medical device suits, the use of anecdotal evidence (stories) instead of empirical evidence to support public policy decisions,⁵⁰ and dozens of other major and minor trends, fads, and cultural factors. Most influential, however, was the trial lawyer. The EFM age saw a medical phenomenon previously unseen in medicine's long history—defensive medicine. Prophylactic medicine administered for protection from trial lawyers. Despite EFM's noble beginnings, EFM became and is today an unscientific legal prophylactic.⁵¹

⁵⁰ See David A. Hyman, *Lies, Damned Lies, and Narrative*, 73 IND. L.J. 797 (1997). Hyman's revealing article condemns the exclusion of empirical research in favor of using narrative, anecdotal evidence (stories) to make public policy decisions. His primary illustration is the Emergency Medical Treatment and Active Labor Act Legislation, passed primarily on the basis of horror stories that, once investigated, turned out to be untrue in almost all salient details. See *id.*

⁵¹ Margaret Lent, *The Medical and Legal Risks of the Electronic Fetal Monitor*, 51 STAN. L. REV. 807, 807 (1999). In a comprehensive, thoughtful analysis, Lent argues that EFM use is medically and legally unsound, exposing obstetricians to liability instead of protecting them from liability as most obstetricians believe. Lent notes that continued EFM use is often attributed to physicians' malpractice concerns, as well as profession inertia. *Id.* at 808-09. Quoting a *Boston Globe* reporter's interview with Dr. Fredric D. Frigoletto, Jr., regarding why EFM has not been abandoned in view of its lack of efficacy, Frigoletto is quoted as saying: "Everybody's waiting for the next person to get brave." *Id.* at 808 n.5. Doctors' lawsuit fears and defensive medicine reactions are not limited to EFM, nor are they new. As Albany Law School professor Allen Redlich noted in his analysis of the 1974-1976 medical malpractice crisis and subsequent "Legislative Panic," "the average physician believes he was always in danger of being sued." Allen Redlich, *Ending the Never-Ending Medical Malpractice Crisis*, 38 MAINE L. REV. 283, 303 (1986). Doctors' lawsuit fears are said to be a problem that "touches almost every facet of our healthcare delivery system," by a presidentially inspired 1973 HEW Medical Malpractice Commission study. *Id.* at 288 n.18. Defensive medicine, including EFM use, and its cost to the healthcare system have been the subject of numerous articles, editorials, and TV investigative reports. E.g., CRICO STRATEGIES, 2010: ANNUAL BENCHMARKING REPORT, MALPRACTICE RISKS IN OBSTETRICS (2010), available at [http://www.rmfstrategies.com/Products-and-Services/Comparative-Data/~media/Files/Strategies/Reports/2010 annual benchmark.pdf](http://www.rmfstrategies.com/Products-and-Services/Comparative-Data/~media/Files/Strategies/Reports/2010%20annual%20benchmark.pdf) (revealing that the most frequent OB case and the most expensive is birth asphyxia and the most common alleged cause of the asphyxia is failure to recognize and respond to EFM indications). CRICO is the Harvard Medical Institutions' medical malpractice company; since 1998 CRICO has shared malpractice data with other national and international malpractice insurers. Deborah LaValley & Jack Hoffman, *Obstetrics-Related Malpractice Cases 1997-2007* 25 FORUM 2 (Sept. 2007). Obstetrical-related cases were 7% of all claims from 1997 to 2007 but accounted for 14% of total incurred costs; among all perinatal cases, the most frequent allegation is failure to recognize and respond to EFM fetal distress. *Id.* at 2. Dionne Searcy & Jacob Goldstein, *Tangible and Unseen Health-Care Costs*, WALL ST. J., Sept. 3, 2009, at A13, available at <http://online.wsj.com/article/SB125193312967181349.html> (last visited May 23, 2012). John Stossel, *Cost of Personal Injury Lawyers*, 20/20, July 23, 2004, available at <http://abcnews.go.com/2020/GiveMeABreak/story?id=124251&page=1#.T72xsUWL6FJ>. Peter D. Jacobson, *Medical Liability and the Culture of Technology*, in MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 115 (detailing the statistics on neurologically impaired infant cases, most of which are related to EFM interpretive failures, which are acknowledged as the "driving factor in litigation"). Barry Manuel, *The Crisis in Professional Liability: It's the Systems, Stupid!*, 23 FORUM 12 (Feb. 2003); U.S. DEP'T HEALTH & HUMAN SERVS., OFFICE OF DISABILITY, AGING AND LONG-TERM CARE POLICY, ADDRESSING THE NEW HEALTH-CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE (2003), available at <http://aspe.hhs.gov/daltcp/reports/medliab.pdf>. [hereinafter *Litigation System 2003*] "[T]he excesses of the litigation system are an important contributor to defensive medical—medical treatment provided for the purpose of avoiding litigation." *Id.* at 1; "[T]he costs of the runaway litigation system are paid by all Americans." *Id.* at 11; ELIZABETH CARTWRIGHT

B. Deus Ex Machina

EFM's promise was that obstetricians could continually monitor the fetal well-being, intervening to save the fetus experiencing abnormal heart patterns with a quick cesarean section or instrumented delivery.⁵² In the early and mid-1970s, this thesis seemed to be borne out by non-randomized, retrospective reports that EFM produced better outcomes than intermittent auscultation.⁵³ It seemed as if EFM really was a *deus ex machina*.

The first prospective, randomized, controlled trial was reported in 1976.⁵⁴ It showed no EFM benefit compared to intermittent auscultation. The study did detect a higher C-section rate with EFM. A subsequent study followed the original study's children for three years.⁵⁵ It, too, showed no EFM benefit.⁵⁶ More studies followed. By 1995, 12 randomized, controlled EFM trials had been published.⁵⁷ All concluded that with the exception of a reduced rate of neonatal seizures, EFM had no measurable impact on morbidity and mortality.⁵⁸ Moreover, the reduction in seizures as a benefit was questionable.⁵⁹ Follow-up studies concluded that the seizures' long-term neurologic effects were minimal.⁶⁰

& JAN THOMAS, CONSTRUCTING RISK, MATERNITY CARE, LAW, AND MALPRACTICE IN BIRTH BY DESIGN 218 (Raymond DeVries et al., eds., 2001); Carolyn Lochhead, *Civil Justice Memo No. 21 May 1990: Liability and the Crisis in Obstetrics*, MANHATTAN INSTITUTE FOR POLICY RESEARCH (May 24, 2012), http://www.manhattan-institute.org/html/cjm_21.htm.

⁵² Greene, *supra* note 6; MacDonald, *supra* note 8, at 659; R.K. Freeman, *Intrapartum*, *supra* note 33, at 624-25.

⁵³ E.g., *id.* at 625. Intermittent auscultation with fetoscope or stethoscope was condemned as grossly inadequate before EFM had been vetted in even one legitimate clinical trial. Quilligan & Paul, *supra* note 36, at 97.

⁵⁴ Albert D. Haverkamp et al., *The Evaluation of Continuous Fetal Heart Rate Monitoring in High Risk Pregnancy*, 125 AM. J. OBSTETRICS & GYNECOLOGY 310, 310 (1976); see R.K. Freeman, *Intrapartum*, *supra* note 33, at 625 (summary of the Haverkamp study).

⁵⁵ *Id.*

⁵⁶ Sharon Langendoerfer et al., *Pediatric Follow-Up of a Randomized Controlled Trial of Intrapartum Fetal Monitoring Technique*, 97 J. Peds. 103, 103 (1980); R.K. Freeman, *Intrapartum*, *supra* note 33, at 625.

⁵⁷ Stephen B. Thacker et al., *Efficacy and Safety of Intrapartum Electronic Fetal Monitoring: An Update*, 86 OBSTETRICS & GYNECOLOGY 613, 618 (1995).

⁵⁸ *Id.* In recognition of EFM's negative impact on labor and delivery decisions and the profession's lack of agreement on EFM definitions, nomenclature and interpretation, the National Institute of Child Health and Human Development held workshops to try and develop standardized and unambiguous EFM definitions. In workshops held between May 1995 and November 1996, no consensus could be reached.

⁵⁹ *Id.*

⁶⁰ *Id.*; see also Ernest M. Graham et al., *Intrapartum Electronic Fetal Heart Rate Monitoring and the Prevention of Perinatal Brain Injury*, 108 OBSTETRICS & GYNECOLOGY 656, 656 (2006) (summarizing EFM history and clinical studies and concluding that EFM has no effect on perinatal mortality or pediatric neurologic morbidity).

C. Beguiled by Technology⁶¹

Two decades following EFM's clinical introduction, EFM had become a classic oxymoron. Enthusiasm for EFM's promises had substantially declined, but its use had multiplied exponentially. In 1980, EFM was used in 45% of all labors; in 1988, 62%; in 1992, 74%; and 85% in 2002.⁶² The increasing EFM use occurred with the well-documented knowledge that EFM was introduced without proof of efficacy or safety⁶³ and in spite of continuous publication of irrefutable studies proving that its use produced no better outcomes than intermittent auscultation.⁶⁴ Why?

Twelve controlled trials proving EFM's promises illusory were disturbing. Even more disturbing was the dawning reality that the EFM courtroom experts, possessed of the uncanny ability to deliver neurologically intact, healthy children in the courtroom, something their colleagues could not do in the delivery room, were proving to be voluble charlatans.

D. EFM Courtroom Experts Unmasked

The courtroom experts had a huge advantage: a computer-like machine with lights, dials, switches, a digital readout, and a continuous tracing on precisely spaced graph paper. It looked scientific. It looked like the precise mathematical calculations of the apogee/perigee of Apollo 11's moon mission. And the courtroom experts matched the graph's precision with precise pronouncements of the exact minute each baby should have been delivered. Their unambiguous calculations were backed by their own books and articles displaying the fetal heart rate patterns they said predicted a fetus's sure and certain neurologic doom.⁶⁵ These experts dismissed and distinguished each of the 12 randomized contrary studies as they were published: the study population was not uniform, the study population was not large enough, there were too few controls, there were too many differences in techniques, and so on.⁶⁶ The courtroom experts held firm. In their hands, EFM was indeed a *deus ex machina*.

⁶¹ Dr. Roger Rosenblatt, quoted in a 1988 *New York Times* article concerning EFM use, which, even in 1988, was recognized as not producing healthier babies. Dr. Rosenblatt said EFM would remain the norm despite contrary studies both because "we are beguiled by technology" and because of malpractice concerns. Tamar Lewin, *Despite Criticism, Fetal Monitors Are Likely to Remain in Wide Use*, N.Y. TIMES, Mar. 27, 1988, at 24, available at <http://www.nytimes.com/1988/03/27/us/despite-criticism-fetal-monitors-are-likely-to-remain-in-wide-use.html> (last visited May 24, 2012).

⁶² ACOG Practice Bulletin 106, *supra* note 3.

⁶³ Greene, *supra* note 6; R.K. FREEMAN ET AL., *supra* note 7, at 4; MacDonald, *supra* note 8, at 659; Thacker et al., *Efficacy*, *supra* note 57, at 619.

⁶⁴ Greene, *supra* note 6; R.K. FREEMAN ET AL., *supra* note 7, at 4; MacDonald, *supra* note 8, at 659; Thacker et al., *Efficacy*, *supra* note 57, at 619.

⁶⁵ E.g., Schiffrin et al., *supra* note 35; R.K. FREEMAN ET AL., *supra* note 7; Shields & Schiffrin, *supra* note 35; Keegan et al., *supra* note 35; Hon, *supra* note 34.

⁶⁶ Graham et al., *supra* note 60, at 659-62; Jenkins, *supra* note 23, at 211-12.

The courtroom experts also ignored other EFM realities. An electronic fetal monitor is not a monitor at all. It is merely a recorder. A monitor is a machine that monitors incoming data, taking actions when parameters are exceeded—turns off, turns on, decreases, increases, or sounds an alarm. EFM merely records data that must be interpreted. Interpretation is an art. It always leaves room for bias, especially, as with EFM, when there is little scientific data supporting the interpretation.⁶⁷ Thus, studies of the experts revealed that their courtroom interpretation precision did not exist. Tested under controlled circumstances, experts frequently disagreed with each other and themselves. Inter-observer/intra-observer variability was the rule, not the exception—exactly the opposite of the experts' courtroom testimony. Harmless fetal heart rate changes were interpreted as fetal distress. Ominous tracings were designated as reassuring. The studies were not done under the stress of delivering a baby and making the right decisions. They were done in controlled, relaxed environments.⁶⁸

In one study, experienced obstetricians agreed in only 20% of cases. Two months later, the same tracings were presented to the same interpreters. Twenty percent were interpreted differently.⁶⁹ In another study, 12 national EFM experts interpreted 14 abnormal tracings. On average, two experts disagreed one-third of the time when asked to classify the patterns as innocuous, non-reassuring, or ominous, and they disagreed with almost the same frequency over the issue of continuing the labor or delivering immediately.⁷⁰ In a British study, the experts classified 32% of the normal tracings, the controls, as having ominous tracings in the second stage of labor.⁷¹ Inconsistent, unreliable fetal heart tracing interpretation by experts was really old news. A 1978 British study had already revealed inconsistent EFM interpretations by five experienced observers.⁷²

⁶⁷ Jenkins, *supra* note 23, at 211.

⁶⁸ Mark P. Umstead et al., *Intrapartum Cardiotocography and the Expert Witness*, 34 *AUSTL. & N.Z. J. OBSTETRICS & GYNECOLOGY* 20 (1994); A. Larssen, *The Role of the Obstetrician in Preventing Fetal Asphyxia*, in *BRAIN LESIONS IN THE NEWBORN* 361 (H.C. Lou et al. eds., 1994); Geraldine Gaffney et al., *Case-Controlled Study of Intra-Partum Care, Cerebral Palsy, and Perinatal Death*, 308 *BRIT. MED. J.* 743 (1994); Patrick E. Shrout et al., *Reliability and Reproducibility of Non-Stress Test Readings*, 159 *AM. J. OBSTETRICS & GYNECOLOGY* 554 (1988); T.V. Nielsen et al., *Intra- and Inter-Observer Variability in the Assessment of Intrapartum Cardiotocograms*, 66 *ACTA OBSTETRICAL & GYNECOLOGICA SCANDINAVICA* 421 (1987); Alan B. Cohen et al., *Electronic Fetal Monitoring and Clinical Practice: A Survey of Obstetric Opinion*, 2 *MED. DECISION MAKING* 79 (1982); J.B. Trimbos & M.J. Kerse, *Observer Variability in Assessment of Antepartum Cardiotocograms*, 85 *BRIT. J. OBSTETRICS & GYNAECOLOGY* 900 (1978).

⁶⁹ Larssen, *supra* note 68, at 366.

⁷⁰ Cohen et al., *supra* note 68, at 84.

⁷¹ Gaffney, *supra* note 68, at 746.

⁷² Trimbos & Keirse, *supra* note 68.

E. Courtroom Experts: EFM Hindsight Bias

EFM tracing misinterpretation and intervention timing disagreements were one thing, but other studies were revealing what had been known for many years—courtroom experts were biased by knowing that there was a poor neonatal outcome.⁷³ The first physician hindsight bias experiment demonstrated the substantial bias generated when anesthesiologists, knowing that there had been a poor outcome, analyzed colleagues' anesthesia records.⁷⁴ A similar EFM study with 36 board-certified obstetricians and perinatologists practicing obstetrics reflected a similar substantial bias. True case histories and EFM tracings were prepared. For each true case, an exact duplicate sham case was prepared with the opposite neonatal outcome. One month intervened between data reviews. When the outcome changed to permanent disability, 33% of the participants changed their opinions, “demonstrating that knowledge of poor neonatal outcome makes reviewers more likely to criticize another obstetrician’s management and find evidence of fetal hypoxia on fetal heart rate tracings.”⁷⁵ But despite the evidence that courtroom experts were

⁷³ Harry A. Zain et al., *Interpreting the Fetal Heart Rate Tracing: Effect of Knowledge of Neonatal Outcome*, 43 J. REPRODUCTIVE MED. 367, 367 (1998).

⁷⁴ Robert Caplan et al., *Effect of Outcome on Physician Judgments of Appropriateness of Care*, 265 J.A.M.A. 1957 (1991). Practicing anesthesiologists judged anesthesia care not knowing the outcome, then later knowing that the outcome was death or severe injury but unaware that they were reviewing charts they had previously assessed. There was a 30% shift in judgment from appropriate care rendered to inappropriate care rendered when the outcome was known. *Id.*

⁷⁵ Zain et al., *supra* note 73, at 369. Physicians are not the only experts subject to hindsight-outcome biases. A recent study of fingerprint experts revealed a surprising lack of objectivity in what is thought of as infallible science. Professor Ipiel Dror, then professor of psychology at South Hampton University, arranged to have six experts from the UK, United States, and Australia, none of whom knew they were participating in a study, make judgments on fingerprints they had previously judged as matches or exclusion in court testimony. Ipiel Dror & Robert Rosenthal, *Meta-Analytically Quantifying the Reliability and Biasability of Forensic Experts*, 53 J. FORENSIC SCI. 900, 901 (2008). Out of 48 tests, the experts changed their decisions in six cases. *Id.* Only two experts were consistent with their previous decisions in all 48 cases. *Id.* It was found that the experts were more likely to change their opinions if given contextual information such as the suspect has confessed or the suspect has an alibi. *Id.* at 903. Dr. Dror has published many other articles on expert bias and has others in preparation. He is now principal consultant and researcher at Cognitive Consultants International Ltd. See also Michael Cherry et al., *Another “View” of Fingerprint Evidence*, 94 JUDICATURE 306 (2011) (attacking the reliability of fingerprint examination testimony); *Strengthening Forensic Science in the United States: The Path Forward: Hearing Before the S. Comm on the Judiciary*, 111th Cong. (2009) (statement of Hon. Harry T. Edwards, Sr. Cir. Judge and C.J. Emeritus, D.C. Cir. and Visiting Professor of Law, N.Y.U. Sch. L. and Co-Chair, Comm. on Identifying the Needs of the Forensic Sci. Community the Research Council of the National Academies) (concluding that all but two of the forensic sciences, including fingerprint analysis, are not based on proven scientific data), available at <http://www.judiciary.senate.gov/pdf/09-03-18EdwardsTestimony.pdf> (last visit May 24, 2012). For commentary on the National Academy Report, see Jennifer L. Mnookin et al., *The Need for a Research Culture in the Forensic Sciences*, 58 UCLA L. REV. 725 (2011); Joseph P. Bono, *The Blame Game Has Run Its Course: Strengthening Forensic Investigation*, 74 TEXAS B.J. 592 (2011). Bono, a past president of the American Academy of Forensic Sciences, argues that the forensic sciences are not broken as indicated by the NAS report but that they need strengthening by more “targeted research into

really self-anointed and biased, CP verdicts continued to increase every year. Why?

F. Simple Theory, Greater Risk

EMF theory is irresistibly simple: monitor, identify fetal distress, intervene in the labor by simple cesarean section, and rescue a child in distress from a life of neurologic devastation. In actuality, however, fetal monitors did not involve new concepts, beyond the intricacies involved in the computer algorithm. EFM automated information recording previously manually recorded after intermittent auscultation. But, of course, EFM being continuous, it presented exponentially more of the same auscultation data. EFM came to be thought of as an infallible method of detecting fetal asphyxia, “and somehow even the act of attaching a machine to the patient would confer a protected status.”⁷⁶

It was this exponential increase in data that allowed the courtroom experts to claim to be able to do what medicine had been unable to accomplish: pinpoint the exact time when the fetus sustained irreversible brain damage.⁷⁷ That point on the fetal monitor chart became the “moving finger”⁷⁸ writing out the jury’s damage award against the inattentive and uneducated physicians and nurses who allowed labor to continue past that point without intervening. The intervention of choice was cesarean section.

Survivable C-sections were occurring in different parts of the world by the nineteenth century, although cesarean section had been a part of the history of many cultures since ancient times.⁷⁹ Today, with advances in anesthesia, antibiotics, blood transfusions, and the modern hospital, it is very popular in many countries. C-section rates are estimated to be 46% in China, 27%

using these methods to individualize evidence.” *Id.* at 593. Finally, even the shaken baby syndrome has come under attack, with a polar shift in mainstream medical opinion. Mark Hansen, *Unsettling Science*, A.B.A.J., Dec. 2011, at 48.

⁷⁶ Jenkins, *supra* note 23, at 211.

⁷⁷ See Graham et al., *supra* note 60, at 662.

⁷⁸ Omar Khayyám, *The Rub‘aiy‘at*, in *INTERPRETATIONS: EDWARD FITZGERALD’S THE RUB‘AIY‘AT OF OMAR KHAYY‘AM*, 4 (Harold Bloom ed., 2004) (Edward FitzGerald trans., 1859).

The Moving Finger writes, and having writ, Moves on: nor all your Piety nor Wit shall lure it back to cancel half a Line, Nor all your Tears wash out a word of it.

Id.

⁷⁹ See Jane E. Sewell, *Cesarean Section—A Brief History: A Brochure to Accompany an Exhibition on the History of Cesarean Section at the National Library of Medicine, April 30–August 31, 1993*, NATIONAL LIBRARY OF MEDICINE, NATIONAL INSTITUTES OF HEALTH, available at <http://www.nlm.nih.gov/exhibition/cesarean/index.html> (last visited May 19, 2012).

across Asia,⁸⁰ and above 30% in the United States, with similar rates in other developed countries around the world.⁸¹ Without doubt, cesarean section is popular.

C-sections have not always been so popular, however. When EFM was introduced into clinical practice, the U.S. C-section rate was six percent.⁸² Why the five-fold increase? That question has generated a fierce 40-year debate. Every conceivable group has decried the increase, laying the blame at the feet of greedy hospitals and physicians, physicians' fears of malpractice suits, physicians' convenience, women's convenience, and dozens of other reasons.⁸³

Implicit in the C-section debate among consumers and obstetricians, however, was the assumption that C-sections were absolutely necessary to save distressed infants who would otherwise experience CP or other neurologic injury if not promptly delivered after EFM-diagnosed fetal distress. Courtrooms were full of experts who were saving hundreds of children from neurologic devastation by correctly interpreting the fetal monitoring patterns and quickly performing a simple, easy C-section, something the defendant physicians could have done. But that was in the courtroom. Results there are often self-fulfilling prophecies. Such was the case for the EFM fetal distress rescue by timely C-section canard.

The first suggestion that EFM-motivated C-sections did not decrease perinatal morbidity or mortality was the 1976 Haverkamp Denver study.⁸⁴ EFM proponents attacked the conclusion with explanations to explain EFM's

⁸⁰ China's 46% is the world's highest rate, according to the World Health Organization. *C-Section Rates Around Globe at "Epidemic" Levels*, MSNBC, Jan. 12, 2010, available at <http://www.msnbc.msn.com/id/34826186/> (last visited May 24, 2012). The motivation? For hospitals, it may be money. *Id.*

⁸¹ *Id.*

⁸² Benjamin P. Sachs, *Is the Rising Rate of Cesarean Sections a Result of More Defensive Medicine?*, in PROFESSIONAL LIABILITY AND THE DELIVERY OF OBSTETRICAL CARE 31 (Table 2) (Victoria P. Rostow & Roger J. Bulger eds., 1989).

⁸³ E.g., Jennie Yabaff, *Birth, The American Way*, NEWSWEEK, Jan. 28, 2008, at 46. Yabaff describes a documentary film, *The Business of Being Born*, the message of which is that C-sections should not be the first choice for healthy mothers. Hospitals are a target, with the suggestion that the profit motive propels them to push (no pun intended) for C-sections that "cost three times as much as a normal birth," according to the documentary makers. *Id.*; Jeffrey Ecker & Fredric D. Frigoletto, *Cesarean Delivery and the Risk Benefit Calculus*, 356 NEW ENG. J. MED. 885 (2007) (arguing that the increased C-section rate is explained primarily by modern women's risk adverse attitude that physicians must accommodate); Earl Ubell, *When Is a Cesarean Really Necessary?*, PARADE MAG., Oct. 25, 1992; Todd Ackerman, *Cesarean Sections on the Rise Again*, HOUS. CHRON., Aug. 29, 2000, at A1; Jane Brody, *4 Childbirth Experts Challenge U.S. Goal to Limit Cesareans*, HOUS. CHRON., Jan. 7, 1999, at A8.

⁸⁴ The Haverkamp and other EFM randomized studies are analyzed in Graham, et al., *supra* note 60, at 659-62. Graham and his co-authors identified 1,628 MEDLINE articles on EFM and its relation to specific neurologic outcomes published between 1966-2006. Forty-one studies met selection criteria for in-depth analysis. The authors conclude, as did hundreds of other worldwide studies, that EFM has no effect on perinatal mortality or pediatric neurologic morbidity. See also Sartwelle, *Defending*, *supra* note 2 (analyzing the worldwide literature).

failure.⁸⁵ More studies followed. Those studies also questioned EFM's association with high cesarean rates, high infection rates, high costs, and no demonstrated fetal benefits.⁸⁶ EFM proponents attacked those studies' conclusions as well. Defending EFM as the standard of care is best illustrated by the newspaper account of a 1981 Oklahoma City trial, finding an obstetrician negligent for not using a fetal monitor. Dr. Edward Hon, EFM's inventor, was a plaintiff expert.⁸⁷ EFM's courtroom advantages won the day.

Outside the courtroom, however, EFM interpretation as to when a C-section was needed did not fare nearly as well. Obstetricians, given a certain data set about a mother and fetus, would opine that a C-section was necessary but given the same data later would favor vaginal delivery.⁸⁸

In 1994, EFM's basic foundation, preventing CP, MR, and epilepsy, was severely eroded. Despite almost one-quarter of the babies born in the United States being delivered by C-section, neither the rate of CP nor that of any other childhood neurologic problems had been affected in the slightest.⁸⁹ In 1996, National Institutes of Health (NIH) neuroepidemiologist Dr. Karin Nelson set out to explore associations between specific EFM heart patterns and long-term neurologic outcomes. Nelson and her colleagues found that, in term and near-term infants, multiple late decelerations and increased beat-to-beat variability, long heralded as ominous signs of fetal distress demanding rapid delivery, were associated with a significant increase in CP risk. None of the other supposedly ominous EFM findings populating the EFM textbooks and courtroom testimony were associated with an increased CP risk. But almost three-quarters of the children who had CP did not have multiple late decelerations or decreased beat-to-beat variability. On the other hand, most of the children with multiple late decelerations or decreased beat-to-beat variability did not have CP. EFM had a false-positive rate of 99.8%.⁹⁰ EFM's foundation had been destroyed.

G. EFM: An Absurd Machine?

Subsequent EFM analysis continued to reveal EFM's futility. The evidence left no doubt that EFM combined with C-sections resulted in no decrease in perinatal deaths, no fewer admissions to NICU, no fewer APGAR scores

⁸⁵ Graham et al., *supra* note 60, at 659.

⁸⁶ *Id.* at 659.

⁸⁷ *Id.* at 660.

⁸⁸ Joseph M. Scheller & Karin B. Nelson, *Does Cesarean Delivery Prevent Cerebral Palsy or Other Neurologic Problems of Childhood?*, 83 *OBSTETRICS & GYNECOLOGY* 624 (1994); Richard Lilford et al., *The Relative Risk of Cesarean Section and Vaginal Delivery*, 97 *BRIT. J. OBSTETRICS & GYNAECOLOGY* 883, 889-91 (1990).

⁸⁹ *Cf.* Scheller & Nelson, *supra* note 88, at 629.

⁹⁰ Karin B. Nelson et al., *Uncertain Value of Electronic Fetal Monitoring in Predicting Cerebral Palsy*, 334 *NEW ENG. J. MED.* 613 (1996).

below 7 or below 4, and no decrease in cerebral palsy rates or any other childhood neurologic problems in any of the world's developed countries.⁹¹ The scientific EFM verdict was delivered by peer-reviewed research and editorial opinion: "There is no evidence of good quality that surgical delivery can prevent cerebral palsy"⁹²; "clearly, the hoped-for benefit from intrapartum electronic fetal monitoring has not been realized"⁹³; "advances in maternal-fetal medicine and neonatology have resulted in dramatic reductions in the mortality of high-risk infants. ... Unfortunately, there has been no progress in reducing the prevalence of cerebral palsy"⁹⁴; "when electronic fetal monitoring was rigorously assessed, however, the results provided little support for its use"⁹⁵; "a test leading to an unnecessary major abdominal operation in more than 99.5% of cases should be regarded by the medical community as absurd at best. ... Operative intervention based on electric fetal monitoring has probably done more harm than good. . . ."⁹⁶

The greatest harm came from the increased risks associated with cesarean sections, such as hemorrhage, infection, and thromboembolic events like air or amniotic fluid embolization.⁹⁷ A recent study found women having a non-emergency C-section have double the risk of complications, even death, compared to a vaginal birth.⁹⁸ Yet even today EFM continues unabated, as do EFM-dictated C-sections. Why?

A lesser, but still important, EFM harm were the verdicts against physicians and nurses that juries wrongfully convicted of negligently destroying young lives because courtroom experts said EFM was the *deus ex machina*. Why do these charlatans, so clearly espousing obsolete rubbish mixed with medical myth, continue unabated?

⁹¹ Russell Miller & Richard Depp, *Minimizing Perinatal Neurologic Injury at Term: Is Cesarean Section the Answer?*, 35 CLINICS PERINATOLOGY 549 (2008); Zarko Alfievic et al., *Continuous Cardiotocography (CTG) as a Form of Electronic Fetal Monitoring (EFM) for Fetal Assessments During Labor (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2008), available at <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006066/pdf> (last visited May 19, 2012); Graham et al., *supra* note 60; Stephen Clark & Gary Hankins, *Temporal and Demographic Trends in Cerebral Palsy—Fact and Fiction*, 188 AM. J. OBSTETRICS & GYNECOLOGY 628 (2003).

⁹² Nelson, *supra* note 17, at 1768.

⁹³ R.K. Freeman, *Intrapartum*, *supra* note 33, at 625.

⁹⁴ Jon E. Tyson & Larry C. Gilstrap, *Hope for Perinatal Prevention of Cerebral Palsy*, 290 J.A.M.A. 2730 (2003).

⁹⁵ Greene, *supra* note 6, at 2247.

⁹⁶ Clark & Hankins, *supra* note 91, at 631. Clark & Hankins were an echo from the past. In a 1979 review article, British Emeritus Professor of Child Health, Ronald S. Illingworth, noted that EFM had done nothing to improve fetal well-being. Illingworth, *supra* note 15, at 800. He concluded by saying: "That which is most up-to-date and new is not necessarily the best." *Id.*

⁹⁷ Nelson, *supra* note 17, at 1768.

⁹⁸ Jose Villar et al., *Maternal and Neonatal Individual Risk and Benefits Associated with Cesarean Delivery: Multi-Center Prospective Study*, 335 BRIT. MED. J. 1025 (2007).

EFM began with a noble purpose and pure motives, but was based on a catastrophic misunderstanding of fetal pathophysiology.⁹⁹ What began as innocent misinformation about cerebral palsy's causal relationship to labor and delivery and EFM's ability to predict cerebral palsy was turned into disinformation by the perfect litigation storm that engulfed society in the 1960s and beyond. Cerebral palsy, EFM, and the birth process were kidnapped in the midst of the storm. Society and the physicians, nurses, and midwives unjustly convicted of causing cerebral palsy are paying the ransom. At the same time the American Congress of Obstetricians and Gynecologists (ACOG) and its worldwide sister organizations¹⁰⁰ did little if anything of practical value to educate its members or the public about the disinformation or rescue the extortion victims from their courtroom afflictions.

It is ACOG et al.'s inaction that answers the why questions. Why did EFM proliferate despite proof positive it produced no better outcomes but increased C-sections? Why did self-anointed courtroom experts wreak such havoc? Why does EFM continue today? The answers are because ACOG and its worldwide sister organizations would not and will not take a stand with its members against EFM's ubiquity nor explain to the lay public EFM's weaknesses and limitations especially when used as a courtroom blackjack.

ACOG et al. should have taken these stands long ago, before the EFM myth became solidified. Early in EFM's proliferation, ACOG et al. could have published official practice bulletins, as well as explained to the lay public that EFM is useful because it saves labor costs but its clinical efficacy needs to be extensively studied before it is accepted as the standard of care in delivery rooms or courtrooms. But they did no such thing. ACOG et al. could have said EFM's courtroom use is pseudoscience and unreliable. But they did no such thing.

ACOG et al. chose to lead from behind. They chose to let trial lawyers', the public's, and even physicians' belief in magic and myth, rather than science, win the day. Perhaps we are slipping into a new form of darkness, one where it is politically correct to suppress science.¹⁰¹ And, as we will see, even if ACOG et al. decided today to become the EFM thought leader, it is doubtful that they could quickly dispel the EFM-CP myths.

⁹⁹ Fritz K. Beller, *The Cerebral Palsy Story: A Catastrophic Misunderstanding in Obstetrics*, 50 OBSTETRICS & GYNECOLOGY SURVEY 83 (1995).

¹⁰⁰ These organizations will be referred to collectively as ACOG et al. which includes all U.S. and worldwide professional societies interested in CP causation, as well as EFM. Those would include obstetricians, pediatricians, perinatologists, maternal fetal medicine specialists, pediatric critical care medicine, as well as the nursing and midwife societies involved in labor and delivery.

¹⁰¹ See STEVE MILLOY & MICHAEL GOUGH, *SILENCING SCIENCE* (1998).

H. ACOG et al. and EFM: A History of Dereliction of Duty

For two score years, ACOG and related societies worldwide have been paralyzed while trial lawyers and their EFM courtroom experts transformed EFM from a glorified electronic heartbeat counter into a miracle machine, the magnum opus of obstetrics. In courtrooms across the US as well as in other industrialized nations worldwide, EFM was the mainstay for increasingly large and frequent CP verdicts against physicians, hospitals, nurses, and midwives.¹⁰² The culmination today is an international medical liability crisis, much of which is centered around CP-EFM and alleged obstetrical malpractice.¹⁰³ The cause of the crisis is multifaceted but primarily related to the oxygen deprivation solely causes CP myth.¹⁰⁴ What is inexplicable is ACOG's and other worldwide societies' nonresponse to the crisis and the

¹⁰² Jacobson, *supra* note 51, at 120. The Physician Insurance Association of America (PIAA) statistics indicate EFM to be the driving factor in neurologically impaired infant cases. *Id.* at 122-23. In the 1997 PIAA survey, EFM and fetal distress appeared in 88% of cases, making it reasonable to conclude that EFM technology actually resulted in higher physician exposure to liability claims. *Id.* at 123. This was Lent's point, as well. Lent, *supra* note 51, at 807. Since EFM's beginning, CP-neurologically injured baby cases have routinely involved allegations of failure to monitor with EFM or, having monitored, the failure to properly read, interpret and act on the EFM strip. *E.g.*, Lochhead, *supra* note 51; Cartwright & Thomas, *supra* note 51; MOLLY E. CONDRA, CREATING SAFER PERINATAL DEPARTMENTS IN HOSPITALS (2006), available at <http://www.healthleadersmedia.com/content/80905.pdf> (last visited May 19, 2012) (Healthstream, the publisher, is an HCA associated association with access to HCA statistics). EFM is a hospital's most challenging risk management problem because the most frequent perinatal allegation is delayed EFM diagnosis of fetal distress. *Id.* LaValley & Hoffman, *supra* note 51, at 3; CRICO STRATEGIES, *supra* note 51, at 8, 16.

¹⁰³ As to an international obstetrical malpractice crisis, see, e.g., Alastair MacLennan et al., *Only an Expert Witness Can Prevent Cerebral Palsy*, 8 OBSTETRICS & GYNECOLOGY 28 (Autumn 2006) (analyzing cerebral palsy and EFM litigation in Australia and US, concluding that it is gradually destroying the Australian maternity services); Alastair MacLennan et al., *Who Will Deliver Our Grandchildren?*, 294 J.A.M.A. 1688 (2005) (describing a worldwide medical malpractice crisis, much of which centers around alleged obstetrical malpractice and EFM); Gene Bishop, *Letter to the Editor*, 295 J.A.M.A. 626 (2006) (discussing *Who Will Deliver Our Grandchildren?*, suggesting CP children face extraordinary health care costs that could be met by a national health care system); AlastairMacLennan et al., *Cerebral Palsy Litigation—Reply to a Letter*, 295 J.A.M.A. 626 (2006) (in reply to Bishop, the authors pointed out that Australia, Britain, and Canada have national health care systems, but also have significant malpractice litigation with high rates of obstetrical malpractice allegations); John V. Banta, *Medical Liability Crisis: An International Problem*, 45 DEVELOPMENTAL MED. & CHILD NEUROLOGY 363 (2003) (the title reflects the author's premise); Karen Birchard, *No-Fault Awards for Babies with Cerebral Palsy in Ireland?*, 356 LANCET 664 (2000) (Birchard writes that Ireland was instituting a CP no-fault compensation scheme in July 2001 because of high obstetrical insurance costs prompted by frequent claims and high awards; in one CP suit, the child recovered a multi-million-dollar award, but the legal fees were almost twice as much as the award).

¹⁰⁴ Stated otherwise, EFM is premised on the "knowledge" that a fetus experiencing heart rate abnormalities on a fetal monitor is experiencing oxygen deprivation, hypoperfusion and/or ischemia and, if unrelieved, will quickly suffer permanent brain damage. This premise is, simply put, still as unproven today as it was in 1870 or 1970. *See, e.g.*, Obladen, *supra* note 28 (causal connection between CP and asphyxia, hypoxia, ischemia never established); MacLennan et al., *Only*, *supra* note 103 (no evidence that non-resassuring heart rate patterns reflect impending cerebral palsy or, if they do, that the process is reversible); MacLennan et al., *Who*, *supra* note 103, at 1689 ("birth can be a hazardous journey, and EFM does not help"); John M. Freeman & Karin B. Nelson, *Intrapartum Asphyxia and Cerebral Palsy*,

undeniable data refuting EFM's fundamental premise—fetal heart rate alterations reflect fetal distress.¹⁰⁵

The data against EFM's use in labor and delivery suites and the world's courtrooms began to accumulate before EFM was in use clinically. Adverse EFM data continued accumulating for four decades and continues today. ACOG et al., after first ignoring the obvious developing EFM dichotomy—adverse data but continued widespread use—began to develop practice bulletins and other literature directed only to practitioners. But these bulletins were written in timid, noncommittal language neither confirming nor denying EFM efficacy or the risks associated with excessive C-sections or trying to assist physicians and nurses assaulted in the courtroom with false EFM science.

How could ACOG et al. have helped? First, it could have recognized the accumulating data and the increasing risks of harm from the exponential rise in C-sections and firmly, declaratively, and plainly stated, both to physicians and the public, that EFM must be clinically vetted before it is declared reliable. Second, it could have addressed the legal drama where EFM courtroom experts were convincing lay jurors EFM was magical and error-free. Courtroom experts learned early in the process to articulate their EFM mantra in plain, confident courtroom language, eschewing the inherent incertitude of ACOG et al.'s noncommittal medical-scientific language that filled ACOG et al.'s only EFM communications—professionally directed practice bulletins. Unfortunately, ACOG et al. has failed this rather simple language lesson repeatedly throughout the years, despite multiple opportunities to reveal EFM's shortcomings. Even today, as we will see, ACOG's latest attempt to bring perspective to EFM—Practice Bulletin 106 (P.B. 106)—still has not fully embraced the simple declarative statement that says: EFM is unreliable; use with caution in the delivery room and not at all in the courtroom. ACOG's failure to take a definitive position, even in P.B. 106, reinforces the oft-repeated courtroom fable that EFM is a machine that predicts the unknowable—the development of cerebral palsy.

EFM's history from the 1960s to the present is a roadmap of opportunities for ACOG et al. to have protected women and babies in labor and delivery suites, as well as their colleagues in the courtrooms. Unfortunately, the roadmap is one of impotence rather than action, timidity rather than boldness, and a testament to dereliction of duty to patients and colleagues alike.

82 PEDIATRICS 240 (1988) (there is no proof asphyxia-hypoxia associated with EFM patterns or that any such patterns indicate sufficient degree, duration, or severity to cause irreversible brain damage).

¹⁰⁵ *Id.*

I. ACOG et al. in the 1960s and 1970s: Red Flags—No Penalties

As EFM was being introduced into clinical practice, its very intrinsic essence—fetal heart rate reflects fetal distress—was undermined by the Collaborative Perinatal Study's auscultated fetal heart rate data. In 1968, Benson and colleagues concluded there was no "reliable indicator of fetal distress in terms of fetal heart rate save in extreme degree."¹⁰⁶ Despite this and other early red flags¹⁰⁷ professional societies raised no alarms nor suggested further study or clinical trials. Instead, EFM rocketed into labor and delivery rooms worldwide like the Beatles rocketed to stardom.

Haverkamp, the first randomized EFM trial in 1976, raised more "noEFM benefit" red flags,¹⁰⁸ as did the 1980 follow-up to the original Haverkamp trial.¹⁰⁹ In the 1970s, individual commentators made strong challenges to EFM's alleged infallibility and began sounding an alarm pointing out EFM's false premise, the increasing Caesarean sections accompanying EFM use, its non-efficacy compared to auscultation, as well as the conflicting EFM data interpretation by experienced EFM observers.¹¹⁰ ACOG et al. remained quiet.

As the 1970s ended, Banta and Thacker wrote that the data compelled the conclusion that EFM had low predictive value, was of high cost to the individual and society, and had been prematurely diffused into clinical practice.¹¹¹ The EFM courtroom experts ignored these red flags, continuing their courtroom EFM infallibility advocacy and thereby greatly assisting the 1970s medical malpractice crisis to peak.¹¹² Despite the escalating EFM courtroom blame barrage indicting obstetricians for causing CP, ACOG et al. remained firmly on the sidelines, uninterested that almost every physician being blamed for causing a lifelong neurologic birth injury was indicted by a markedly dubious technology interpreted by biased experts whose courtroom interpretations were repeatedly proven to be inconsistent at best.

J. ACOG et al. in the 1980s: More of the Same

The 1980s saw more randomized trials. Each concluded EFM had no better outcomes than auscultation but did provoke substantially higher

¹⁰⁶ Benson et al., *supra* note 20, at 533.

¹⁰⁷ E.g., R.W. Beard et al., *The Significance of the Changes in Continuous Fetal Heart Rate in the First Stage of Labor*, 78 J. OBSTETRICS & GYNECOLOGY BRIT. COMMONWEALTH 865 (1971) (questioning EFM's premise); J.W. Crawford et al., *The Use of Computers in Fetal Monitoring*, 34 OBSTETRICS & GYNECOLOGY SURVEY 627 (1974) (EFM machine is nothing more than an electronic recorder, not a monitor); Norman Walker, *The Case for Conservative Management of Fetal Distress*, 2 BRIT. MED. J. 1221 (1959) (calling into question the clinical criteria for diagnosing fetal distress).

¹⁰⁸ See Haverkamp et al., *supra* note 54.

¹⁰⁹ Langendoerfer et al., *supra* note 56, at 103.

¹¹⁰ H.D. Banta & F.B. Thacker, *Assessing the Costs and Benefits of Electronic Fetal Monitoring*, 34 OBSTETRICS & GYNECOLOGY SURVEY, 627 (1979); Trimbo & Keirse, *supra* note 68.

¹¹¹ *Id.*; see Jenkins, *supra* note 23, at 211–12 (summarizing early published EFM critiques).

¹¹² See, e.g., Danzon, *supra* note 41.

C-section rates and increased forceps use with attendant increase in C-section morbidity and mortality.¹¹³ Other studies verified the inherent interobserver-intra-observer bias resulting in frequent, significant monitor strip misinterpretation.¹¹⁴ Even the lay press noted EFM's failure to produce healthier babies despite widespread use.¹¹⁵ ACOG et al. continued their silence while juries continued believing physicians caused CP and EFM could predict and prevent CP. Verdicts multiplied as did the cost of litigation.¹¹⁶

As the 1980s ended, an Institute of Medicine committee studying obstetrical care delivery in the United States issued a comprehensive report on all aspects of OB care. One chapter focused on medical professional liability and its effect on OB practice.¹¹⁷ Among other things, the committee noted that "46% of obstetrical legal claims involved EFM."¹¹⁸ Claims of "failure to monitor" are commonplace in these cases.¹¹⁹ One insurer stated that CP was the second highest diagnosis in total indemnity dollars following breast cancer.¹²⁰

The committee observed that EFM's initial adoption was fueled in part by medical liability concerns. Concluding that the medical evidence "overwhelmingly" proved that EFM did nothing to improve infant mortality or morbidity, the committee recognized that the professional liability climate contributed to its continued use. The chapter concludes by acknowledging that the incidence of cerebral palsy is "still popularly and erroneously believed by many to be the result of fetal asphyxia, [which] had not been reduced by EFM."¹²¹ Not only were there no demonstrated EFM benefits, but it was also costly in terms of increased health care costs and increased patient morbidity due to increased C-section surgeries.¹²²

About the same time, a similar EFM sentiment was published by United Kingdom Ob-Gyn professor H.M.L. Jenkins. After tracing EFM development and clinical use and the associated efficacy studies, Jenkins concluded that

¹¹³ E.g., Freeman & Nelson, *supra* note 104, at 241.

¹¹⁴ ShROUT et al., *supra* note 68; Nielsen et al., *supra* note 68; Cohen et al., *supra* note 68.

¹¹⁵ Lewin, *supra* note 61.

¹¹⁶ See, e.g., Lent, *supra* note 51. Beller notes that in the early 1980's WHO labeled EFM costly and unproven technology unwarranted for export to undeveloped countries who could better use their resources for midwives. Beller, *supra* note 99. "A number of obstetric societies protested saying WHO was irresponsible." *Id.* This is proof that at least some professional societies could find a voice when it came to EFM. They apparently could not find that voice to help their colleagues in the courtroom however.

¹¹⁷ COMM. STUDY MED. PROF'L LIAB. & DELIVERY OBSTETRICAL CARE, INST. MED., DIV. HEALTH PROMOTION & DISEASE PREVENTION, 1 MED. PROF. LIABILITY & DELIVERY OB. CARE 73-91 (1989) [hereinafter 1 MEDICAL LIABILITY].

¹¹⁸ *Id.* at 81.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.* at 81-82.

¹²² *Id.*

EFM did not improve fetal evaluations in labor and could not be reinterpreted in an unbiased fashion.¹²³ In short, the problem with EFM was that obstetricians and midwives had been “thoroughly inept” at using EFM.¹²⁴ EFM not only was not very good, but was often contradictory. Jenkins noted that EFM did not really help anyone except lawyers: “The lawyers are now able, with the power of hindsight, to pillory anyone” who fails to act on even slight EFM aberrations “even though the fetus may be in good condition.”¹²⁵

These two EFM critiques were published in 1989. They were among the first to acknowledge the lawsuit reality facing obstetricians, midwives, and labor nurses. Without doubt, EFM performed poorly in clinical practice. Amazingly, it had become the worldwide default standard of care in spite of the evidence. Without it, one was automatically held liable whenever there was a bad result. With it and with the traditional advice to save every strip,¹²⁶ obstetricians presented the EFM courtroom experts with instant replay—an opportunity to re-analyze every nanosecond frame-by-frame and convince juries there was a missed opportunity to save a neurologically devastated child. It was a no-win situation for anyone delivering babies.

Where were ACOG and the other professional organizations? Faced with overwhelming data that EFM was “not very good,”¹²⁷ that courtroom interpretation was inconsistent and biased,¹²⁸ that a fetus is resistant to oxygen deprivations, that the degree of hypoxia needed to produce permanent brain damage was close to that which is lethal,¹²⁹ not to mention increased C-section mortality and morbidity,¹³⁰ should ACOG et al. have stepped in separately or together to curtail the use of an ineffective, perhaps harmful, medical device? At the very least should some organization have published an analysis summarizing EFM’s status and declaring it potentially helpful as a labor saving device but scientifically unsubstantiated and unreliable in order to at least help those physicians accused of EFM malpractice?

Apparently, the professional organizations thought the mounting negative EFM evidence was not yet sufficient to warrant a pronouncement that EFM was unreliable. National and international meetings were held where EFM critics were ignored in favor of issuing guidelines for EFM’s clinical use, along with revisions to nomenclature.¹³¹ Absent from these guidelines

¹²³ Jenkins, *supra* note 23, at 213. Jenkins, however, was not advocating EFM be abandoned. *Id.* He strongly urged more development effort because an assessment tool was desperately needed. *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 212.

¹²⁶ 1 MEDICAL LIABILITY, *supra* note 117, at 81.

¹²⁷ Jenkins, *supra* note 23, at 213.

¹²⁸ See, e.g., Gaffney et al., *supra* note 68.

¹²⁹ E.g., Freeman & Nelson, *supra* note 90, at 241.

¹³⁰ E.g., 1 MEDICAL LIABILITY, *supra* note 117, at 82.

¹³¹ A brief EFM history with descriptions of some early investigations and EFM conferences is found in Bonnie Flood Chaz & Suzanne McMurtry Baird, *Electronic Fetal Heart Rate Monitoring, Where Are*

was recognition of negative data, especially the ever-increasing C-section rate and its associated mortality-morbidity. Rather than having a frank discussion about the ever-increasing EFM risks, ACOG et al. simply called for more EFM research.¹³² Also unrecognized and absent from discussions and resulting guidelines was recognition of EFM's courtroom use or the courtroom experts' ability to unerringly deliver perfect courtroom babies with a device that in the real world was universally acknowledged as flawed. The dichotomy of continuing universal EFM clinical use and as courtroom evidence while holding national and international conferences to develop standardized nomenclature, definitions, techniques, interpretations, and responses to EFM patterns was apparently lost on the experts attending the conferences and authoring the How To guidelines.

At one point ACOG was apparently ready to abandon EFM as the standard of care according to a 1988 article by *New York Times* reporter Tamar Lewin. Interviewing Dr. Roger Freeman, the then-Chairman of ACOG's Committee on Maternal Fetal Medicine, Lewin confirmed the Committee's recommendation to abandon EFM as the standard of care, but also confirmed that many obstetricians intended to continue EFM use as legal protection, because every patient was seen as a potential litigant.¹³³

No such change ever occurred. EFM remained ACOG's standard of care, even as it does today. No contemporary account can be found explaining ACOG's retreat. Abandoning EFM as the standard of care could have been one of the most important life preservers that could have been given to mothers undergoing C-sections and to physician defendants and their lawyers. An ACOG pronouncement that EFM was unreliable and was not the standard of care would certainly have decreased pressure on physicians to do C-sections and, while not definitive in the courtroom, it would have changed the dueling experts portion of a trial to favor the defendant. As it turned out, however, ACOG allowed the plaintiffs' EFM courtroom experts to proceed unimpeded

We Now?, 25 J. PERINATAL NEONATAL NURSING 180 (2011). The International Federation of Gynaecology and Obstetrics (FIGO) may have been the first organization publishing EFM "how to" guidelines. Based on a March 1985 workshop attended by experts from virtually all industrialized countries, the 1986 guidelines were written by a FIGO subcommittee on Standards in Perinatal Medicine. The guidelines are an EFM endorsement, without mention of any published criticisms. Goesta Booth et al., *Guidelines for the Use of Fetal Monitoring*, 23 INT'L J. OBSTETRICS & GYNECOLOGY 159 (1986), available at http://www.geburtshilfe.usz.ch/Documents/HealthProfessionals/Guidelines/fetal_monitoring.pdf (last visited June 20, 2011). Numerous other workshops and conferences were held, with and without published notes, minutes, or guidelines. They are too numerous to mention, but mention of many of these meetings in the US, Canada, UK, and other countries can be found in various contemporary EFM articles. The most informative include: *ACOG-AAP*, *supra* note 17; Kennedy, *supra* note 7; Nat'l Inst. of Child Health & Human Dev. Research Planning Workshop, *Electronic Fetal Heart Rate Monitoring: Research Guidelines for Interpretation*, 177 AM. J. OBSTETRICS & GYNECOLOGY 1385 (1997) [hereinafter *1995 NIH EFM Workshop*].

¹³² E.g., *ACOG-AAP*, *supra* note 17, at 81.

¹³³ Lewin, *supra* note 61.

by any meaningful, plain, unambiguous, official ACOG pronouncement that EFM does not produce healthier babies in or out of the courtroom.

K. ACOG et al.: The 1990s and Beyond

The 1990s saw major accomplishments by ACOG et al. in unraveling the birth asphyxia, hypoxic ischemic neonatal encephalopathy (HIE), cerebral palsy non-relationship and in establishing positive evidence based on objective criteria defining when an intrapartum event could be a causative link to cerebral palsy.¹³⁴ Despite the incredible proliferation of research, guidelines, and consensus statements on cerebral palsy, asphyxia, HIE, and related topics, the 3,000-pound elephant—EFM—remained unaddressed despite the accumulating evidence confirming the criticisms from the 1970s and 1980s. EFM was not efficacious, was pushing C-section rates ever higher, and was the mainstay in CP lawsuits with ever-increasing verdicts. ACOG et al.'s only answer was the oft-repeated call for more EFM research.

In 1996, Dublin's Dermot McDonald summed up almost 30 years of clinical EFM use: "Fetal monitoring promised much but has achieved little."¹³⁵ A few began to wonder aloud why EFM critics would not call for EFM's abandonment.¹³⁶ The answer was a controversy-avoiding non-answer: a euphemistic reference to "medical legal pressures" that influenced physicians' decisions.

While EFM critics continue to publish articles and editorials condemning EFM use but failing to call for use curtailment, proponents continued to ignore the accumulating research, the ever rising C-section rate and its undeniable morbidity, defending EFM's original illusion that more of the same heartbeat data originally collected by auscultation magically would turn pumpkins into chariots.

¹³⁴ ACOG-AAP, *supra* note 16; Int'l Cerebral Palsy Task Force, *supra* note 17; Am. Coll. Obstetricians & Gynecologists Committee Opinion No. 197, *Inappropriate Use of the Terms Fetal Distress and Birth Asphyxia* (1998); Soc'y Obstetricians & Gynecologists of Can., *Task Force on Cerebral Palsy and Fetal Asphyxia*, 18 J. SOC'Y OBSTETRICIANS & GYNECOLOGISTS OF CAN. 1267 (1996); Fiona Stanley et al., Australian & New Zealand Perinatal Society, *The Origins of Cerebral Palsy—A Consensus Statement*, 162 MED. J. AUSTRAL. 85 (1995); Am. Coll. Obstetricians & Gynecologists, Committee Opinion No. 138, *Utility of Umbilical Cord Blood Acid-Based Assessment* (1994); Martin Bax et al., *Birth Asphyxia: A Statement*, 35 DEVELOPMENTAL MED. & CHILD NEUROLOGY 1022 (1993); Am. Coll. Obstetricians & Gynecologists, Technical Bulletin No. 163, *Fetal and Neonatal Neurologic Injury* (1992); AM. ACAD. PED. & AM. COLL. OBSTET. & GYNECOL., *supra* note 16; AM. COLL. OBSTET. & GYNECOL. COMM. OP. NO. 91, *Acute Intrapartum Hypoxic Encephalopathy* (1991).

¹³⁵ MacDonald, *supra* note 8, at 659.

¹³⁶ "[T]he obvious conclusions: that absent special circumstances, electronic fetal monitoring should be abandoned, and that Cesarean section (in view of its risks) should not be performed unless there is some indication other than late decelerations." Jay A. Gold, *Letter to the Editor*, 335 NEW ENG. J. MED. 287 (1996) (discussing Nelson et al., *supra* note 88).

L. Another NIH EFM Workshop

In 1995 and 1996, NIH held an EFM workshop with EFM luminaries. The purpose was to develop standardized, unambiguous EFM definitions. Why? Because “a major impediment to progress in the evaluation and investigation of [EFM] is lack of agreement in definitions and nomenclature of [EFM] patterns despite the plethora of publications on the subject.”¹³⁷ In plain language, at least a few recognized that EFM pattern interpretation supposedly signifying fetal jeopardy and the need for immediate delivery was adventitious at best, derived from the inexact, unquantifiable, and often unrepeatable mind’s eye of individual interpreters. In the end, the workshop accomplished almost nothing. There was little agreement among the participants as to how EFM patterns were to be interpreted and how they were to be used as a clinical management tool.¹³⁸ Despite the research dearth and the inability to agree on clinical management guidelines, there was no call to reduce EFM’s clinical use, nor any reference to the courtroom experts and their pseudo-scientific ability to pinpoint the exact time neurologic damage occurred when no one else in the universe could.

Another golden opportunity to displace EFM as the obstetrical default standard of care was squandered by the groundbreaking 1999 International Cerebral Palsy Task Force,¹³⁹ as well as the 2003 ACOG-AAP consensus statement.¹⁴⁰ Both task forces arrived at virtual consensus on the criteria necessary to suggest when an intrapartum asphyxial event was sufficient to cause CP.¹⁴¹ When addressing EFM, however, both defaulted. Both acknowledged EFM does not predict CP, did not prevent CP, and that retrospective analysis when the outcome was known was biased.¹⁴² Yet rather than make a profound statement about EFM’s lack of efficacy in labor rooms and courtrooms, they defaulted to the NIH workshop report with its vapid retreat into “more research is needed.” The International Task Force’s concluding EFM statement perfectly summarizes both task forces’ noncommitment to their patients facing C-sections and their colleagues facing the courtroom experts who could and did predict and prevent CP in the world’s courtrooms: “The Committee further decided . . . it was impossible . . . to reach consensus on the management of all other patterns [other than normal and/or near-death].

¹³⁷ 1995 NIH EFM Workshop, *supra* note 131, at 1385.

¹³⁸ *Id.* at 1388.

¹³⁹ Int’l Cerebral Palsy Task Force, *supra* note 17; see Sartwelle, *Defending*, *supra* note 2, at 202-03 (for a discussion of the details of this consensus statement).

¹⁴⁰ ACOG-AAP, *supra* note 17; see Sartwelle, *Defending*, *supra* note 2, at 204-05 (discussion of the details of this consensus statement).

¹⁴¹ ACOG-AAP, *supra* note 17, at xii. In the forward to the American report, Alastair MacLennan, Int’l Cerebral Palsy Task Force Chair, characterized the conclusions of both reports as complimentary and non-conflicting except in occasional minor details. *Id.*

¹⁴² ACOG-AAP, *supra* note 17, at 26-29; Int’l Cerebral Palsy Task Force, *supra* note 17, at 1057.

. . . Such recommendations will have to await further research on . . . ability of monitoring as a means of avoiding outcomes by prompting obstetric action.”¹⁴³

Further research? It is difficult to discern exactly what research these task forces needed to confront the spiraling C-section rate and the ever-increasing lawsuit verdicts. The Committees could have written that EFM was a labor-saver, which justified its use in place of a one-on-one nurse, but that its use to make clinical decisions was highly limited, unproven by research, and that courtroom delivery decisions based on reinterpreting EFM data were unscientific and biased. But they did no such thing. Perhaps some members of the task forces still believed that EFM was clinically efficacious in its CP-predictive value and, therefore, consensus among the participants on that topic was unachievable. Perhaps. But what should have been true consensus was the undeniable courtroom reinterpretive bias, and substantial, continual clinical interpretation and intervention timing inconsistencies, all of which had been proven and re-proven in published papers across the decades not only with EFM but also a wide variety of specialties.¹⁴⁴ Put simply, there is nothing contradicting the proof that clinical and courtroom experts were not experts at all. Yet, ACOG, et al. ignored the junk science free-for-all being played out in hospitals and courtrooms across the nation. Why?

There is simply no answer in the written medical literature. The legal literature, however, in at least one instance, analyzed EFM’s use and, finding it medically and legally unsound, exposing obstetricians to liability rather than protecting them from liability, did what ACOG et al. refused to do: called for EFM’s abandonment.¹⁴⁵

III. A CLARION CALL

Drs. Steven Clark and Gary Hankins, two maternal fetal medicine thought leaders,¹⁴⁶ wrote a 2003 landmark EFM-CP article. The article was “landmark” not because it announced new evidence or new techniques, but because it was the first time medical professionals abandoned medical speak for plain language, abandoned euphemisms for concrete expressions, and abandoned passive acceptance of the status quo for medical accountability.¹⁴⁷

¹⁴³ *Id.* at 1057.

¹⁴⁴ See, e.g., Zain et al., *supra* note 73.

¹⁴⁵ Lent, *supra* note 51, at 808.

¹⁴⁶ Steven L. Clark, M.D., Maternal Fetal Medicine, is Medical Director for Women and Newborn Services, St. Mark’s Maternal Fetal of Utah; Gary D.V. Hankins, Maternal-Fetal Medicine, is Obstetrics-Gynecology Department Chair and Distinguished Professor at University of Texas Medical Branch, Galveston.

¹⁴⁷ Clark & Hankins, *supra* note 91.

Clark and Hankins set out to answer a canard EFM courtroom experts used to answer the inconvenient fact that the industrialized world's CP rate remained the same during EFM's 35 years of increasing use, proving EFM-fetal distress-C-sections were not saving babies from CP. The courtroom experts contended that EFM was actually reducing term infant CP because the increased survival of neurologically impaired very premature infants was masking an actual CP reduction in term infants.¹⁴⁸

Using worldwide statistics and medical literature, Clark and Hankins engaged a four-prong confutation to expose the courtroom experts' fable. The primary comparison was between CP rates in industrialized countries to those lacking EFM or the capacity for 30-minute emergency C-section. The data confirmed the CP rates in underdeveloped areas were the same or lower than in developed countries relying on EFM and 30 minute or less C-sections. Proof, once again, CP is almost exclusively a developmental event uninfluenced by the EFM-fetal distress-C-section trifecta.¹⁴⁹ More striking even than the clear proof repudiating the courtroom experts' fable was Clark's and Hankins' conclusion. Having labeled EFM absurd and possibly having done more harm than good, they wrote:

[I]t is important to clearly understand that with the exception of the obstetric catastrophes outlined above [maternal cardiac arrest and uterine rupture], no data exists in the entire medical literature to demonstrate that intervention based on any single or combination of fetal heart rate patterns reduces the risk of cerebral palsy in any population. When associated with newborn neurologic impairment, such abnormal patterns will, in most cases, reflect the presence of preexisting developmental abnormalities rather than ongoing development of such impairment.¹⁵⁰

During the next half-decade worldwide EFM criticism continued to mount,¹⁵¹ but only Clark and Hankins were audacious and bold enough to deal with EFM reality, branding EFM motivated fetal distress C-sections absurd,

¹⁴⁸ *Id.*; e.g., Robert L. Conason & Steven E. Pegalis, *Neurologic Birth Injury: Protecting the Legal Rights of the Child*, 31 J. LEG. MED. 249, 272-73 (2010).

¹⁴⁹ *Id.* at 629. A recent report from R.S. Pura Town, India, a poor underserved rural area, determined the CP prevalence rate in children less than 10 years old. The calculated rate, 2.27/1000 was comparable with the rates from developed countries. Sunil K. Raina et al., *Prevalence of Cerebral Palsy in Children Less Than 10 Years of Age in R.S. Pura Town of Jammu and Kashmir*, 57 J. TROPICAL PEDIATRY 293 (2010).

¹⁵⁰ *Id.* at 631.

¹⁵¹ E.g., Miller & Depp, *supra* note 91; Zarco Alfrevic et al., *supra* note 91; F. Pecino Martinez et al., *Back to the Initial Issues: Efficacy of Electronic Fetal Monitoring for Antepartum Fetal Assessment in Low Risk Pregnancy*, 2 ITAL. J. PUB. HEALTH 287 (2005) (recommendation of the Spanish Society of Gynecology and Obstetrics to use EFM as an optional indication in low-risk pregnancy and only after 40 weeks' gestation because EFM has no significant effect on perinatal mortality or morbidity); Graham et al., *supra* note 60; Stephen B. Thacker & Donna F. Stroup, *Revisiting the Use of the Electronic Fetal Monitor*, 361 LANCET 445 (2003) (calling for elimination of EFM on admission of low-risk pregnancies because there is no evidence of improved neonatal outcomes).

noting the potential harm it had done to mothers and babies and calling for severely restricted EFM-dictated C-sections.

IV. EFM WORKSHOP: NICHD

In 2008, a two-day EFM workshop was co-sponsored by ACOG, the Maternal-Fetal Medicine Society, and the Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD).¹⁵² The workshop's purpose was the same as earlier workshops—to revisit EFM nomenclature and interpretation and try to gain agreement on common definitions and management actions.¹⁵³ It was agreed to reclassify tracings using a three-tier category system: Category I is *normal*; Category III is *abnormal*; and Category is II *indeterminate*, or tracings which can neither be classified as Category I nor Category III.¹⁵⁴ Otherwise, not much was new.¹⁵⁵ It was reiterated that a labor evaluation is dependent on clinical judgment¹⁵⁶ and, of course, that more research was needed.¹⁵⁷

ACOG et al. were presented with yet another opportunity to speak clearly about EFM and say the obvious as had Clark and Hankins. For example, they could have said: The difficulty and expense of one-on-one nurses performing intermittent auscultation makes EFM easier and cheaper, and provides more data; thus, EFM is here to stay; however, using EFM's data to dictate C-section deliveries because of presumed fetal distress is unproven, unscientific, and inconsistent with the overwhelming evidence, logic and common sense and should be abandoned except in the highly limited instances outlined in the International Consensus Statement; medical malpractice accusations based on failure to perform C-sections because of alleged abnormal EFM patterns are based on unscientific, unproven, and untrustworthy ipse dixit of a minority of physicians and is unreliable; and finally, EFM and fetal physiology must undergo further extensive research before EFM will be a reliable intrapartum fetal evaluation tool.

But they did no such thing.

V. NICE CONFRONTS REALITY

In March 2008, NICE issued Clinical Guideline 62—*Antenatal Care: Routine Care for the Healthy Pregnant Woman*. NICE recommended no fetal

¹⁵² George A. Macones et al., *The 2008 National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring*, 112 *OBSTETRICS & GYNECOLOGY* 661, 661 (2008).

¹⁵³ *Id.* at 661-62.

¹⁵⁴ *Id.* at 664.

¹⁵⁵ *Id.* at 664-65.

¹⁵⁶ *Id.* at 662.

¹⁵⁷ *Id.* at 664-66.

monitoring for women with uncomplicated pregnancies. Why? The evidence did not support routine EFM fetal assessment in low-risk pregnancies.¹⁵⁸ The guideline says that healthcare professionals are expected to exercise clinical judgment taking into account the patient's clinical presentation before making a final clinical decision to monitor.¹⁵⁹

In an instant, U.K.'s physicians, midwives, and obstetrical nurses had a new standard of care, one that immediately had traction in the courtroom—40 years of medical evidence that routine EFM monitoring is not required in healthy pregnancies. NICHD, on the other hand, continued with the status quo. And American caregivers were stuck with every patient being a potential plaintiff and facing more hindsight-biased EFM courtroom reinterpretations. Dr. Barrett Robinson and Dr. Latasha Nelson, reviewing the 2008 NICHD guidelines, said: "Despite evidence demonstrating no neonatal benefit, the medicolegal climate in the United States requires obstetricians to integrate continuous intrapartum surveillance into their care."¹⁶⁰

VI. FINDING THE ANSWER

Robinson and Nelson's thought that the medicolegal climate requires EFM for every pregnancy is merely the unrequited wish that if things go bad, somehow the EFM strip confers protection against a lawsuit.¹⁶¹ The direct opposite is actually true, which has been pointed out in the legal and medical literature.¹⁶² Unfortunately, these explanations went unread. Obstetricians generally continue to believe EFM's "own ubiquity suggests that it is the exclusive standard of care"¹⁶³ and believe in its protective ability even though "EFM has historically been more of a tool for plaintiffs' lawyers than a safe harbor for the defense."¹⁶⁴ ACOG et al. and most obstetricians blindly blame a host of boogymen for four decades of increasing lawsuit numbers and larger and larger verdicts: trial lawyers; a litigious national climate necessitating "defensive medicine" strategies; patients' desire for a perfect outcome

¹⁵⁸ NHS NICE, ANTENATAL CARE, ROUTINE CARE FOR THE HEALTHY PREGNANT WOMAN, NICE CLINICAL GUIDELINE 62, 37, available at <http://www.nice.org.uk/nicemedia/pdf/CG062NICEguideline.pdf> (last visited July 4, 2011).

¹⁵⁹ *Id.* at 2.

¹⁶⁰ Barrett Robinson & Latasha Nelson, *A Review of the Proceedings from the 2008 NICHD Workshop on Standardized Nomenclature for Cardiotocography*, 1 REV. OBSTETRICS & GYNECOLOGY 186, 186 (2008).

¹⁶¹ *Id.*

¹⁶² E.g., Lent, *supra* note 51, at 826; Sachs, *supra* note 82, at 27-40; Emanuel A. Friedman, *The Obstetrician's Dilemma: How Much Fetal Monitoring and Cesarean Section Is Enough?*, 315 NEW ENG. J. MED. 641 (1986).

¹⁶³ Lent, *supra* note 51, at 830-31.

¹⁶⁴ *Id.* at 835.

guarantee; medicolegal pressures; buffeting forces; perfect product every time; and several dozen others.¹⁶⁵

Physicians have been blind to one of the primary reasons for the decades-long medical malpractice crises: their colleagues.¹⁶⁶ In virtually every state and every country with a blame system, medical malpractice lawsuits cannot proceed without a physician willing to point a finger and testify the defendant practiced below the standard of care, causing the injury or death. There is, of course, real medical malpractice in the world that must be dealt with, and physicians must be willing to testify and prosecute substandard medical care. But allowing the courtroom experts to use EFM junk science as the foundation for the finger-pointing, given the weight of four decades of overwhelming data, is shameful when the remedy for this mendacity has been in ACOG et al.'s hands all along, unused. Junk science's antidote is to call it what it is in medical articles, Practice Bulletins, Guidelines, Standards, newspaper and magazine articles, patient brochures, and courtroom testimony—unreliable—the key word that defeats junk science.¹⁶⁷ Individual commentators through the years have labeled EFM unreliable, but nowhere has ACOG officially and publicly taken the “EFM is unreliable” stance. If they had done so, their colleagues in the courtroom would have benefitted greatly.

To understand why ACOG et al.'s communications on EFM's unreliability is important, we need to briefly examine the experts' role in EFMCP-neurologic injury cases. Obviously, each side to a lawsuit calls experts to support their arguments. Generally, the parties are limited as to the number of experts they can present, both as a matter of practicality and court rules, the general rule being one expert per specialty per side. Thus, one plaintiff EFM expert is opposed by one defendant EFM expert, and so on. Presumably, each expert has a polar opposite EFM opinion. In effect, jurors are reduced to being judges in a beauty contest. Each expert articulates his opinions and the jury must decide whom to believe. But, based on what? Who looks better? Who

¹⁶⁵ *Id.* at 822-23; Friedman, *supra* note 165, at 641; *see also* Redlich, *supra* note 51 (1986 law review article exploring the 1974-1976 medical malpractice crisis and subsequent state legislative reactions to quell physicians' and the public's panic; especially relevant is Redlich's exploration of physicians' fear and ignorance of all things related to law, lawyers, courts, judges, and medical malpractice litigation). *Id.* at 303-06. As one physician summarized: “Ignorance breeds fear.” *Id.* at 305.

¹⁶⁶ *E.g.*, MacLennan et al., *Only*, *supra* note 103; *see* Charles B. Hammond & Peter A. Schwartz, *Ethical Issues Related to Medical Expert Testimony*, 106 *OBSTETRICS & GYNECOLOGY* 1055 (2005) (guidelines for punishing egregious courtroom testimony); Leonard Berlin, *Bearing False Witness*, 180 *AM. J. ROENTGENOLOGY* 1515 (2003) (need to enforce expert witness standards because certain expert witnesses are bearing false witness against their neighbor radiologists); Aubrey Milunsky, *Lies, Damned Lies, and Medical Experts: The Abrogation of Responsibility by Specialty Organizations and a Call for Action*, 18 *J. CHILD NEUROLOGY* 413 (2003) (the festering problem of expert witness false testimony is ongoing).

¹⁶⁷ The scientific reliability requirement was articulated in *Daubert v. Merrill Dow Phar. Inc.*, 509 U.S. 579 (1993). Since then, thousands of articles and cases have interpreted scientific evidence and its reliability. *E.g.*, Harvey Brown, *Eight Gates for Expert Witnesses*, 36 *Hous. L. Rev.* 743 (1999).

did I like best? Who dressed the best? Which expert's slides and props were more entertaining?

Determining how juries decide which witness is believable has been the subject of much study. The reality is that believability is unrelated to the soundness of the medical opinions.¹⁶⁸

Another problem with experts, faced by both sides, is that the vast majority of physicians simply refuse to testify because litigation is unpredictable, difficult, time-consuming, and often involves difficult lawyers and sometimes personal attacks. Many physicians simply refuse to be involved in litigation no matter what. That attitude, justified or not, reduces substantially the available expert pool.

The expert beauty contest could have been greatly assisted by an official ACOG et al. EFM position. No matter how poorly the defendant EFM expert was perceived, an official pronouncement by recognized professional organizations, particularly if those positions are articulated in plain, declarative language understandable to everyday jurors, would have provided defendants with a firm foundation that the other side lacked. Is it a guarantee? No. But it is a good start.

Imagine that in 1980 ACOG had issued a simple Practice Bulletin and patient brochure stating that, based on 10 years of clinical use and several clinical trials, EFM had proven to be a device that saved nursing labor costs but was not yet proven efficacious for general clinical use and was unreliable as evidence of negligence in the courtroom and, therefore, EFM should not be considered the standard of care either in labor rooms or courtrooms. Would that have relieved the malpractice fears compelling obstetricians to use EFM on every patient? Would it have perhaps diminished the C-section rate? And would it have assisted defendants in courtrooms? Unquestionably, it would have.

Recently, Dr. Roger K. Freeman proposed another remedy for HIE junk science—specialized courts “in which judges were more knowledgeable and better able to exclude evidence based on junk science from jury deliberations,” and expert witnesses retained by the court rather than the lawyers.¹⁶⁹ These and other similar junk science remedies have been proposed in various ways

¹⁶⁸ David Berg, *The Trial Lawyer, What It Takes to Win*, ABA Section of Litigation 15 (2006) (likeability is believability); Robert Gordon, *In Litigation, as in Life, Likeability Is the Key*, FOR THE DEFENSE, May 2005, at 20 (“Decades of litigation research clearly show” witness credibility has to do with likeability. “No other factor—including witness testimony—comes close for jurors, arbiters, and even for judges.”); SONYA HAMLIN, *WHAT MAKES JURIES LISTEN TODAY?* (1998) (visual and aural images cancel out the words); JACK E. HORSLEY & JOHN CARLOVA, *TESTIFYING IN COURT* (1988) (jury reception of doctors’ testimony dependant more on dress, style, mannerisms, and speech than on substance); David B. Givens, *Posture Is Power*, 8 BARRISTER 14 (1981) (how a witness moves, points, stands, or sits influences a jury more than all the witness’s arguments put together).

¹⁶⁹ Roger K. Freeman, *Medical and Legal Implications for Necessary Requirements to Diagnose Damaging Hypoxic-Ischemic Encephalopathy Leading to Cerebral Palsy*, 199 AM. J. OBSTETRICS & GYNECOLOGY

for decades.¹⁷⁰ Very few of the suggested reforms have ever been adopted, suggesting that voices like Dr. Freeman's are like the falling tree with no one around to hear it. Does it make a sound? Judging from ACOG et al.'s past reaction to EFM data, the answer is no. Recently, ACOG had an opportunity to make amends for its past lack of action when P.B. 106 was published. Sadly, another opportunity to transmogrify EFM was squandered.

A. EFM Redux: Practice Bulletin 106

The ACOG Practice Bulletin Committee periodically develops Bulletins to guide clinical management decisions. Published in July 2009, Practice Bulletin 106 was to guide physicians on EFM nomenclature, interpretation, and general management principles.¹⁷¹ Prepared under Dr. George A. Macones' guidance, No. 106 replaced PB No. 70, published in 2005.¹⁷² Number 70 had been a testament to ACOG's impotency and EFM doublespeak, offering no solutions to EFM's high C-section rate, nor any practical clinical guidance to EFM use in labor rooms, nor any remonstrance against EFM's use against defendant physicians by courtroom experts.

Despite ample opportunity for improvement, PB 106 is little better than its predecessor. Practice Bulletin 106 confronts some EFM deficiencies, but stops well short of using the "U" word—unreliable. Rather than throw a life preserver to physicians facing EFM courtroom experts and their courtroom reinterpretations, ACOG retreated into traditional medical non-commitment implying EFM's unreliability, but timidly refusing to actually say the word out loud or suggest EFM use be curtailed especially in courtrooms.

ACOG adopted NICHD's 2008 three-tier fetal heart rate system as well as the nomenclature. ACOG then departed from NICHD by making a few helpful, even if painfully delayed by decades, official statements: EFM has not reduced perinatal mortality but has increased C-section rates along with increased risks of both vacuum and forceps deliveries; EFM has not reduced the risk of CP; EFM's false-positive rate for predicting CP is "extremely high, at greater than 99%"; inter-observer-intra-observer variability in EFM interpretation is "high," especially when a poor outcome is known and such foreknowledge "may" alter the reinterpretation and such an opinion "may not

585, 585 (2008). A similar voice was heard in the U.K. In 2008, commenting on the new EFM technology, ST analysis, Amer-Wahin compared the delivery room unfavorably to risk management in the airline industry, concluding that obstetrics needs a deeper analysis of the causes of bad outcomes rather than superficially and inefficiently blaming human error through lawsuits. I. Amer-Wahlin & S. Dekker, *Fetal Monitoring—A Risky Business for the Unborn and for Clinicians*, 115 BRIT. J. OBSTETRICS & GYNAECOLOGY 935 (2008).

¹⁷⁰ E.g., Mary Schaefer, *Medical Malpractice Tort Reform Across America: An Overview*, 23 FORUM 3 (Feb. 2003); *Litigation System 2003*, *supra* note 51; Jacobson, *supra* note 51; 1 MEDICAL LIABILITY, *supra* note 117, at 1-13.

¹⁷¹ ACOG Practice Bulletin 106, *supra* note 3.

¹⁷² *Intrapartum Fetal Heart Rate Monitoring*, ACOG Practice Bulletin No. 70 (Dec. 2005).

be reliable.”¹⁷³ Finally, the ACOG stated that the terms hyperstimulation and hypercontractility were undefined and should be abandoned.¹⁷⁴

In an interview with *New York Times* reporter Jane Brody about PB 106, Macones said: “Honestly, the technology [EFM] rolled out before we knew if it worked or not”; only 4% of CP result solely from events in labor and delivery; “lawyers pick through every finding on the tracing and say the physician should have done a cesarean here and saved the baby, even though that’s seldom the case, since most cases of cerebral palsy don’t happen during labor”; and with physicians’ liability fears, “many babies with ‘nonreassuring’ readings who might have done just fine with a natural vaginal delivery are being delivered surgically or with forceps.”¹⁷⁵

Macones’ statements to *The New York Times* are exactly what ACOG should have written in PB 106. Plain language that judges and jurors can understand. Plain language the plaintiffs’ courtroom EFM experts must confront and disprove with their own studies and articles. Instead, PB 106 retreats into uncertainty by relying heavily on the detensifier “may.” Ultimately, PB 106’s tergiversation about EFM’s use, clinically and in the courtroom, leaves judges everywhere more than enough room to continue finding EFM reliable for use as a plaintiff courtroom causation device.

Another PB 106 shortcoming is revealed in Macones’ interview with a JAMA reporter, summing up PB 106’s three-tier categories. Macones said the categories were easy to teach and that “the main change in the document is that we are trying to move closer to much better and clearer communication among the entire healthcare team to avoid ambiguity.”¹⁷⁶ This quotation suggests, as does PB 106 itself, that despite EFM’s listed shortcomings—does not predict CP; increases C-sections; 99% false-positive rate; high inter-observer/intra-observer interpretation variability and bias—EFM has utility if only we can teach EFM interpretation through the use of these new and easily understood three-tier categories.

PB 106 is far short of where ACOG should be after studying and using EFM for 40 years. In the first place, the categories are distinctly unhelpful. Normal, abnormal, and indeterminate cannot overcome EFM’s inherent and present-from-the-beginning-defect—EFM tracing interpretation is art, not science. How many more studies will it take showing that highly trained experts cannot consistently interpret tracings, or make the same decisions based on

¹⁷³ ACOG Practice Bulletin 106, *supra* note 3, at 195-96.

¹⁷⁴ *Id.* at 193.

¹⁷⁵ Jane Brody, *Updating A Standard: Fetal Monitoring*, N.Y. TIMES, July 7, 2009, at D7, available at <http://www.nytimes.com/2009/07/07/health/07brod.html?ref=janebrody> (last visited July 7, 2011).

¹⁷⁶ Mike Mitka, *Group Issues Revised Guidelines for Fetal Heart Rate Monitoring During Labor*, 302 J.A.M.A. 935 (2009).

the same tracing interpreted on different days,¹⁷⁷ before EFM is designated unreliable?

Stated bluntly, EFM, other than as a labor-saver, does not “help, and sometimes makes things worse.”¹⁷⁸ ACOG, however, has once again convinced itself EFM will heel to its command by simply teaching better, clearer communication. This is a laudable goal, no doubt, but in the meantime, C-sections in 2008, due in large part to EFM-driven deliveries from fear of lawsuits, reached 32% overall¹⁷⁹ and much higher in some select cities. C-sections have substantial risks,¹⁸⁰ with the annual deaths resulting causally from C-sections in the US estimated at twenty.¹⁸¹ Put simply and directly, “electronic fetal monitoring harms women.”¹⁸² It wastes “money and time . . . increases operative deliveries yet offers no lasting benefit to children.”¹⁸³ With EFM’s mediocre validity, its “positive predictive value” for fetal death in labor or cerebral palsy is near zero.¹⁸⁴ “[F]ew clinicians who routinely use electronic fetal monitoring in labor would use a pregnancy test (or home smoke detector) that is wrong almost every time a positive signal appears.”¹⁸⁵ Is it time for ACOG et al. to listen?

B. Post-PB 106 Evidence of EFM Failure

A Cochrane EFM Review was published in 2010 updating the first review 10 years earlier.¹⁸⁶ The conclusion was the same: No clear evidence that EFM improves outcomes.

Inter-observer/intra-observer variability was still being tested. The familiar refrain heard since EFM was introduced into clinical practice was again reported in three different countries: Inter-intra-observer agreement on EFM

¹⁷⁷ E.g., Gaffney et al., *supra* note 68.

¹⁷⁸ Rachel Walden, *ACOG Offers Mixed Bag of Practice Guidelines*, National Women’s Health Network, Women’s Health Activists Newsletter, Nov./Dec. 2009, available at <http://www.nwhn.org/acog-offers-mixed-bag-practice-guidelines> (last visited July 9, 2011).

¹⁷⁹ T. J. Matthews et al., *Annual Survey of Vital Statistics*, 127 PEDIATRICS 146 (2011).

¹⁸⁰ E.g., Villar et al., *supra* note 98 (women having a non-emergency C-section have double the risk of complications compared to a vaginal birth).

¹⁸¹ Steven L. Clark et al., *Maternal Deaths in the 21st Century: Causes, Prevention, and Relationship to Cesarean Delivery*, 199 AM. J. OBSTETRICS & GYNECOLOGY 36.e1, 36.e1 (2008).

¹⁸² David A. Grimes & Jeffrey F. Peipert, *Electronic Fetal Monitoring as a Public Health Screening Program: The Arithmetic of Failure*, 116 OBSTETRICS & GYNECOLOGY 1397, 1399 (2010).

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* But see Harr-Yang Chen et al., *Electronic Fetal Heart Rate Monitoring and Its Relationship to Neonatal and Infant Mortality in the United States*, 204 AM. J. OBSTETRICS & GYNECOLOGY 491.e1, 491.e1 (2011) (a study presented in part at the annual Society for Maternal Fetal Medicine in February 2011 concludes EFM is associated with a substantial decrease in early neonatal mortality and morbidity that lowered infant mortality).

¹⁸⁶ R.M. Grivell et al., *Antenatal Cardiotocography for Fetal Assessment*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS 2010, available at <http://apps.who.int/whl/reviews/CD007863.pdf> (last visited May 21, 2012).

pattern interpretation and decision making is poor.¹⁸⁷ NICHD's and ACOG's three-tier system was no better. Inter-intra agreement was moderate for CAT I and II but poor for CAT III.¹⁸⁸ The addition of ST segment analysis [STAN] to EFM shows some promise, as does computerized analysis, but more experience with the new technology is needed before adoption into routine clinical practice.¹⁸⁹ Past mistakes should not be repeated by even prosaic students of EFM history.¹⁹⁰

A large Dutch randomized, multi-center clinical trial failed to show that internal tocodynamometry provided better information about fetal distress and resulting in fewer C-sections than external monitoring.¹⁹¹ And in Norway, a unique study was concluded that again deprecated the idea that EFM was the key ingredient to prevent CP. Clinicians typically regard 37-41 weeks as term birth with low risk, especially for CP. Even though risk is lower among term births, however, about three-fourths of all infants with CP are born after 36 weeks. So the Norwegian team set out to explore CP's relationship to term and post-term births. Analyzing more than 1.6 million patient records from 1967 through 2001, with follow-ups through 2005, the conclusion was that, compared to delivery at 40 weeks' gestation, delivery at 37 or 38 weeks, or at

¹⁸⁷ M. Westerhuis et al., *Inter- and Intra-Observer Agreement of Intrapartum ST Analysis of the Fetal Electrocardiogram in Women Monitored by STAN*, 116 BRIT. J. OBSTETRICS & GYNAECOLOGY 545 (2009); Suneet P. Chauhan et al., *Intrapartum Nonreassuring Fetal Heart Rate Tracing and Prediction of Adverse Outcomes: Inter-Observer Variability*, 199 AM. J. OBSTETRICS & GYNECOLOGY 623 (2008); Kati Ojala et al., *Inter-Observer Agreement in the Assessment of Intrapartum Automated Fetal Electrocardiography in Singleton Pregnancies*, 87 ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA 536 (2008).

¹⁸⁸ Sean C. Blackwell et al., *Inter-Observer and Intra-Observer Reliability of the NICHD3-Tier Fetal Heart Rate Interpretation System*, 205 AM. J. OBSTETRICS & GYNECOLOGY 378 (2011).

¹⁸⁹ E.g., Lawrence D. Devoe, *Fetal ECG Analysis for Intra-Partum Electronic Fetal Monitoring: A Review*, 54 CLINICAL OBSTETRICS & GYNECOLOGY 56 (2011); I. Amer-Wahlin & Lisa Miller, *ST Analysis as an Adjunct to Electronic Fetal Monitoring: An Overview*, 24 J. PERINATAL & NEONATAL NURSING 231 (2010); M. Westerhuis et al., *Cardiotocography Plus ST Analysis of Fetal Electrocardiograms Compared with Cardiotocography Only for Intrapartum Monitoring: A Randomized Controlled Trial*, 115 OBSTETRICS & GYNECOLOGY 1173 (2010).

¹⁹⁰ See GEORGE SANTAYANA, *THE LIFE OF REASON* 82 (1955). The Japan Society of Ob-Gyn recognized the three-tier EFM system proposed for the U.S., Canada, and U.K., noting it was as yet unproven. They adopted a five-tier system with color codes for each tier and a standardized management protocol for doctors and midwives, suggesting further research to validate the guidelines' effectiveness. Takashi Okai et al., *Intrapartum Management Guidelines Based on Fetal Heart Rate Pattern Classification*, 36 J. OBSTETRICS & GYNECOLOGY RESEARCH 925 (2010). In a similar vein, John M. Freeman, editor of the groundbreaking *Collaborative Perinatal Study*, issued a warning regarding the proposed use of the amplitude-integrated EEG into neonatal nurseries to detect and treat seizures, calling on EFM history as the example of technology introduced without evidence of efficacy leading to unintended adverse medical and legal outcomes. John M. Freeman, *The Use of Amplitude-Integrated Electroencephalography: Beware of Its Unintended Consequences*, 119 PEDIATRICS 615 (2007); see also Greene, *supra* note 6 (comparing fetal oxygen saturation measurements, a failure after clinical trials, to EFM's introduction and use with no clinical trials).

¹⁹¹ Jannet J.H. Bakker et al., *Outcomes After Internal Versus External Tocodynamometry for Monitoring Labor*, 362 NEW ENG. J. MED. 306 (2010).

42 weeks or later, was associated with an increased risk of CP.¹⁹² A plausible causal interpretation is that fetuses predisposed to CP have a disturbance in delivery timing like other neurologic malformations of cerebral function that disrupt delivery timing such as anencephaly, trisomy 18, Downs Syndrome. Having already experienced the cerebral damage later expressed as CP, that damage also disrupts delivery timing.¹⁹³ Thus, it is easy to see “if the time of delivery affects CP risk, then intervention at 40 weeks might reduce CP risk, while elective delivery at 37 or 38 weeks might increase it. If infants prone to CP are disrupted in their delivery times, the prevalence of CP would be unchanged regardless of time of delivery.”¹⁹⁴

It would seem that if the Norwegians are right, EFM has been barking up the wrong tree all along.

C. A PB 106 Skeptic

Dr. Roger K. Freeman editorialized on PB 106.¹⁹⁵ Freeman, first noting PB 106’s position that EFM had not reduced CP, had a 99% false-positive rate, and excessively increased C-sections, set out to refute these conclusions. He recognized that if the conclusions were correct it “might more logically lead to a recommendation against the use of” EFM.¹⁹⁶ He did not believe the conclusions were correct, however. His counter to the 99% false-positive rate was the argument that epidemiologic calculations were done assuming EFM was designed to predict one specific outcome—CP. In his view, EFM is used to detect hypoxia, and allow intervention, “to prevent fetal injury” including central nervous system damage, rather than to accurately predict the specific adverse outcome of CP. “EFM is a diagnostic tool that was never proposed as a predictor of outcomes.”¹⁹⁷

Freeman’s distinction between EFM as a diagnostic tool to prevent “central nervous system damage” and EFM not being a predictor of CP outcomes seems artificial and forgetful. Not that long ago, two EFM pioneers wrote that the then-new EFM technology would predict CP and reduce by one-half the incidence of CP, mental retardation, and intrapartum deaths.¹⁹⁸

¹⁹² Dag Moster et al., *Cerebral Palsy Among Term and Post-Term Births*, 304 J.A.M.A. 976, 979 (2010).

¹⁹³ *Id.* at 979.

¹⁹⁴ *Id.* at 981.

¹⁹⁵ Roger K. Freeman & Michael P. Nageotte, *Comments on American College of Obstetricians and Gynecologists Practice Bulletin No. 106*, 202 AM. J. OBSTETRICS & GYNECOLOGY 411 (2010).

¹⁹⁶ *Id.* at 411. R.K. Freeman & Nageotte noted the disjunction posed by PB 106, on the one hand, suggesting its uselessness because it does not predict CP and increases the C-section rate, but, on the other hand, recommending its general use with the three-tier system. *Id.*; see also Julian T. Parer & Tekoa L. King, *Letter to the Editor*, 117 OBSTETRICS & GYNECOLOGY 986 (2011) (responding to Grimes & Peipert, *supra* note 186).

¹⁹⁷ R.K. Freeman & Nageotte, *supra* note 195, at 411.

¹⁹⁸ Quilligan & Paul, *supra* note 36, at 98; Greene, *supra* note 6, at 2248.

Freeman's editorial comment ends with his appeal to common belief being common wisdom regardless of the accumulated weight of EFM research evidence: "We really do not believe that the technique of EFM would continue to be so widely accepted if practicing clinicians were of a mind that it [EFM] has no value."¹⁹⁹

The age-old canard that common belief is common wisdom because so many believe it, is as illogical today as it was when first made. It is an *argumentum ad populum*: appeal to the people; many believe it, therefore it is so. Popular names for this phenomenon today would include conventional wisdom, argument by expert consensus, and the bandwagon fallacy.²⁰⁰

Obviously, the rationalization that EFM is widely accepted and therefore evidence of ineffectiveness and possible harm can be ignored is not only unscientific, it is dangerous. Millions of people still smoke. Should we say, then, smoking must be healthy despite the scientific evidence? Science requires evidence proving a procedure's merits. But this appeal to common practice by a learned physician illustrates the distinctly unique EFM conundrum: Many physicians still believe the century-old assumption that oxygen deprivation alone causes CP and if obstetricians can act quickly enough to EFM-indicated fetal distress they can prevent CP. This "pure misinformation"²⁰¹ myth among physicians²⁰² about neonatal brain damage causation has been highlighted in research, articles, and editorials for dozens of years to no avail.²⁰³ This deep-rooted belief, anchored somewhere in the collective unconscious of a seeming majority of physicians, precipitates their utter inability to recognize EFM's flaws and shortcomings. Why does this myth persist? What can possibly dispel it?

VII. SEARCHING FOR SOMEONE OR SOMETHING TO BLAME—LAME FROM BIRTH²⁰⁴

If EFM is based on faulty pathophysiology, never lived up to its promises, and causes more harm than good, why is it the most common obstetrical procedure in the United States, monitoring 85% of all labors and births?²⁰⁵ Perhaps the question should be framed as why, in the face of virtually unchallenged

¹⁹⁹ R.K. Freeman & Nageotte, *supra* note 195, at 412.

²⁰⁰ The term *argumentum ad populum* [Latin] is defined as an argument appealing to the crowd. BLACK'S LAW DICTIONARY 122 (Bryan A. Garner ed., 9th ed. 2009).

²⁰¹ J.M. Freeman & A.D. Freeman, *supra* note 16, at 726.

²⁰² E.g., *id.*; Morgan et al., *supra* note 16; Hankins, *supra* note 16; cf. Collaborative Perinatal Study, *supra* note 15, at 3.

²⁰³ E.g., Int'l Cerebral Palsy Task Force, *supra* note 17, at 1059; MacLennan et al., *Only*, *supra* note 103; MacLennan et al., *Who*, *supra* note 103; ACOG-AAP, *supra* note 17.

²⁰⁴ Obladen, *supra* note 28.

²⁰⁵ See, e.g., Int'l Cerebral Palsy Task Force, *supra* note 17.

data about cerebral palsy causes and EFM's impotence to prevent cerebral palsy,²⁰⁶ do current lawyer websites and national verdict search sites feature multiple hundreds of multi-million-dollar verdicts and settlements describing physicians' liability for supposedly causing cerebral palsy due to failure to timely institute C-sections in the presence of fetal distress revealed on electronic monitors?²⁰⁷

Birth injury medical malpractice verdicts and settlements must be supported by expert testimony. Obviously, there are physicians still willing to testify that fetal distress causes cerebral palsy and EFM, interpreted their way, pinpoints the precise time delivery should have occurred. And there are lay jurors, having heard plaintiff experts cross-examined with the studies cited in this article, and having heard evidence from knowledgeable defense witnesses, still willing to hold liable physicians for causing cerebral palsy by failing to perform a timely C-section. Why?

The answer, as with most questions, is multi-faceted. It involves: belief in superstition and myth, both by physicians and the public; the unrequited human search for the answer to "why"; the centuries-old human preoccupation with blame; the legal system and its unpredictable random lottery-like recoveries,²⁰⁸ the fear the legal system infuses into medical decision-making; lawyer advertising; the Internet; and shifting societal attitudes. There are

²⁰⁶ Obladen, *supra* note 28.

²⁰⁷ Type "Jury Verdicts in USA for Cerebral Palsy" into Google. In 1.6 seconds 52,600 results are returned. It seems like, although the percentages will remain a guess, at least 99% are lawyer websites advertising the multi-million dollar verdicts and settlements received from birth injury cases. Type "Cerebral Palsy" into Google. In 0.10 seconds, 25,200,000 results are returned. Out of these, it seems that 90% are also lawyer websites, many of which are advertising multimillion dollar verdicts and settlements. Many of the cases found with either search ascribe cerebral palsy to oxygen deprivation due to the doctor failing to deliver the child sooner based on EFM findings. Some attorneys have created innocent sounding and looking "informational" websites that are admitted to be attorney advertising in the fine print on the bottom of the page. *E.g.*, Cerebral Palsy and Special Needs Children's Organization, 4 My Child, created by lawyer Ken Stern, *available at* <http://www.cerebralpalsy.org/>. No doubt many good deeds have been done through this site. There are other examples displayed throughout the first few Google pages. The common denominator of the attorney cerebral palsy/birth injury websites is the statement that CP/birth injuries are often due to physician negligence and those "injuries" are primarily due to oxygen deprivation. Analysis of 1452 closed U.S. medical malpractice claims between 1995 and 2000 revealed, 19% involved neonates. D.M. Studdert et al., *Claims, Errors and Compensation Payments in Medical Malpractice Litigation*, 354 *NEW ENG. J. MED.* 2024, 2026 (2006). The malpractice risk according to physician specialty was recently calculated using malpractice data from 1991-2005. The conclusion: the cumulative risk of facing a malpractice claim is high in all specialties. By age 65, 75% of physicians in low risk specialties had faced a malpractice claim, as compared with 99% of physicians in high risk specialties. Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 *NEW ENG. J. MED.* 629, 633 (2011).

²⁰⁸ See, e.g., Mehlman, *supra* note 45. A 2002 Department of Health and Human Services report surveying the U.S. medical liability system characterized the tort system as unpredictable, costly, slow, unable to accurately identify negligence, failing to deter bad conduct, and unable to provide justice. *Healthcare Crisis 2002*, *supra* note 46. Harvard's Risk Management Foundation characterizes birth injury litigation as a "lottery" without justice. John L. McCarthy, *Commentary: Looking for a Better Way*, 23 *FORUM 2* (Feb. 2003).

bound to be other reasons but these seem obvious. None is dominant by itself. Together, however, they have so far thoroughly defeated reason and science. Today, despite overwhelming contrary evidence, countless physicians, lawyers, and laypersons alike still believe the oxygen-deprivation-at-birth-solely-causes-cerebral-palsy myth. They also firmly believe the myth that EFM can identify and precisely time exactly when a fetus should be delivered to prevent cerebral palsy.

A. Superstition and Myth: Are Physicians Immune?

Physical deformities like cerebral palsy have been attributed to supernatural causes since antiquity.²⁰⁹ Beliefs have included the evil eye, God's wrath, intercourse between witch and devil, pregnant women seeing dreadful, frightful, or strange sights, and difficult teething, the latter being proposed by the eminent physician Sir William Osler.²¹⁰

Although nascent neurologic explanations began to emerge in the late 1700s and early 1800s,²¹¹ it was not until the mid-1800s, when London orthopedist William John Little published his authoritative theory that asphyxia was the cause of perinatal brain damage during birth, that the oxygen deprivation theory gained traction. Little's emphasis on premature and difficult labors, unnatural presentations, precipitous deliveries, and cord entanglements was merely the prelude to what he believed to be the real cause of CP—*asphyxia neonatorum*—a lack of adequate oxygen.²¹² Little's theory was embraced by 1800s medicine. But it was also embraced by twentieth and twenty-first century medicine. As Obladen noted, "opinions on perinatal brain damage" being caused by a lack of oxygen "are still influenced by . . . Little" today.²¹³

Among those accepting Little's theories today are obstetricians and other physicians, the lay public, and particularly trial lawyers. This persistent and now century-old belief exists in spite of a literal worldwide research explosion occurring since the 1985 publication of the then-largest CP, neurologic birth disorders study ever undertaken—The Collaborative Perinatal Study.²¹⁴ This study's findings should have forever changed not only medicine's view of Little's speculation, but the public's as well. Dr. John Freeman, the study's editor, wrote an eloquent summary of the study's impact on medical beliefs which had suddenly become outdated. Dr. Freeman declared:

²⁰⁹ Obladen, *supra* note 28.

²¹⁰ *Id.* at 248-50.

²¹¹ *Id.* at 250-51.

²¹² *Id.* at 251-52; e.g., Sartwelle, *Defending*, *supra* note 2, at 182-83.

²¹³ Obladen, *supra* note 28, at 251.

²¹⁴ See *Collaborative Perinatal Study*, *supra* note 15.

If we believe that we should teach only what we know to be true, as opposed to what we know to be myth, then much of what we “know” about pre- and perinatal causes of cerebral palsy (CP), mental retardation (MR) and epilepsy should no longer be taught. Over the past two decades, few areas in medicine have changed as rapidly as those of obstetrics and neonatology. Yet, many of our assumptions about the factors associated with brain disorders, such as CP, MR and epilepsy, remain rooted in outdated knowledge.²¹⁵

In the same year, a British medical study group also warned physicians that their cerebral palsy causative concepts were dangerously ignorant and those of the general public even more so.²¹⁶ A few years later, American physicians and the public also came under criticism for their CP causation ignorance.²¹⁷ These warnings had little impact on physicians, as illustrated by the results of two ACOG surveys of its members, the primary physician group expected to be the most knowledgeable about CP causation but in reality who are the most ignorant.

The first survey in 2001 tested practicing obstetricians’ neonatal encephalopathy and CP causation knowledge, including knowledge of etiology and pathology.²¹⁸ Over half of the 643 respondents rated their knowledge as poor or deficient. The participants’ test answers, the authors wrote, were “consistent with this pessimistic self-assessment, as . . . (65.3%) correctly answered less than half of the knowledge questions.”²¹⁹ The conclusion: “Issues of neonatal encephalopathy, pathogenesis and histopathology are not well understood by practicing obstetricians throughout the United States.”²²⁰

In 2005, there was a similar survey.²²¹ The survey followed the 2003 publication of ACOG-AAP’s definitive work on the causes of neonatal encephalopathy and cerebral palsy²²² as well as the 1999 International Cerebral Palsy Task Force Consensus Statement.²²³ It was designed in part to measure ACOG-AAP’s impact on practicing obstetricians’ subject matter knowledge. Surveyed participants included 33% of the members participating in the first survey. As expected, there was some improvement in knowledge base, with a strong association between familiarity with the ACOG-AAP study and knowledge about encephalopathy and CP. Still, substantial knowledge gaps

²¹⁵ *Id.* at 1.

²¹⁶ J.M. Freeman & Nelson, *supra* note 104 (citing E. Hey, *Fetal Hypoxia and Subsequent Handicap: The Problem of Establishing a Causal Link*, in LITIGATION AND OBSTETRICS AND GYNECOLOGY 233-42 (Geoffrey V.P. Chamberlain et al. eds., 1985)).

²¹⁷ See, e.g., Pschirrer & Yeomans, *supra* note 16.

²¹⁸ Hankins et al., *supra* note 16.

²¹⁹ *Id.* at 15.

²²⁰ *Id.* at 16.

²²¹ Morgan et al., *supra* note 16.

²²² ACOG-AAP, *supra* note 17.

²²³ Int’l Cerebral Palsy Task Force, *supra* note 17.

remained. More than one-third of those surveyed rated their knowledge regarding causation as poor or deficient.²²⁴

B. Willful Blindness?

Is this demonstrated ignorance willful blindness or simply a continuum of beliefs in the devil, the evil eye, and God's wrath? The very group most affected by the asphyxia-is-the-sole-cause-of-birth-brain-injuries mantra, the group that should be in the forefront of the educate-the-public effort, is the most ignorant. And this ignorance is not recent in origin. As we have seen, challenges to EFM-and-asphyxia-as-a-cause-of-CP logic began in the mid-1970s, followed in 1985 with the publication of the Collaborative Perinatal Study data that, as Dr. Freeman noted, "intrapartum physical trauma as a cause of brain damage has largely been eliminated."²²⁵ Research exploded worldwide on all aspects of CP and birth injuries, including questioning EFM's efficacy.²²⁶ The 1999 International Consensus Statement was followed by the 2003 ACOG-AAP statement, interspersed with uncontradicted data proving EFM's foundation misguided and faulty. Despite the research, EFM use increased, along with the C-section rate, not to mention CP lawsuit damage verdicts. Why?

Perhaps Mark Twain said it best: "It ain't what you don't know that gets you into trouble. It's what you know for sure that just ain't so."²²⁷ Many physicians, despite supposed training as scientists, are not scientists at all. They are practitioners.²²⁸ And as Dr. Freeman pointed out in his Collaborative Perinatal comments, they are capable of sincerely believing and teaching long-held myth as truth.²²⁹ Professor Fritz Beller labeled physicians' belief in fetal distress, hypoxia, and asphyxia as causes of cerebral palsy and brain damage as being belief based on assumptions, false analogous conclusions, and a catastrophic misunderstanding of fetal pathology.²³⁰

C. Medicine and Myth

Recently, two Indiana University medical researchers demonstrated how common physicians' belief in myth really is. Researching seven commonly accepted beliefs passed on by physicians to patients for decades and longer, they found all the beliefs were unproven or totally untrue.²³¹ The myths: people

²²⁴ Morgan et al., *supra* note 16.

²²⁵ *Collaborative Perinatal Study*, *supra* note 15, at 1.

²²⁶ Sartwelle, *Defending*, *supra* note 2.

²²⁷ This is attributed to Mark Twain. See, e.g., BRAINY QUOTE, available at <http://www.brainyquote.com/quotes/quotes/m/marktwain109624.html> (last visited May 30, 2012).

²²⁸ Huber, *supra* note 38, at 87.

²²⁹ *Collaborative Perinatal Study*, *supra* note 15, at 1.

²³⁰ Beller, *supra* note 99.

²³¹ Rachel C. Vreeman & Aaron E. Carroll, *Medical Myths*, 335 BRIT. MED. J. 1288 (2008).

should drink eight glasses of water a day; we use only 10% of our brains; hair and fingernails continue to grow after death; shaving hair causes it to grow back faster, darker, or coarser; reading in dim light ruins your eyesight; eating turkey makes people especially drowsy; and mobile phones create considerable electromagnetic interference in hospitals.²³² Their conclusion: "Physicians would do well to understand the evidence supporting their medical decision making. . . . While belief in the described myth is unlikely to cause harm, recommending medical treatment for which there is little evidence certainly can."²³³ They should have added electronic fetal monitoring to their myths list.

VIII. EFM-CP AND THE MEDICAL LIABILITY SYSTEM

Since EFM came into widespread clinical use, the vast majority of neurologically-impaired infant birth injury claims have alleged failure to appropriately monitor with EFM or appropriately respond to alleged EFM fetal distress.²³⁴ EFM provided the smoking gun tangible evidence that trial lawyers and their courtroom experts dramatically analyzed and reanalyzed in the courtroom.²³⁵ The primary reasons these claims dominate is the undeniable fact that fault based tort systems are biased toward high damage claims.²³⁶ The now famous Harvard study of malpractice claims concluded the only significant predictor of malpractice payment was disability.²³⁷ "There

²³² *Id.*

²³³ *Id.* at 1290.

²³⁴ See, e.g., CRICO STRATEGIES, *supra* note 51, at 5, 7 (analysis of 200,000 malpractice claims from academic and community hospitals, commercial and captive insurance carriers; most common allegation: delay in treatment of fetal distress; most frequent OB case: birth asphyxia; 44% of OB cases closed with payment; payment in all OB cases between 2005-2009 revealed 12% closed with a payment of more than \$1 million; average cost of all closed cases was \$947,000); Steven M. Donn, *Malpractice Crisis Has Forced Pediatricians to Manage Risk, Improve Quality of Care*, 28 AAP NEWS 11 (Feb. 2007) (Physician Insurers Association of America data on neurologically impaired infants 1988 to 1998 reveals 47% result in payment); LaValley & Hoffman, *supra* note 51, at 3 (among perinatal cases at the Harvard medical institutions, the most frequent allegation was failure to recognize and respond to fetal distress; OB-related cases resulted in more than twice the average indemnity payment for all claims combined); MacLennan et al., *Only*, *supra* note 103, at 29 ("The cerebral palsy litigation industry is gradually destroying the Australian maternity services."); CONDRA, *supra* note 102, at 2 (over 12-year period in 263 hospitals majority of claims were perinatal injuries related to labor and delivery, fetal distress, and EFM); Jacobson, *supra* note 51 (PIAA data reveals EFM driving factor in impaired infant cases, with EFM-related claims rising from 41% of cases to 88% of cases in 1997 survey); Cartwright, *supra* note 51 (most common claim in obstetrics is failure to recognize and treat fetal distress); Cf. 1 MEDICAL LIABILITY, *supra* note 117, at 81 (46% of obstetrical claims involve EFM).

²³⁵ See, e.g., Schiffrin et al., *supra* note 35; Huber, *supra* note 38, ch. 5.

²³⁶ See Lucchese, *supra* note 46.

²³⁷ Troyen A. Brennan et al., *Relation Between Negligent Adverse Events and the Outcome of Medical Malpractice Litigation*, 335 NEW ENG. J. MED. 1963, 1963 (1996).

was no association between an adverse event due to negligence or an adverse event of any type and payment” to the plaintiff.²³⁸

A. Simple Narrative, Big Damages

There is simply no better damage claim a trial lawyer could present to a jury than that of a neurologically-devastated child: a child permanently neurologically devastated at the hands of ignorant and inattentive physicians and nurses, care providers who, according to the EFM courtroom experts, had in their hands a machine that could have changed the outcome if only they had paid attention. That simple liability narrative, coupled with the raw emotional appeal of a spastic, incontinent, mentally challenged, sometimes blind, sometimes deaf, sometimes both, wheelchair-bound child fed through a stomach tube connected to a giant plastic syringe, explains how CP-EMF lawsuits became a cottage industry with mega jury verdicts rivaling business litigation cases.²³⁹

Exponentially increasing mega verdicts drew adverse attention. Back-to-back 2002 and 2003 United States Department of Health and Human Services reports on the national medical liability system and its impact on health care provided particularly forceful criticism: litigation system excesses contribute to defensive medicine; the system raids the wallet of every American; litigation system is broken; small proportion of cases with extreme judgments influence settlements in other cases and are the litigation crisis driving force; the litigation system inaccurately judges medical negligence causing physicians to react with fear, distrust, and more defensive medicine; runaway litigation system costs every American through higher premiums and higher taxes; litigation system is unpredictable and random, costly, slow, a litigation lottery, does not accurately identify negligence, or deter bad conduct or provide justice.²⁴⁰ These reports singled out, among all medical specialties, the

²³⁸ *Id.*; cf. Troyen A. Brennan, et al., *Incidence of Adverse Events and Negligence in Hospital Patients: Results of the Harvard Medical Practice Study*, 324 NEW ENG. J. MED. 370 (1991). The well-known Harvard study is reported in a series of articles and at least one book. Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients*, 324 NEW ENG. J. MED. 377 (1991); cf. A. Russell Locallo et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, 325 NEW ENG. J. MED. 245 (1991); Paul C. Weiler et al., *Proposal for Medical Liability Reform*, 267 J.A.M.A. 2355 (1992); Paul C. Weiler et al., *The Economic Consequences of Medical Injuries*, 267 J.A.M.A. 2487 (1992); PAUL C. WEILER ET AL., *A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION* (1993).

²³⁹ Lucchese, *supra* note 48; Healthcare Crisis 2002, *supra* note 46; Litigation System 2003, *supra* note 51.

²⁴⁰ *New Healthcare Crisis 2002*, *supra* note 46, at 11–13, 17. Medical malpractice reform driven by birth injuries-CP verdicts and settlements have been the subject of dozens of studies, editorials, articles, and proposals for many years, many of which reiterate the language of the HHS report. *E.g.*, MacLennan, *Only*, *supra* note 89; MacLennan, *Who*, *supra* note 103; Kathryn Whetten-Goldstein et al., *Compensation for Birth-Related Injury: No-Fault Programs Compared with Tort System*, 153 ARCH. PED. & ADOLESCENT MED. 41 (1999); Arnold S. Relman, *Changing the Malpractice System*, 322 NEW ENG. J.

disproportionate increases in verdicts and settlements affecting obstetricians and gynecologists with median awards increasing 43% in one year alone.²⁴¹

Thus, despite the repetitive accumulating evidence that EFM does not reduce CP rates, does not predict cerebral palsy, and does not identify abnormalities that are reversible, mega jury verdicts continue increasing. These verdicts, in turn, drive up the cost of settlements, as well as stoking fears among physicians of ever trying a birth injury case and becoming a victim of the next headline mega verdict.²⁴² Curiously, despite the litigation lottery,²⁴³ it is known that most people believing they are a medical error victim do not file a claim, and those who do file medical negligence claims—perhaps nine out of ten (estimates vary)—result in no payment to the patient.²⁴⁴

B. CP Verdicts Benefit Only a Few

In CP cases, it is estimated that less than 10% of patients receive any compensation whatsoever.²⁴⁵ This estimate is said by some to prove that juries understand EFM-CP and that defendants, by cross-examination and reliance on knowledgeable testifying experts, can win the vast majority of CP trials. Such an analysis may be correct, but misses the point. In the first place, even if physicians win, the expense of trying these cases is high, both in terms of dollars, emotional turmoil, and potential reputational damage.²⁴⁶ The dollars are potentially insurable, even though insurance for individual practitioners is limited and expensive, and the worry of exceeding those limits causes considerable financial concern, in addition to the usual emotional stresses of litigation.²⁴⁷

MED. 626 (1990); Barry M. Manuel, *Professional Liability—A No-Fault Solution*, 322 NEW ENG. J. MED. 627 (1990); 1 MEDICAL LIABILITY, *supra* note 117; COMM. STUDY MED. PROF'L LIAB. & DELIVERY OBSTETRICAL CARE, INST. MED., DIV. HEALTH PROMOTION & DISEASE PREVENTION, 2 MED. PROF. LIABILITY & DELIVERY OB. CARE (Victoria P. Rostow & Roger J. Bulger eds., 1989); Victoria P. Rostow et al., *Medical Professional Liability and the Delivery of Obstetrical Care*, 321 NEW ENG. J. MED. 1057 (1989).

²⁴¹ *Id.*

²⁴² Peter W. Huber, *Junk Science in the Courtroom*, FORBES, July 8, 1991, at 68-72; cf. Francis Patrick Hubbard, *The Physician's Point of View Concerning Medical Malpractice: A Sociological Perspective on the Symbolic Importance of "Tort Reform,"* 23 GA. L. REV. 295, 344-45 (1989); PETER W. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* (1990); Redlich, *supra* note 51.

²⁴³ E.g., *Healthcare Crisis 2002*, *supra* note 46, at 10.

²⁴⁴ *Id.*; David Leonhardt, *Malpractice Anxiety*, N.Y. TIMES, Aug. 17, 2011, available at <http://economix.blogs.nytimes.com/2011/0817/malpractice-anxiety/> (commenting on the *New England Journal of Medicine* article by Jena et al., *supra* note 207, and analyzing the latest data regarding success of filed malpractice claims: 9 out of 10 led to no payment).

²⁴⁵ Leonhardt, *supra* note 244.

²⁴⁶ Jena et al., *supra* note 207, at 635.

²⁴⁷ MacLennan et al., *Only*, *supra* note 103 ("fear of litigation" was a major reason obstetricians are disappearing from the Australian maternity services); MacLennan et al., *Who*, *supra* note 103 (litigation fears and costs now dominate obstetricians' reasons for avoiding or retiring from obstetrical practice). Sartwelle, *Defending*, *supra* note 2, at 212 n.177 (litigation stress "has been a professional concern for

But more important than dollars and stress to an individual physician is that this analysis supposes that plaintiffs in 90% of CP cases not receiving compensation is somehow a victory for the system. In fact, it is a devastating defeat, not only for CP victims and their families, who desperately need help coping, but also for society and the legal system. The question is how many of these cases should be filed in the first place given the overwhelming evidence that lack of oxygen causes only a small proportion of CP, that CP due to birth asphyxia is not preventable and that EFM and 30-minute delivery has not reduced CP anywhere in the world.²⁴⁸ A more pertinent question is why we continue misdirecting time and energy and billions of dollars to a broken litigation system when those dollars could be better utilized in causal research and supporting all of the children and families living with the often devastating, life-changing consequences of CP. CP-EFM litigation today is merely a demonstration of the tort system's inability to reliably distinguish junk science. In essence, as commentators have observed, CP litigation uses obstetricians, nurses, and hospitals "as an inefficient and expensive de facto extra social welfare system" for the fortunate 10% that do recover money.²⁴⁹

C. CP-EFM and the Trial Lawyer

Why does CP litigation continue? This is especially relevant when for four decades less than 10% of CP kids have benefited from this system. And why does EFM continue in spite of evidence of general uselessness and possible harm? The answer to both questions is not complex. The primary, but not the sole, influence was and is the trial lawyer. At first, trial lawyers took advantage of opportunities presented by changing societal norms and society's recently acquired skepticism toward government, institutions, corporations, and the medical profession. Later, just before the turn of this century, trial lawyers took advantage of newfound advertising freedoms and adroitly exploited perhaps the greatest public CP-EFM misinformation tool ever—the Internet. This combination has allowed trial lawyers for the last 40 years to outmaneuver most medical malpractice reforms put forth by scholars, medical societies, and legislators alike.²⁵⁰ And, if history is a guide, it seems unlikely to change soon.

many years. It has led to changes in medical practice habits, changes in attitudes toward patients, and, of course, development of defensive medicine diagnostic reflexes").

²⁴⁸ MacLennan et al., *Only*, *supra* note 103, at 29; MacLennan et al., *Who*, *supra* note 89, at 1688.

²⁴⁹ MacLennan et al., *Only*, *supra* note 103, at 29.

²⁵⁰ For contemporary accounts of failed malpractice reforms, see Phillip G. Peters, Jr., *Health Courts?*, 88 BOSTON U.L. REV. 227 (2008); PAUL C. WEILER, *MEDICAL MALPRACTICE ON TRIAL* (1991). Metzloff commended Weiler's book for being nonpartisan. Thomas B. Metzloff, *Understanding the Malpractice Wars*, 106 HARV. L. REV. 1169, 1169 (1993). The book review is almost as long as the book and in many respects more comprehensive. *See id.*

D. EFM Goes to Court

Obstetrical practice in this and other industrialized countries has been transformed in the last half century by the assumption that lawyers somehow identified fixes to neurologic birth injuries that the medical profession could not or would not correctly implement—EFM and rapid C-sections. The trial lawyer influence over obstetrical care seems to divide into roughly two time periods—the 1970s to the mid-to-late 1990s and from there to the present.

In the 1970s-1980s to about the mid-1990s, when EFM and the quick C-section cure were called into serious question by several medical studies, trial lawyers and their experts were overcoming the science by taking advantage of a public readily disposed to belief in myth as well as the public's recently acquired skepticism of institutions and rejection of medical paternalism and a concomitant expanded notion of tort responsibility as the judicial system expanded tort liability and new concepts of damage recovery.²⁵¹ The public's skepticism of medicine, however, has only recently arrived.

E. The Age of Innocence?²⁵²

In 1954, five pharmaceutical companies competed to be the first to market a new miracle polio vaccine. The vaccine was developed by scientist Jonas Salk, a son of Russian immigrant parents, born in New York City only two years before the 1916 New York polio plague killed thousands and left thousands more paralyzed.²⁵³ By 1955, Americans by the millions were unquestioning as they lined up to receive the Salk vaccine, trusting the integrity of the scientific process and scientists like Jonas Salk. He was a genuine American Hero, as were most scientists and physicians even down to the family physician with the medical office on the corner.²⁵⁴ Although these small general practice medical offices were familiar, the physicians of the 1950s were curing sick patients like never before in history with newly available medicines, and a new scientific knowledge that doubled and tripled yearly. Physicians, scientists, pharmaceutical companies, and the medicine and vaccines that they made were trusted.

²⁵¹ E.g., G. EDWARD WHITE, *TORT LAW IN AMERICA, AN INTELLECTUAL HISTORY* 289-90 (expanded ed. 2003).

²⁵² See EDITH WHARTON, *THE AGE OF INNOCENCE* (1920), available at <http://www.online-literature.com/wharton/innocence/> (last visited May 30, 2012).

²⁵³ The story of polio, its devastation, and its defeat at the hands of scientists like Salk and Albert Sabin (who were definitely not friends) is only a small part of a larger incredible story of the miracles of vaccines. The polio and other vaccines story is told in many books and articles, none better written than those by Dr. Paul Offit, Chief of Infectious Disease at the Children's Hospital of Philadelphia and Seth Mnookin a contributing editor at *Vanity Fair*: PAUL A. OFFIT, *DEADLY CHOICES* (2011); AUTISM'S FALSE PROPHETS (2008); VACCINATED (2007); THE CUTTER INCIDENT (2005); SETH MNOOKIN, *THE PANIC VIRUS* (2011).

²⁵⁴ See PAUL STEPANSKY, *THE LAST FAMILY DOCTOR: REMEMBERING MY FATHER'S MEDICINE* (2011) (a son's tribute to his father's general medical practice that began in 1948 in small rural communities in eastern Pennsylvania).

F. Innocence Lost

The public's reverence, however, faded. Reverence was replaced by skepticism, uncertainty, and suspicion, not only of government and of corporations, but also of long-trusted institutions, including medicine. The exact time and exact reasons suspicion replaced trust are still mysterious and are the subject of thousands of books, theses, editorials, and essays.²⁵⁵ What is evident, as we have seen, is that juries' skepticism toward medicine met the trial lawyer sometime in the 1960s, causing the first medical malpractice insurance crisis in the early 1970s.²⁵⁶ Large malpractice verdicts, for that era, precipitated large settlements, resulting in a defensive medicine frenzy. Obstetricians, caught up in the frenzy, irrationally refused to let go of the technology that they saw as a salvation from being sued—EFM. Clinging to the very technology that was, in fact, the instrument most useful to trial lawyers was a product of physicians' abject legal system fears, a system they simply did not, or refused to, understand.²⁵⁷ A physician involved in one of the studies of the causes of the first medical malpractice crisis in the early 1970s explained physicians' litigation fears:

A medical degree does not confer an intelligent knowledge of government, law, insurance and consumer action. Medical-legal problems, complexities of the insurance industry, governmental function, and consumerism are subjective areas of intellectual destitution for many physicians, and ignorance breeds fear.

It may be hard to believe, but we are a frightened profession. . . .

Community reputation is a socioeconomic asset for a physician. The malpractice problem, he believes, tends to destroy this.²⁵⁸

IX. EFM IN COURT, 2000 AND BEYOND

The 2002 HHS medical malpractice study noted the average jury verdict rose 76% from 1996 to 1999. The increase was disproportionate for physicians delivering babies, increasing 43% in one year alone.²⁵⁹ Mirroring increased jury awards, settlements also steadily rose, as did the expense of defending

²⁵⁵ Search Google for any number of subjects coupled with “distrust”—government, corporations, institutions, medicine—and Google returns thousands of results, from books to essays to theses, magazines, special reports, and blogs. Causes for the public's distrust of once trusted institutions include Vietnam, Nixon, the Tuskegee syphilis study, vaccines, and hundreds of other public events.

²⁵⁶ See, e.g., Danzon, *supra* note 41.

²⁵⁷ Redlich, *supra* note 51, at 303–08 (describing the “players” in the malpractice crisis, two of which are doctors and lawyers); see also *Healthcare Crisis 2002*, *supra* note 46, at 6–7, 10–13 (describing contemporary physicians' medical malpractice system fears).

²⁵⁸ Redlich, *supra* note 51, at 305; see also Jena et al., *supra* note 213, at 635.

²⁵⁹ *Healthcare Crisis 2002*, *supra* note 46, at 9; cf. Jena et al., *supra* note 207.

claims.²⁶⁰ These trends have continued through this century's first decade.²⁶¹ What changed?

Undoubtedly, many things. Identifiable over-arching changes, however, that expanded the public's belief in the EFM-CP myths include lawyer advertising; the Internet; the public's continuing skepticism of medicine, led by instant Internet experts associated with groups that oppose various treatments, drugs, and vaccines; the rise of post-Modern philosophy and its relativism that makes truth relative to each person's experience. And, finally, a dominant change exponentially increasing skepticism of medicine are the labels *du jour*—conflict of interest and conspiracy. These labels are used by opposition groups like the anti-vaccine movement. Recently these labels have been adopted by trial lawyers to denigrate EFM-CP research and the individual scientists engaged in the effort to understand neonatal pathophysiology and birth.

A. Lawyer Advertising

Lawyer advertising is now a part of life. As ubiquitous as lawyer advertising is today—on TV, radio, internet, billboards, and newspapers—many forget that advertising was totally prohibited before the U.S. Supreme Court cracked open the door in 1977.²⁶² By the mid-1990's, the door was off its hinges.²⁶³ Particularly aggressive were ads for cerebral palsy and other medical malpractice cases. In 2004, medical malpractice TV ads were counted; there were more than 10,150²⁶⁴ In 2008, there were 156,000—nearly a 1400% increase, with spending increasing from \$3.8 million to \$62 million.²⁶⁵ The message of each CP birth injury ad is the same: Lack of oxygen causes CP and physicians and nurses could prevent CP if they only paid attention and timely addressed problems during labor including the EFM.²⁶⁶

²⁶⁰ *Healthcare Crisis 2002*, *supra* note 46, at 13.

²⁶¹ Lucchese, *supra* note 46; Jena et al., *supra* note 207.

²⁶² See, e.g., Sartwelle, *Your Doctor*, *supra* note 44.

²⁶³ See, e.g., Peyton Paxson, *Have You Been Injured? The Current State of Personal Injury Lawyers' Advertising*, 36 J. POPULAR CULTURE 191 (2002).

²⁶⁴ U.S. Chamber Institute for Legal Reform, *Trial Lawyer TV Ads for Medical Malpractice Lawsuits Grew 1,400 Percent in Last Four Years, Study Shows*, U.S. CHAMBER INSTITUTE FOR LEGAL REFORM (Sept. 8, 2009), at <http://www.instituteforlegalreform.com/media/press/trial-lawyer-tv-ads-for-medical-malpractice-lawsuits-grew-1400-percent-in-last-four-year> (last visited May 30, 2012).

²⁶⁵ *Id.*

²⁶⁶ E.g., Gair, Gair, Conason, Steigman, Mackauf, Bloom & Rubinowitz, <http://www.gairgair.com/lawyer-attorney-1430305.html> (last visited May 22, 2012); *About Cerebral Palsy, Medical Malpractice and Cerebral Palsy*, available at <http://www.about-cerebral-palsy.org/diagnosis/negligence-malpractice.html> (last visited May 22, 2012) (website sponsored by Lawyers Incorporated, PC & Sheldon Zisook, Attorney); Lawyers Incorporated, P.C. (Sheldon Zisook), available at <http://www.lawyersincorporated.com/> (last visited July 31, 2011).

Google “birth injury,” “baby injury,” “pregnancy injury,” “common birth injuries,” “birth injury lawyer” or similar phrases.²⁶⁷ In less than one second, between 4,000,000 and 7,000,000 results will be returned. It is impossible to say that all are attorney websites, but reviewing many scores of the Google results strongly suggests that possibility.²⁶⁸ And at every website, the refrain is the same: If your baby has CP or any birth injury, it is likely that your physician and the nurses were not paying attention to the electronic fetal monitor that tells them when a baby is in distress and not getting enough oxygen;²⁶⁹ birth injuries are often caused by a medical mistake depriving the child of oxygen during labor and delivery.²⁷⁰ Of course, no attorney website supports these generalizations with articles or citations to authority, except articles authored by the attorney whose website is accessed.²⁷¹ Accompanying these statements in many websites are verdicts and settlements²⁷² that, of course, are exceedingly large. Trial lawyers effectively use the old sales aphorism, “sell the sizzle, not the steak.”

Just as ubiquitous and just as lacking in scholarship is another form of advertising—blogs. This newest “information” forum makes anyone with a computer and a little time an instant expert.²⁷³ Blogs run the gamut from lawyers to consumers to advocacy groups and on down the line. As Mark Twain remarked: “Our opinions do not really blossom into fruition until we have expressed them to someone else.”²⁷⁴ If true, the internet is a fertile flower garden.

Lawyer advertising, whether a paid ad, a website, a blog, or a billboard, is virtually unregulated as to the substance of the message. For example: “Most birth injuries are caused by doctors;”²⁷⁵ or “birth asphyxia is a rare event is a

²⁶⁷ The combination of phrases leading to lawyer web sites seems to be endless. “Birth” and “injury” seem to be common denominators, but the Google algorithm somehow leads to the attorney web sites regardless of the combination of words used.

²⁶⁸ Cf. A.B.A., *National Lawyer Population by State*, at http://www.americanbar.org/content/dam/aba/migrated/marketresearch/PublicDocuments/2011_national_lawyer_by_state.authcheckdam.pdf (last visited May 30, 2012). The number of licensed lawyers in the United States in 2010 was 1,225,452. *Id.* Of this number, approximately three-quarters were in private practice. Thus, the Google return suggests either that the algorithm gives preference to lawyer web sites or lawyers have learned how to game the search engine, because reviewing several score of Google search pages reveals primarily lawyer web sites.

²⁶⁹ E.g., THE HELLER LAW FIRM, <http://www.seriousinjury.org/BlogRetrieve.aspx?PostID=304705&A=SearchResult&SearchID=1898615&ObjectID=304705&ObjectType=55> (last visited May 22, 2012).

²⁷⁰ E.g., GOLDBERG & OSBORNE, <http://1800theeagle.com/practice-areas/medical-malpractice/cerebral-palsy/> (last visited May 22, 2012).

²⁷¹ E.g., GAIR, GAIR, *supra* note 266.

²⁷² See, e.g., *id.*

²⁷³ E.g., CULLAN & CULLAN, LLC., <http://www.nebraskatriallawyersblog.com/cerebral-palsy/> (last visited May 30, 2012). The impact of blogs and the instant “experts” they create is chronicled in ROBERT GOLDBERG, *TABLOID MEDICINE* 19-20 (2010).

²⁷⁴ See www.twainquotes.com/ Directory of Mark Twain’s maxims, quotations, and various opinions, <http://www.twainquotes.com/Opinion.html> (last visited May 30, 2012).

²⁷⁵ GAIR, GAIR, *supra* note 266.

myth”; “it is a doctor myth that EFM is an unreliable way to assess fetal well-being.”²⁷⁶ Lawyer advertising is constitutionally protected,²⁷⁷ but unlike ads for health products, drugs, supplements, consumer goods, and food, lawyer ads are not closely regulated when it comes to medical, factual statements and claims. In fact, it seems that bar associations are uninspired when it comes to enforcing the few lawyer advertising rules that do exist.²⁷⁸

B. The Internet Meets Post-Modern Philosophy

The most pervasive purveyor of myths is the Internet, having come from “an academic curiosity to all-encompassing cultural juggernaut,”²⁷⁹ sometime between December 1996 and November 1999.²⁸⁰

The Internet’s ubiquity and popularity intersected with postmodernism’s relativism at precisely the right time, making everyone with a computer an expert, a graduate of the University of Google. The Internet has completed postmodernism’s devaluation of truth and knowledge as absolute and solidified the concept that truth is relative to each person’s experience.²⁸¹ As a result, the Internet is a haven for “a class of ‘instant experts’ who range from the dangerously uninformed to the credentialed and opportunistic.”²⁸² For the past decade, groups in opposition to virtually everything from drugs to vaccines have established websites, as have sufferers of every disease and condition known to mankind. While sharing knowledge and common difficulties

²⁷⁶ Howard A. Janet, *How Electronic Fetal Monitoring Can Prevent Cerebral Palsy*, available at http://www.medlawlegalteam.com/article_janet_power_knowledge.html (last visited May 22, 2012).

²⁷⁷ Sartwelle, *Your Doctor*, *supra* note 44.

²⁷⁸ See Fred C. Zacharias, *What Lawyers Do When Nobody’s Watching: Legal Advertising as a Case Study of the Impact of Underinforced Professional Rules*, 87 IOWA L. REV. 973 (2002) (exploring lawyer ads in the San Diego Yellow pages and cataloguing the numerous unpunished violations of the California rules on legal advertising; Professor Zacharias also surveyed advertising violations across the country, detailing the lack of bar association discipline for violations); Keith Swisher, *Disciplinary Authority and Choice of Law in Online Advertising: Disclaimers or Double Deontology*, 21 PROF. LAWYER 8 (2011) (discussing the possible unauthorized advertising charges that could be brought against lawyers aiming advertising into states where they are not authorized to practice law).

²⁷⁹ Robert Keyes, *When Did the Internet Become Popular?*, available at <http://www.sinister.com/inetpop.html> (last visited May 22, 2012).

²⁸⁰ *Id.*; Rob Spiegel, *When Did the Internet Become Mainstream?*, E-Commerce Times (Nov. 12, 1999), available at <http://www.ecommercetimes.com/story/1731.html> (last visited May 22, 2012).

²⁸¹ Paradoxically, the reader is referred to hundreds of Internet sites defining, describing, and discussing Post-Modernism so the reader may determine the relative truth of the definition. *E.g.*, Geoff Haselhurst & Karene Howie, *Postmodernism*, <http://www.spaceandmotion.com/Philosophy-Postmodernism.htm> (last visited May 22, 2012). “Finally, if nothing can be truly asserted, even the following claim would be false, the claim that there is no true assertion.” *Id.* (quoting Aristotle). “The ONLY ABSOLUTE TRUTH is there are NO ABSOLUTE TRUTHS.” *Id.* (quoting Feyerabend).

²⁸² GOLDBERG, *supra* note 273, at viii. Dr. Goldberg’s book explores how the Internet has created medical myths and anti-drug, anti-medicine sentiment. Those taking advantage of the new information age and the spread of “tabloid medicine” include sloppy journalists, irresponsible politicians, trial lawyers, and opportunistic, publicity seeking physicians and academics, all of whom, intentionally or not, spread false data in the guise of research and exposé.

and triumphs is one of the web's spectacular successes, the disturbing fact is that the web is timeless, and therefore misinformation replicates itself a thousand times over, remaining easily accessible and retaining a patina of current verity even though long since proven invalid. Myths are not only reinforced on the Internet—they have eternal life.

Trial lawyers, through their Internet advertising, websites, and blogs, perpetuate the CP-EFM myths, bypassing 40 years of science. Thus, some unknown number of the public coming to jury duty have already had their beliefs in the birth myths reinforced—oxygen deprivation alone causes CP, physicians with EFM can prevent CP. Where on the Internet is a plain-language rebuttal—an ACOG et al. plain-language site for those skeptical of lawyer ads, blogs, and articles? It does not exist. For example, there is currently an online article by a lawyer, "How Electronic Fetal Monitoring Can Prevent Cerebral Palsy."²⁸³ Written in 2005, the article is completely devoid of citations to medical or other authority. Statements are made that intrapartum asphyxia is common and preventable, that EFM is reliable and has reduced the incidence of CP, and that physicians deliberately rely on outdated research to hide EFM's reliability to shield themselves from liability for malpractice.²⁸⁴ Where would the curious turn to see if ACOG et al. had a plain-language rebuttal? A plain-language Google search turns up nothing by medical organizations on current EFM use and little in plain language on CP.

ACOG et al. are losing the public information battle to trial lawyers. ACOG et al.'s approach has been the typical medical approach—practice bulletins, medical articles, meetings, and conferences, all directed at physicians and nurses. As we have seen, that educational effort has had exceedingly poor results.²⁸⁵ CP-EFM plain-language consumer information does not seem to exist on the internet. ACOG et al. have failed to recognize that educating their patients, prospective patients, and the public will probably accomplish more than all the medical journal articles arguing for no-fault CP courts.²⁸⁶

Perhaps even more important for ACOG et al. is that prospective jurors and judges in every birth injury trial today and for the last several years have had pre-trial exposure or will have in-trial exposure to the special farrago of EFM-CP-birth injury misinformation permeating trial lawyer websites, blogs, and advertising.²⁸⁷

²⁸³ Howard A. Janet, *supra* note 276.

²⁸⁴ *Id.*

²⁸⁵ See, e.g., Hankins et al., *supra* note 16.

²⁸⁶ See, e.g., MacLennan et al., *Who*, *supra* note 103.

²⁸⁷ Julie Blackman & Ellen Brickman, *Let's Talk: Addressing the Challenges of Internet-Era Jurors*, 23

JURY EXPERT 35 (Mar. 2011), available at <http://www.thejuryexpert.com/wp-content/uploads/2011/03/TJEv23Num2Mar2011.pdf> (last visited May 22, 2012).

C. Google Mistrials

Not long ago a judge was stunned to learn “prospective jurors Googled a case over lunch in the midst of voir dire.”²⁸⁸ A “Google mistrial” is the current description of mistrials declared because of jurors’ use of the Internet during trial.²⁸⁹ Even amid the widespread adoption of explicit jury instructions forbidding internet use, “reports of jurors using the Internet [during trial] come even more frequently.”²⁹⁰

The reality today is that jurors are blogging and tweeting about cases and turning to the Internet to research aspects of what they hear in trial, despite judicial orders to the contrary.²⁹¹ Unfortunately for the physicians and nurses on trial today, there is precious little plain-language ACOG et al.–sponsored EFM–CP–birth injury information to be obtained by those jurors who will invariably be Googling the plaintiff’s expert’s testimony.²⁹²

ACOG et al. should accept advice from a vaccine proponent as to how the public relations war with the anti-vaccine movement should be conducted. Dr. Rahul Parikh, Kaiser Permanente, pointed out how parents refused vaccines for their children after seeing an *Oprah* episode. The refusers were adamant even though the CDC’s statement about vaccine safety and thimerosal were read aloud on the program in its entirety.²⁹³ But the CDC statement was couched in typical medicalese, with the prototypical ambiguity that left parents certain that vaccines were unsafe, just as Oprah’s anti-vaccine parent guest had said.²⁹⁴ Parikh pointed out that medicine, when confronted with controversy, has one of two reactions, neither of which is effective: issue a CDC-like ambiguous statement filled with bureaucratic medicalese and puny scientific qualifiers or ignore the controversy and stay silent, pretending that staying above the fray is a dignified professional response.²⁹⁵ Silence, however, can be and is interpreted by the public as concealing the truth. As Parikh phrased it, there is a failure to persuade.²⁹⁶ His solution? Plain-language rebuttals that

²⁸⁸ *Id.* at 13.

²⁸⁹ *Id.*

²⁹⁰ *Id.* at 14.

²⁹¹ *Id.* at 15.

²⁹² The solution proposed by Blackman and Brickman is to allow jurors to search the Internet but instruct them to consider such information inferior or secondary to the courtroom evidence. *Id.* at 20–22.

²⁹³ Rahul K. Parikh, *Fighting for the Reputation of Vaccines: Lessons from American Politics*, 121 *PEDIATRICS* 621 (2008).

²⁹⁴ Thimerosal is red herring that may well have cost some children their lives. Removed from virtually all childhood vaccines in 2001, rates of autism have not declined. In addition, 10 independent epidemiological studies have proven MMR vaccines do not cause autism. Six have eliminated thimerosal as a cause, with three demonstrating thimerosal does not cause subtle neurological problems. *E.g.*, OFFIT, *AUTISM’S FALSE PROPHETS*, *supra* note 253, at 245–47.

²⁹⁵ See Parikh, *supra* note 293, at 622.

²⁹⁶ *Id.*

admittedly are not in the DNA of most physicians or scientists. As he notes, however, “it is time we changed.”²⁹⁷

The key is to provide accurate, effective, plain-language information that emphasizes the depth and breadth of medical knowledge about CP-EFM, admitting there is much unknown but that medicine is seeking to find out. A plain-language committee should be established in every professional society, with a plain-language website and plain-language speaker’s bureau. FAQ sections of the website can address statements made in lawyers’ websites, blogs, and ads. As relevant new studies are published, plain-language summaries could be added with explanations as to the strength of the evidence and how the information adds to the existing knowledge.

Most physicians will say it is impossible to reduce complex medical studies about CP-EFM to plain language. But expert witnesses do it in American’s courtrooms. Why not do the same thing before the lawsuit is filed?

D. Conflict of Interest and Conspiracy

Forty years of obstetrical claims analysis document that EFM-fetal distress lawsuits dominates the obstetrical malpractice scene.²⁹⁸ The reason is perfectly clear. A newborn’s injuries evoke maximum sympathy from juries and, in our system, individual juries end up deciding what it costs to provide lifetime care for any particular child, thereby enhancing the chances for a mega-verdict that rivals business litigation cases.²⁹⁹ Such cases are lucrative for trial lawyers, and their incentive to maintain the “EFM prevents CP, fetal distress is diagnosed by EFM, and quick C-sections prevent CP” myths are extraordinarily high. Thus, as we have seen, trial lawyers have used advertising, websites, and blogs to successfully dominate the birth story information battle with obstetricians. Recently, trial lawyers began using a new weapon, copied from contemporary society’s debates with medicine over efficacy and necessity of vaccines, the causes of autism, and other debates—labels. The preferred labels today are “conflict of interest” and “grand conspiracy.” These labels are directed primarily against CP-EFM investigators and researchers, ACOG et al., NIH, and any others who want to end the lucrative birth-injury litigation lottery.

E. To Hear It Is to Believe It³⁰⁰

The novel *The Human Stain*, by Phillip Roth, tells the story of a prominent classics professor and dean at a fictional college in western Massachusetts in the late 1990s. The dean is forced to retire after two of his students make

²⁹⁷ *Id.*

²⁹⁸ See, e.g., Lent, *supra* note 51.

²⁹⁹ See, e.g., Lucchese, *supra* note 46.

³⁰⁰ PHILLIP ROTH, *THE HUMAN STAIN* 290 (2000).

a totally false, unjustified racism accusation. Musing on his college community's willingness to accept the charge without any proof and despite his lifelong devotion to the college, the dean thinks: "To hear the allegation is to believe it. No motive for the perpetrator is necessary, no logic or rationale is required. Only a label is required. The label is the motive. The label is the evidence. The label is the logic."³⁰¹

Today, "conflict of interest" and "grand conspiracy" labels have been used by consumer medical disease support groups, anti-drug groups, and anti-vaccine groups to denigrate research, researchers or institutions not supporting the group's beliefs.³⁰² One conflict of interest allegedly tainting the work of scientists and researchers today is, of course, money—whether received from government or industry. It is an appeal to the well worn belief that everyone is in someone's pocket.³⁰³ Often accompanying conflict of interest allegations are accusations that a grand conspiracy is deliberately hiding medical truth in favor of industry profits.³⁰⁴ The conspirators at various times are a combination of the government, NIH, FDA, FTC, pharmaceutical companies, various highly placed physicians within the medical profession, the entire medical profession, research scientists, and so on. One only need review the internet to find a conspiracy *du jour*. Robert Goldberg labels the rise of internet health care by instant experts "tabloid medicine."³⁰⁵ These experts, whether consumer groups, disease advocacy groups, lawyers, or whomever, have as their core weapon against research contrary to their advocated view, the "grand conspiracy narrative in which the truth is being hidden by a cabal of the self-interested that includes drug companies, government agencies, physicians, scientific researchers, and anyone else who disagrees with its orthodoxy."³⁰⁶

True or not, these allegations, repeated in news reports, magazines, TV, on the internet, have almost instant credence with the public sufficient to taint the individual, the research, or both, simply by being made. It is not clear why the old phrase "Cui Bono" or its modern equivalent, "follow the money" has gained such traction, especially in regard to the medical profession and medically related research. What is clear, however, is that it has.

There have, of course, been legitimate industry-medical profession conflicts of interest uncovered through the years. Sensationalized and embellished, the subsequent overreaction by organized medicine and medical

³⁰¹ *Id.*

³⁰² These groups, despite their protestations that they care only about the children, about cures, the truth, justice, and other such subjects, almost all have their own vested interests and/or significant financial interests to protect. The accusers' conflicts of interest, however, often seem to be overlooked entirely.

³⁰³ OFFIT, *AUTISM'S FALSE PROPHETS*, *supra* note 253, at 198-202; GOLDBERG, *supra* note 273, at 135-38; MNOOKIN, *supra* note 253.

³⁰⁴ OFFIT, *AUTISM'S FALSE PROPHETS*, *supra* note 253, at 211-17; GOLDBERG, *supra* note 273, at 173-208; MNOOKIN, *supra* note 253, at 160-69, 221-27.

³⁰⁵ GOLDBERG, *supra* note 273.

³⁰⁶ *Id.* at 176.

schools to the misdeeds of the few results in condemning and prosecuting all. Antidotes in the press, on TV, and circulated on the Internet succeed in keeping the accusations fresh and alive so that conflict of interest and conspiracy accusations “have become an effective and wide-reaching weapon wielded by industry opponents and aggrieved patients as a means to attempt to shut down discussion, undermine research, and attack doctors and scientists.”³⁰⁷

Thus, common sense and the scientific method have been overwhelmed by post-modernism’s insistence that there is no truth except your own truth. Couple that with the Internet’s ability to make everyone an instant expert, even lawyers, and society has been primed to accept trial lawyers’ current attack against the past forty years of CP-EFM research and researchers: ACOG created the research; it is all false, it is junk science; the research was created with the help of NIH and NIH epidemiologist Dr. Karin Nelson, with the specific purpose to manipulate juries and defeat the civil justice system; ACOG and Nelson are part of a conspiracy to obstruct justice with false science.³⁰⁸

F. Electronic Fetal Monitoring and Trial Lawyers

Using contemporary society’s labels, trial lawyers recently began making these charges against CP-EFM investigators and researchers, ACOG et al., NIH, and especially Dr. Karin Nelson, the NIH neuroepidemiologist responsible for so much of the ground-breaking epidemiology related to CP-EFM. Trial lawyers now routinely charge that the last forty years of obstetrical-pediatric peer-reviewed scientific literature published on CP-EFM is corrupt junk science designed to protect negligent physicians from jury verdicts.³⁰⁹ Stated otherwise, physicians worldwide have published false science for forty years in an effort to manipulate the civil justice system, constituting a conspiracy to obstruct justice.³¹⁰ Coordinating this conspiracy are ACOG and Dr. Karin Nelson, who have kept the conspiracy together for 40 years, manipulating physicians and institutions, as well as the public, in order to publish junk science.³¹¹

³⁰⁷ *Id.* at 178; Offit, *AUTISM’S FALSE PROPHETS*, *supra* note 253; MNOOKIN, *supra* note 253.

³⁰⁸ *E.g.*, Conason & Pegalis, *supra* note 148, at 257-58; Dov Apfel, *Intra-partum Asphyxia Is Preventable, Not Inevitable, Cause of Hypoxic-Ischemic Encephalopathy and Cerebral Palsy*, 2 N.Y. LITIG. REV. 22, 28 (2010), available at <http://www.nystla.org/nicecontent/documents/New%20York%20Litigation%20Review,%20Vol.%202,%202010.pdf>; Lee Tilson, *The Necesarean: When Is a C-Section Really Necessary?*, <http://www.opposingviews.com/i/the-necesarean-when-is-a-c-section-really-necessary> (2011) (last visited July 22, 2011); Janet, *supra* note 276; Joel D. Cunningham, *The Litigation Literature*, WASH. STATE ASSOC. JUSTICE, available to members at <http://www.washingtonjustice.org/WA/>. (“ACOG, in turn, relies heavily on its ally at The National Institute of Health, epidemiologist Karin Nelson, M.D.: (As Mark Twain said, ‘There are lies, damn lies, and then there are statistics.’)”). *Id.* at 2.

³⁰⁹ Cunningham, *supra* note 308; Janet, *supra* note 276.

³¹⁰ Conason & Pegalis, *supra* note 148, at 257-58.

³¹¹ *Id.*; Cunningham, *supra* note 308.

Documentation supporting these charges is nonexistent. Not a shred of evidence is cited. There are no citations to any source material. There is not even one article from a former conspiracy member, unable to live with his treachery, who finally breaks the code of silence. And, as with other conspiracy charges, the conspiracy mechanics are unexplained. For example, publishing junk science has to be a worldwide conspiracy, because CP-EFM is studied in every industrialized country. Medical studies confirming virtually all aspects of CP-EFM research published in the United States have also been duplicated and published in virtually all industrialized countries and vice versa. How could such a vast conspiracy be kept together for so long and not be outed? One would think that at least the expert witnesses routinely supporting plaintiffs' EFM-CP claims would have outed the conspiracy years ago with their own publications. They do not exist.

Today, however, as we have seen, "to hear the allegation is to believe it."³¹² Thus, not much more is required for many to accept the alleged conspiracy as true. The only work needed to keep it alive and fresh is to continually repeat the charge in articles and on the internet, which is precisely what trial lawyers have done.³¹³

X. PROTECTING THE CHILDREN

Two recent articles advocating ACOG et al.'s and Nelson's conspiracy bear examination.³¹⁴ One is authored by plaintiff attorneys Robert L. Conason and Steven E. Pegalis, the other by plaintiff attorney Dov Apfel. In addition to the unsubstantiated claims made in both articles, these authors also attempt to prove as true the myths that the majority of cerebral palsy is caused by oxygen deprivation only and the efficacy of electronic fetal monitoring for identifying and preventing CP. Careful examination of these arguments reveals a thin veneer of half-truths, and exceedingly imprecise analysis.³¹⁵

For example, Apfel describes in detail a pathway to CP that he claims represents valid biochemical brain events in a fetus before and after birth resulting in neuronal cell death and irreversible brain damage. The source for these complex processes associated with hypoxia and ischemia is Apfel himself.³¹⁶ Apfel's cited authority is his own three-year-old *Trial* magazine

³¹² ROTH, *supra* note 300.

³¹³ In Google, search for "cerebral palsy and litigation medical literature." Most of the resulting sites are lawyer websites. Many have some reference to ACOG's litigation literature or some similar phrase with similar meaning.

³¹⁴ Conason & Pegalis, *supra* note 148; Apfel, *supra* note 308.

³¹⁵ See *id.*; see also Sartwelle, *Defending*, *supra* note 2, at 233-38 (discussing Dov Apfel, *Using a Differential Diagnosis to Prove that Intrapartum Asphyxia Is a Significant Cause of Cerebral Palsy*, 30 AM. J. TRIAL ADVOC. 89 (2006)).

³¹⁶ Apfel, *supra* note 308, at 23 n.4.

article,³¹⁷ in which can be found a footnote using the same words to describe the same biochemical process without any citation to any authority whatsoever.³¹⁸

Conason and Pegalis also are their own authorities on a similarly worded hypoxic-ischemic brain insult during labor and delivery biochemical description. They move one step closer to being true authorities on the subject, however. They cite nothing to substantiate their statements.³¹⁹

Both articles also contain citations that do not support the propositions in the text material. For example, Conason and Pegalis cite a book by “Kubli” [*sic*] for the proposition that “prominent medical authors have written that, for the full-term infant, ‘near total safety is obtainable’ during labor if one looks for markers of fetal distress early enough to extract the not-yet-comprised fetus.”³²⁰

First, there are no book authors in this nearly quarter-century-old book. The book was edited by the late Dr. Fred Kubli of Heidelberg, who was one of several editors and is listed first.³²¹ The book is a compilation of individual papers presented at a 1986 workshop Kubli organized. He invited prominent internationally recognized CP authorities to present their papers on various CP subjects. One international authority attending by invitation was Dr. Karin Nelson.³²²

The quotation in the Conason/Pegalis text regarding what the multiple prominent authors supposedly wrote is misleading and incorrect. The page cited is to a single paper presented at the workshop by a French physician, C. Amiel-Tison from Paris’s Baudeloque Maternity Hospital. The presentation was entitled “Neurologic Morbidity of Term Infants as an Indicator of Safe Obstetrical Practice.”³²³ The paper summarized birth data from one Paris hospital. The part of the paper quoted by Conason/Pegalis, the summary, has little to do with their textual statement. What Amiel-Tison actually wrote was that one hospital achieved near total safety for full-term infants born in the Level 3 obstetrical center, but careful evaluation was used from the beginning of pregnancy and throughout labor.³²⁴

³¹⁷ *Id.* (citing generally Dov Apfel, *Birth Asphyxia and Cerebral Palsy*, TRIAL, Jan. 2007, at 52).

³¹⁸ Compare *id.* at 56 n.1 with Apfel, *supra* note 308, at 23.

³¹⁹ Conason & Pegalis, *supra* note 148, at 269.

³²⁰ *Id.* at 260.

³²¹ PERINATAL EVENTS AND BRAIN DAMAGE IN SURVIVING CHILDREN (Fred Kubli et al., eds., 1988).

³²² *Id.*

³²³ *Id.* at 175.

³²⁴ *Id.* at 185. In Dr. Kubli’s preface, he writes that he organized the 1986 International Conference because the 1985 Collaborative Perinatal Study showed “how little we know” about CP and “to more clearly separate scientifically based knowledge from myth.” *Id.* at vii. Dr. Kubli died just before the book was published. The book is dedicated to his memory.

Both the Conason & Pegalis and the Apfel articles have other examples, not only of unsubstantiated statements, but also quotations taken out of context and citations that do not support the textual statements.³²⁵

XI. The Volpe Canard

Conason & Pegalis and Apfel base their CP-EFM arguments primarily on the writings of Dr. Joseph Volpe, who is also the source for their primary premise: physicians can prevent most CP; and EFM can identify fetal distress in sufficient time to prevent brain injury and CP. Volpe also served, inappropriately and through no fault of his own, as the source of ad hominem attacks leveled at Dr. Karin Nelson and the other “conspirators” who Conason & Pegalis and Apfel claim have published false science for 40 years.

³²⁵ For example, Conason & Pegalis alleged that in 1987 ACOG unethically advised doctors to collect fetal cord blood to protect themselves in lawsuits. Their text quotes two phrases from a medical article that they connected together as if written one after the other as a continuous thought. Conason & Pegalis, *supra* note 148, at 265 (quoting Richard T. Perkins, *Perspective on Perinatal Brain Damage*, 69 OBSTETRICS & GYNECOLOGY 807, 815 (1987)). Moreover, Conason & Pegalis’s citation of the unconnected quotations in Perkins’ article appear on page 815, a page that is never cited by Conason and Pegalis. *Id.* (quoting Perkins, *supra*, at 815). Finally, as to the supposed advice from ACOG, the Perkins article is written by a single practitioner at the University of New Mexico. *Id.* at 807. The article reveals no connection to ACOG, nor is there any ACOG endorsement in the abstract, the article, or conclusion. See *id.* Apfel relies heavily on an article by Janet Rennie and others, English neonatologists. Janet M. Rennie et al., *Outcome After Intrapartum Hypoxic Eschemia at Term*, 12 SEMINARS FETAL & PERINATAL MED. 398 (2007). Apfel, *supra* note 308, at 25, 35. The Rennie authors sought to review the literature on disabilities attributed to HIE at term, reviewing causal link evidence with various CP-types, attention deficit disorder, and autism. Apfel cites Rennie’s paper as support for his main premise: that the hypothetical case he postulates in his article (taken from the Rennie article) is a viable negligence case to be pursued against a negligent obstetrician. Rennie et al., however, cite nothing supporting Apfel’s statements. The Rennie article begins by opining that the International Consensus Statement and ACOG-AAP criteria for HIE related to birth asphyxia are too strict. Why? Because: “Many parents and clinicians find it difficult to ignore a clear history of ... [HIE] potentially damaging severity as a possible causative factor when their child is later found to have hemiplegic CP, severe lung difficulties, visual problems, or neuropsychiatric disorders. The natural desire to find an explanation for a child’s problems results in consideration of even a vague history of fetal distress and birth asphyxia.” *Id.* at 399 (emphasis added). In a subsequent discussion, the three authors say that they would consider a birth asphyxia diagnosis in the hypothetical case cited in Apfel’s article not only because any “vague history of a birth asphyxia” may be causative, but also because 3 out of 32 children in a Swedish study had a PH greater than 7 at delivery and half were considered not to have met ACOG-AAP’s criteria for cord PH. The Rennie et al. evidence, therefore, that birth asphyxia is a cause of CP consists of 18 children in 1 study, plus the *argumentum ad populum* fallacy that common belief must be evidence because so many people believe it. If great numbers of believers were even the least persuasive, Ptolemy would still be the world’s leading astronomer because his theory that the Earth was the center of the solar system was believed by millions the world over for over a thousand years. People’s beliefs, no matter how sincere, seemingly rational, or long held, should simply never be a part of the scientific method.

Conason & Pegalis and Apfel set Volpe apart from every person ever involved in CP research.³²⁶ Apfel in particular labels Volpe as an international CP causation authority, recognized by “most experts.”³²⁷ In the simplest terms, Conason & Pegalis and Apfel anoint Volpe as the fount of all HIE knowledge. So proclaimed, they proceed to base their arguments on Volpe’s theories, or at least what they interpret as his theories.

Volpe is recognized as one of several thousand, certainly not the only, physicians writing on CP’s causes. Volpe has never anointed himself, nor has he ever been anointed by the CP research community as “the” authority, nor even a leading authority. His textbook, as with all textbooks, does not contain new research findings, but rather is the regurgitation of published data accompanied by Volpe’s interpretations and sometimes his experience. His textbook, like all textbooks, is two or more years out-of-date on the publication date—the lag time between manuscript completion and printing. Thus, the influence of important published studies and data completed since submission to the publisher is absent.³²⁸

More important, however, is what Volpe writes in the introduction to each of his four HIE chapters. These caveats are ignored by Conason & Pegalis and Apfel. Volpe first warns his readers that what he writes on the supposed biochemical and physiologic processes taking place with HIE is mostly “based on experimental data.”³²⁹ The uncertainty of extrapolating from animal experiments and medicine’s extremely limited ability to study neonates *in vivo* is reflected in Volpe’s language throughout these four chapters: “it is likely that”; “the result suggests that”; “may play a role”; “perhaps is related”; “currently it is not known, but.”

³²⁶ See Apfel, *supra* note 308, at 25-27; Conason & Pegalis, *supra* note 148, at 267. Conason and Pegalis cite the outdated 2001 Fourth Volpe Edition rather than the 2008 Fifth Edition. *Id.* at n.63. Apfel cites to the Fifth Edition. Apfel, *supra* note 308, at 22 n.3.

³²⁷ *Id.* at 26.

³²⁸ There are numerous web sites providing up-to-date information on a wide variety of medical topics. One example is UpToDate, <http://www.uptodate.com/index>, a clinical decision support system for clinicians written by recognized experts throughout the world. There are over 9,000 topics that are systematically updated. Thus to access current information on the pathogenesis of neonatal encephalopathy there is far more current information found in an article on UpToDate than would be found in a 2-to-4 year old textbook. *E.g.*, Sidhartha Tan & Yvonne Wu, *Etiology and Pathogenesis of Neonatal Encephalopathy*, available at <http://www.uptodate.com/contents/etiology-and-pathogenesis-of-neonatal-encephalopathy?source=+search+result&search=etiology+and+pathogenesis+of+neonatal+encephalopathy&selectedTitle+1%7E20> (last visited Jan. 16, 2012). Dr. Tan is a University of Chicago neonatologist. Dr. Wu is Professor of Neurology and Pediatrics at UCSF who is renowned for her research on causes of and risk factors for cerebral palsy and newborn brain injuries, and who has published extensively on the pathogenesis of newborn encephalopathy.

³²⁹ JOSEPH J. VOLPE, *NEUROLOGY OF THE NEWBORN* 247 (5th ed. 2008).

The one thing that is clear from Volpe's book is that he does not endorse the prime contention underlying Conason & Pegalis's and Apfel's statements that physicians' malpractice is the cause of much birth asphyxia and birth asphyxia is synonymous with physician negligence. The exact opposite is what Volpe writes: "[I]t is unequivocally clear that true obstetrical malpractice is a rare occurrence and that the obstetrician is called on to deal with perhaps the most dangerous period in an individual's life with inadequate methods."³³⁰ This thought accompanied Volpe's admonition to physicians not to interpret rarely caused birth brain injury as unimportant, because rare events add up to significant numbers when extrapolated worldwide.³³¹ Volpe goes on to write that the task for future research is to develop technologies to define the exact timing of brain injuries and interventions to prevent them and treat them, modalities unavailable to obstetricians today.³³²

XII. TRIAL LAWYERS AND THE EFM LITERATURE

The overwhelming wealth of literature demonstrating EFM's impotency in predicting asphyxia-fetal distress is a problem for trial lawyers. They must maintain EFM as relevant, because it is the vital proof in almost all birth injury cases. The plaintiff's expert's fetal monitor strip courtroom reanalysis

³³⁰ *Id.* at 331.

³³¹ *Id.*

³³² *Id.* at 332. Apfel also places great emphasis on various asphyxial animal models and experiments carried out through the years. Apfel, *supra* note 308, at 23, 29, 36. However, animal models are suspect because of the vast differences between animals and humans. See H. Bart van der Worp et al., *Can Animal Models of Disease Reliably Inform Human Studies?*, 7 PLoS MED. e1000245 (Mar. 2010), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000245> (download pdf for referent pagination) (last visited May 26, 2012). A recent paper from researchers in The Netherlands, Scotland, and Australia again emphasized the translation problem from animals to humans. See *id.* One example was the animal acute ischemic stroke model. *Id.* at 1. About 500 neuroprotective treatments have reportedly improved the outcome in various animal models, yet only two, aspirin and TPA, have proved effective in humans. *Id.* PLoS is a nonprofit organization of scientists and physicians committed to making the world's scientific and medical literature a freely available resource. PLoS: PUBLIC LIBRARY OF SCIENCE, <http://www.plos.org/> (last visited May 26, 2012); see also OFFIT, *AUTISM'S FALSE PROPHETS*, *supra* note 253, at 112 (describing several disease entities in animals that do not predict consequent human disease). Apfel also emphasizes MRI as the vehicle enabling physicians to time and identify a brain injury's etiology. Apfel, *supra* note 308, at 26, 27. Current imaging techniques, however, do not contribute to making a CP diagnosis. Sartwelle, *Defending*, *supra* note 2, at 219 n.210. Diagnosis of CP can only be made by clinical findings and physical examination after a child is a minimum of two years old. Cf. *id.* at 236. Does neuroimaging around the time of birth provide evidence of the timing or etiology of a brain insult? The answer is no according to an extensive literature review. Steven J. Korzeniewski et al., *A Systematic Review of Neuroimaging for Cerebral Palsy*, 23 J. CHILD. NEUROL. 216 (2008). Korzeniewski and colleagues at Michigan State's Department of Epidemiology set out to answer the question, "Does neuroimaging contribute to understanding the causes of cerebral palsy?" After analyzing the literature from 1975 to 2006, they concluded that timing brain insults with neuroimaging is supported by little evidence. *Id.* at 222.

pinpointing the exact moment the baby experienced brain damage is a birth-injury trial's pinnacle.

The Conason & Pegalis and Apfel "EFM is viable and valuable" analysis ignores totally several thousand worldwide EFM studies, analyses, comparisons, meta-analyses, clinical trials, and editorials over the past 40 years. They simply declare EFM's efficacy, citing one or two cherry-picked papers, but primarily relying on no authorities to support their declarations: EFM will identify impending brain damage and allow saving C-sections if only the physicians and nurses pay attention to the monitor's signals.³³³ Thus, in their world, EFM must be retained and used in all labors. Their approach to EFM is typical trial lawyer: Ignore the details and sell the sizzle.

XIII. EVIDENCE TO ABANDON SHIP?³³⁴

The medical profession's 40 years of continual EFM use in spite of overwhelming evidence of uselessness and increased risks to mother and child alike strongly suggests that doing no harm is merely a Madison Avenue derived advertising slogan. As it turns out, however, medicine in general, not just obstetrics, seems based more on theories, personal experience, and biases than on empirical evidence.³³⁵ Studies now suggest that almost half the established medical practices that constitute the core of medical care are wrong.³³⁶ So why not abandon ship?

In the case of EFM, medicine's inability to abandon the EFM ship is for diverse and varied reasons, but seems primarily rooted in the abject fear and ignorance associated with trial lawyers and malpractice lawsuits. But is fear of trial lawyers a reason to continue outdated and potentially dangerous and lethal medical practices? Apparently, the answer is yes if EFM is the example. Such is the power of the trial lawyer today, not only in America, but also, as we have seen, around the world.³³⁷ So what can be done?

Probably nothing until ACOG et al. decide to use science instead of myth to establish the standard of care. There is precedent. In the U.K., as we have seen, NICE changed the standard of care in an instant with a clinical

³³³ Conason & Pegalis, *supra* note 148, at 274-80; Apfel, *supra* note 308, at 31-34.

³³⁴ Title suggested by Vinay Prasad et al., *Reversals of Established Medical Practices: Evidence to Abandon Ship*, 307 J.A.M.A. 37 (2012).

³³⁵ *Id.* at 37.

³³⁶ *Id.* at 38; Vinay Prasad et al., *The Frequency of Medical Reversal*, 171 ARCH. INTERNAL MED. 1675 (2011).

³³⁷ CRICO STRATEGIES, *supra* note 40 (Statistics from U.S. and international malpractice carriers); Asma Khalil & Patrick O'Brien, *Fetal Heart Rate Monitoring—Is It a Waste of Time?*, 56 J. OBSTETRICS & GYNECOLOGY INDIA 481 (2006) (any EFM abnormality leads to litigation with U.K. awards of 5-7 million pounds not uncommon); MacLennan et al., *Only*, *supra* note 103 (describing an international malpractice crisis and the crisis in Australia); MacLennan et al., *Who*, *supra* note 103 (describing an international malpractice crisis centered around obstetrics).

guideline specifying no fetal monitoring for uncomplicated pregnancies.³³⁸ ACOG et al. could do the same. Would an ACOG Practice Bulletin modeled on the NICE guideline along with a plain language public education campaign suddenly reduce CP lawsuits and verdicts to zero? No. But it would help to begin that process. And that is a process that desperately needs to happen.

If society is to ever help the children and families most affected by birth injuries, we must begin to view them through a prism of cooperative research, reaching for answers and solutions rather than viewing birth injuries through the litigation prism of blame, mistrust, accusations, and obfuscations. Litigation is a waste of time and money that could be better used helping all CP kids and families, rather than just the 10% who are successful at the litigation game.

CONCLUSION

Ptolemy's math was impeccable. His calculations were subject to multiple proofs by scholars for well over a thousand years. Every time the conclusion was the same—the Earth was the center of the universe. Not so, said Copernicus in 1543. Geocentricity was a myth. Real world cosmology was heliocentric—the sun was the center of the universe. There were few believers. The myth had stood for more than a thousand years. One hundred years later, Galileo confirmed the new cosmology with a telescope. But the geocentricity myth continued to prevail for another 200 years until in 1835 the Catholic Church ended its opposition to publishing Galileo's works. Is myth powerful?

Geocentricity's modern day equivalent is asphyxia as the sole cause of CP and birth neurologic problems. Maladies that can supposedly be solved with EFM. These myths are deeply rooted with physicians, the public, and especially trial lawyers. Science seems unable to cope with these myths despite multiple hundreds of contrary studies, analyses, editorials, and comments.

Slaying these myths should be ACOG et al.'s mission. But until the myths are attacked in plain, simple, declarative language in the modern media they will no doubt continue flourishing. ACOG et al.'s message is simple. Birth is a dangerous journey. EFM does not help. While we know much about the journey, one thing we do not know is how to prevent CP. And EFM as it currently exists is unhelpful in our understanding of CP and the birth process. Thus, EFM should not be the standard of care except in certain limited circumstances.

³³⁸See NHS NICE, *supra* note 158.

ACOG et al. must educate not only physicians but the public to EFM's realities emphasizing its labor-saving properties but de-emphasizing its supposed ability to predict neuropathology, especially in the world's courtrooms. If ACOG et al. choose not to accept the task, who will?

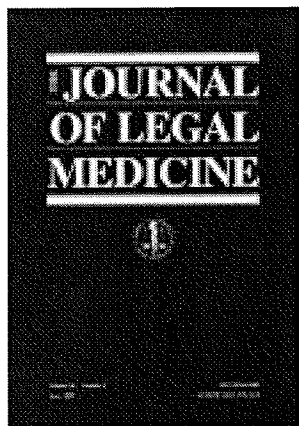
No doubt ACOG et al.'s task will be as difficult as was Galileo's. Difficult, but perhaps not impossible. After all, the Catholic Church finally apologized to Galileo. It only took 350 years.

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Electronic Fetal Monitoring: A Bridge Too Far

Thomas P. Sartwell LL.B., B.B.A. a

a Beirne, Maynard & Parsons, L.L.P., Houston, Texas

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