Cerebral Palsy Litigation: Change Course or Abandon Ship

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Thomas P. Sartwelle, BBA, LLB¹ and James C. Johnston, MD, JD²

Abstract

The cardinal driver of cerebral palsy litigation is electronic fetal monitoring, which has continued unabated for 40 years. Electronic fetal monitoring, however, is based on 19th-century childbirth myths, a virtually nonexistent scientific foundation, and has a false positive rate exceeding 99%. It has not affected the incidence of cerebral palsy. Electronic fetal monitoring has, however, increased the cesarian section rate, with the expected increase in mortality and morbidity risks to mothers and babies alike. This article explains why electronic fetal monitoring remains endorsed as efficacious in the worlds' labor rooms and courtrooms despite being such a feeble medical modality. It also reviews the reasons professional organizations have failed to condemn the use of electronic fetal monitoring in courtrooms. The failures of tort reform, special cerebral palsy courts, and damage limits to stem the escalating litigation are discussed. Finally, the authors propose using a currently available evidence rule—the *Daubert* doctrine that excludes "junk science" from the courtroom—as the beginning of the end to cerebral palsy litigation and electronic fetal monitoring's 40-year masquerade as science.

Keywords

cerebral palsy, electronic fetal monitoring, medical malpractice

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In the last half-century, one medical malpractice claim birth-related cerebral palsy and neurologic injury—recurred so frequently and with such exponentially increasing jury damage awards that it not only substantially altered medical practice but medical ethics as well. Physicians' response to the rising claims was abandonment of the venerable "first do no harm" principle, replacing it with the expedient self-serving ethics of "do whatever is necessary to keep trial lawyers at bay." Insurance premiums skyrocketed. Insurance availability crises occurred and reoccurred every decade or so, despite numerous "permanent" legislative fixes.¹ Fear of birth injury lawsuits rapidly increased. So too did the Caesarean section rate. Maternity units closed. And family practitioners and obstetricians alike quit obstetrical practice.²

The effects of cerebral palsy litigation were worldwide.³ In virtually every industrialized country, even those with government-sponsored universal health care systems, trial lawyers, not physicians, dictated birth practices. And a medical phenomenon previously unseen in medicine's long history appeared—defensive medicine. Prophylactic medicine administered for protection from trial lawyers.⁴

Hundreds of books, articles, and editorials denounced birth injury litigation as fallible, broken, and invidious to physicians.⁵ Fixes by the dozens were suggested but few were adopted, and those adopted were ineffective at best. The frequency and severity of birth injury damage claims worldwide has continued unabated for 40 years.⁶

The cardinal driver of birth injury cerebral palsy claims was and is electronic fetal monitoring. It is the cornerstone of all birth injury lawsuits. Electronic fetal monitoring precipitated, nurtured, and continues to be the primary cudgel against defendant physicians in the world's courtrooms. But electronic fetal monitoring is based on 19th-century childbirth myths. Its scientific foundation is almost nonexistent. Its false positive rate exceeds 99%. It does not predict cerebral palsy.⁷ After 40 years of continuous use and supposed improvements, electronic fetal monitoring has not reduced the cerebral palsy risk. It has, however, increased the cesarian section rate, with the expected increase in mortality and morbidity risks to mothers and babies alike.8 Inter-intraobserver interpretation variability is exceedingly high and courtroom electronic fetal monitoring reinterpretation has long been known to be highly biased and unreliable.⁹ Nevertheless, electronic fetal monitoring is still

Corresponding Author:

¹ Beirne, Maynard & Parsons, LLP, Houston, TX, USA

² Legal Medicine Consultants, LLC, Seattle, WA, USA

James C. Johnston, MD, JD, Legal Medicine Consultants, LLC, 321 High School Road NE, Suite D3-750, Seattle, WA 98110, USA. Email: Johnston@GlobalNeurology.com

endorsed as efficacious by the world's birth-related professional organizations—a myth believed not only by the public and trial lawyers but also by substantial numbers of physicians, including obstetricians.

Electronic fetal monitoring and other birth-related myths are perpetuated by trial lawyers who have substantial vested monetary interests in continuing electronic fetal monitoring use in all labors. Trial lawyers advertise these myths as truth despite hundreds of studies proving cerebral palsy is almost exclusively caused by factors unrelated to obstetrical care during the birth process.¹⁰ Likewise, myriad studies have confirmed that electronic fetal monitoring is virtually useless in most labors.¹¹ Today, it is without question that electronic fetal monitoring use over the past 4 decades has harmed more mothers and babies than it has ever helped.¹²

Many questions arise: Why does birth injury litigation continue today if medical research is so overwhelming and electronic fetal monitoring scientifically unsound? Why have birth-related professional organizations been unwilling to condemn plaintiff courtroom experts blatantly ignoring the research? Why do these organizations continue endorsing electronic fetal monitoring in spite of the harm it perpetrates? Why has worldwide medicine's reaction to the first half-century of cerebral palsy–electronic fetal monitoring litigation been feckless to nonexistent? Only a very few individual physicians have condemned cerebral palsy myths and called electronic fetal monitoring unreliable.¹³ Their voices remain unheard. Why?

There have been proposals to fix cerebral palsy litigation, almost from the day the first verdict was handed down.¹⁴ The proposals' common denominator has been legislating some form of a no-fault system to replace current fault-based lawsuits. No such legislation has occurred for more than 40 years. And it is unlikely to occur in the next half-century. Unfortunately, organized medicine has not overcome the well-worn birth-related myths permeating society's, politicians', and physicians' collective unconscious, and medicine is unlikely to overcome trial lawyers' iron-fisted hold on the birth injury fault-finding tort system.

Birth-related professional organizations have for many years held in their hands the weapon that could end the cerebral palsy birth injury litigation cottage industry. These organizations have inexplicably failed or refused to use this weapon. All they need to do is simply take advantage of an available courtroom evidence rule-Daubert's junk science decision-and officially declare electronic fetal monitoring to be what it is-scientifically unreliable in both labor rooms and courtrooms. These organizations must also begin to address the trial lawyers' public relations advertising battle that so far they have completely lost. If the American College of Obstetricians and Gynecologists and related organizations begin to rebut cerebral palsy-electronic fetal monitoring myths, first with obstetricians and then with the public, in plain declarative language, then cerebral palsy-electronic fetal monitoring-associated birth injury lawsuits and mega verdicts will begin to disappear. These organizations must deliver a simple message: Birth is a dangerous journey, and electronic fetal monitoring does not help.¹⁵ Finally, these organizations must recognize why pleas to reform cerebral palsy litigation have gone unheard by politicians for 40 years and why they will continue to fall on deaf legislative ears. This recognition necessitates an appreciation of medical malpractice history and awareness of the vested interest of trial lawyers determined to perpetuate the litigation system. It will then be apparent that there is only one solution to cerebral palsy litigation without changing the existing fault-based accusatory tort system: *Daubert*.

A History of Enmity

They [malpractice attorneys] followed us like the shark does the immigrant ship.

Medical malpractice traces its roots to English common law and the general law of personal injury negligence.¹⁷ Physicians of the day were not exempt from negligence suits albeit different rules were developed concerning schools of practice, necessity of expert witnesses, geographical locality, and a few other distinguishing features. The early English medical malpractice cases were among the first to use expert witnesses to establish the standard practice the defendant physician should have followed.¹⁸

In the United States, medical malpractice suits were rare to nonexistent until around 1830, and then became quite commonplace. Historians have proposed various reasons for this rising popularity.¹⁹ American medical journal editors of the day became obsessed with malpractice, repeatedly speculating on what could and should be done about the crisis.²⁰ One physician complained that so many lawsuits were being filed without reason or grounds that a spirit of persecution permeated medical practice,²¹ a familiar echo from across the centuries still heard today. Of course, a deep divide developed between doctors and lawyers, a divide that seems to be permanent. Many physicians believed then, as they do today, that the attacks on the medical profession were orchestrated by selfseeking, professionally irresponsible, greedy lawyers.²²

This enmity accelerated at the turn of the 19th century with 2 monumental developments still primarily responsible for failed malpractice reform even today-widespread liability insurance and contingent legal fees. Insurance made every physician a worthy target not just the wealthy. Contingent fees promoted the idea that making someone else responsible could be a painless, inexpensive experience. Sixty years later, these 2 accelerants met the perfect litigation storm composed of several unrelated sociological phenomenon, including massive court-made expansion of tort liability, fundamental changes in societal attitudes towards injury responsibility, a sea change in the prohibition against lawyer advertising, and the death of medical paternalism.²³ As a result, the frequency and severity of claims against physicians suddenly, mysteriously, and rapidly accelerated.²⁴ Claims reached unprecedented levels precipitating the first medical malpractice insurance availability

crisis of the 1970s. In response, virtually every state legislature enacted some type of tort reform to ensure medical malpractice insurance availability. These reforms slowed the trend, but only momentarily. From the 1970s until today, almost every state has seen medical malpractice insurance availability crises in virtually every decade.

One primary reason for the continuing insurance availability crises, and ever-expanding malpractice verdicts and settlements, and the failure to achieve meaningful, permanent malpractice reform has been the trial lawyer. Trial lawyers have accumulated enormous wealth through a loosely regulated contingent fee compensation system.²⁵ Significant sums of this newfound wealth were used to lobby for the trial lawyers' one and only issue-maintaining the present tort system. Trial lawyers are well-funded, make large campaign contributions, and, most important, their one and only goal is to ask that something not be done.²⁶ At the same time, physicians, heavily regulated by thousands of laws, rules, and regulations, lobby for scores of reforms and changes, thereby splitting time, effort, and capital among many agendas. Medicine has achieved no reforms whatsoever on a national level and only limited success on the state level. It is long past time for the medical community to realize that reform is not coming.²⁷ Medicine must change course.

Obstetrics and Malpractice

Before 1970, obstetrical care generated few medical malpractice claims. But by 1985, obstetrical claims represented 10% of all medical malpractice lawsuits.²⁸ Today obstetrical claims are consistently among the highest verdicts and settlements in the USA, some reaching above \$200,000,000, verdicts on a par with business litigation cases.²⁹

What changed?

Before 1970, a fetus was monitored intermittently with stethoscopes or fetoscopes. If a child later developed cerebral palsy, mental retardation, seizures, or similar conditions, no amount of speculation could overcome the obstetrician's recollection that the intermittent auscultation revealed no evidence of fetal distress and thus no reason to intervene.

Electronic fetal monitoring changed everything. Electronic fetal monitoring, to an eager bevy of trial lawyers, was more valuable than the crown jewels: a computer-generated permanent tracing that could be reanalyzed in the courtroom. More importantly, this new instrument of blame was wielded not so much by lawyers as by self-proclaimed electronic fetal monitoring experts whose skills were more evident in courtrooms than in delivery rooms. In courtrooms around the world, these experts delivered babies a second time reanalyzing the electronic fetal monitoring strip, identifying the exact moment the negligent defendant should have delivered what the experts said was a neurologically perfect infant. Instead, the child had been sentenced to lifelong neurologic devastation by the negligent defendant unable to read or react to plainly evident electronic fetal monitoring warnings. Electronic fetal monitoring, according to the experts, enabled physicians to identify a fetus

being asphyxiated in utero. Rescue was only moments away by means of a simple, quick cesarian section.

The testimony was and is false.

Electronic Fetal Monitoring: An Absurd Machine?

Electronic fetal monitoring was overwhelmingly accepted into 1970s obstetrical practice without clinical trials and with no scientific foundation other than 19th-century speculation. There were only a handful of detractors who did not believe the self-styled experts claiming that electronic fetal monitoring alone would reduce by half intrapartum deaths, mental retardation, and cerebral palsy.³⁰ Electronic fetal monitoring use accelerated. When the first clinical study comparing electronic fetal monitoring to intermittent auscultation was published in 1976, there was no electronic fetal monitoring benefit. However, there was a higher electronic fetal monitoring cesarian section rate.³¹ More studies followed. By 1995, 12 published randomized, controlled trials proved electronic fetal monitoring had no measurable impact on morbidity or mortality.³² Nor did electronic fetal monitoring affect the rate of cerebral palsy or any other childhood neurologic problem in the slightest despite a then nationwide 25% cesarian section rate.³³ But electronic fetal monitoring did have a 99.8% false-positive rate.³⁴ Importantly, the self-appointed electronic fetal monitoring experts were also being subjected to their own electronic fetal monitoring interpretation clinical trials. It turned out that, despite the experts' courtroom testimony that they could pinpoint the precise minute a fetus experienced anoxia and fetal distress and brain damage, when tested, the experts' interpretation of electronic fetal monitoring patterns were not only biased by the known outcome, but they frequently disagreed with other experts' interpretation and even with their own previous interpretation of the same electronic fetal monitoring strip.³⁵ Remarkably, from 1976 until today, the negative conclusions regarding electronic fetal monitoring have been affirmed and reaffirmed.³⁶ More remarkable is the fact that there are virtually no credible data contradicting electronic fetal monitoring's uselessness in predicting or preventing cerebral palsy or any other significant childhood malady.

Beguiled by Technology?

Despite the uncontroverted evidence that electronic fetal monitoring is scientifically destitute, its use rose from 45% of all labors in 1980 to 85% today. And the cesarian section rate rose with it. At the same time, cerebral palsy–electronic fetal monitoring birth injury jury verdicts and settlements against physicians rose even faster.

One would logically assume that an unproven medical modality with a 99% false positive rate causing unnecessary surgeries endangering mothers and babies alike, and not preventing the very condition it was designed to detect, would have been quickly abandoned by the medical profession. After all, this is a profession dedicated to the pursuit of healing by proven scientific methods. Rather than reject electronic fetal monitoring, however, the medical establishment actually raised its status to that of deus ex machina.³⁷ Why?

Dereliction of Duty

There is simply no answer to that question. Nor is there an answer to the question of why birth-related professional organizations allowed trial lawyers and their courtroom experts to transform electronic fetal monitoring from a glorified electronic heartbeat counter into a miracle courtroom machine, the magnum opus of obstetrics. Electronic fetal monitoring became the backbone of increasingly large and frequent cerebral palsy verdicts that culminated in today's international medical liability obstetrical crisis. For 40 years, birth-related professional organizations have had the ability to stop this cerebral palsyelectronic fetal monitoring charade but refused to intervene. As we will see, if birth-related professional organizations had declared electronic fetal monitoring unreliable for courtroom use 20 or 30 years ago, cerebral palsy-electronic fetal monitoring trials would be history rather than fulfilling trial lawyers' dreams of achieving nouveau riche status.

Birth-related professional organizations' inattention to electronic fetal monitoring was not accidental. Data against electronic fetal monitoring began accumulating even before it was in clinical use. The Collaborative Perinatal Study's auscultated fetal heart rate data led Benson and colleagues to conclude there was no "reliable indicator of fetal distress in terms of fetal heart rate save in the extreme degree."³⁸ That was 1968. Other researchers also raised early red flags regarding electronic fetal monitoring's indispensable premise: heart beat patterns reflect fetal distress.³⁹ Despite these warnings, professional societies raised no alarms nor suggested further studies or clinical trials. By default, dereliction, and neglect, electronic fetal monitoring was allowed to rocket to stardom along with the Rolling Stones.

In the decades following electronic fetal monitoring's introduction, scores of studies and commentaries regarding the obstetrical malpractice crisis were published alongside studies challenging electronic fetal monitoring's alleged infallibility and underlying premise that it identified fetal distress which, if unchecked, led to cerebral palsy. Some commentators bemoaned electronic fetal monitoring's increased cesarian sections (implying the danger to mothers and babies), whereas others pointed to the conflicting interpretations by the electronic fetal monitoring "experts" as being emblematic of electronic fetal monitoring's fallibility.40 The electronic fetal monitoring courtroom experts, however, ignored the accumulating negative electronic fetal monitoring data. They continued blaming obstetricians and nurses for failing to accurately interpret what they swore were infallible electronic fetal monitoring signals. As a result, juries continued holding doctors and nurses responsible for causing cerebral palsy and other devastating neurologic outcomes. Birth-related professional organizations, however, remained firmly on the sidelines, uninterested that almost every physician or nurse being blamed for causing a child's crippling life-changing injuries was being indicted by a markedly dubious cerebral palsy causation theory and an even more dubious technology being interpreted by experts whose courtroom interpretations were repeatedly proven to be biased and unscientific at best and fraudulent at worst.

Electronic Fetal Monitoring Workshops: More of the Same

Birth-related professional organizations' answer to the unscientific evidence supporting the cerebral palsy-electronic fetal monitoring verdicts was the electronic fetal monitoring conference or workshop.⁴¹ Forty years of intense study in conferences and workshops worldwide have merely produced another conference or workshop. Almost all concluded that before electronic fetal monitoring unanimity could be reached, "more research is needed." The reason for the additional research was summed up by the published purpose for a 1995-1996 National Institutes of Health (NIH) electronic fetal monitoring workshop: "[A] Major Impediment to progress in the evaluation and investigation of [electronic fetal monitoring] is lack of agreement in definition and nomenclature of [electronic fetal monitoring] patterns despite the plethora of publications on the subject."⁴² This workshop in similar fashion to all previous and subsequent conferences ended up accomplishing nothing. There was little agreement how electronic fetal monitoring patterns were to be interpreted. There was also no call to abandon electronic fetal monitoring or to declare electronic fetal monitoring unreliable despite the inability to agree on clinical management guidelines. Nor was there condemnation of electronic fetal monitoring courtroom experts and their pseudoscientific testimony despite the well-published dramatic verdicts being handed down against doctors and nurses who were accused of misinterpreting the magic black box that the courtroom experts testified was able to predict the future.

Consensus Opinions

The International Cerebral Palsy Task Force Report⁴³ was published in 1999. Soon thereafter, the 2003 American College of Obstetricians and Gynecologists-American Academy of Pediatrics Cerebral Palsy Consensus Statement was published.44 Both acknowledged that electronic fetal monitoring does not predict cerebral palsy, does not prevent cerebral palsy, and that retrospective electronic fetal monitoring reanalysis with a known outcome was highly biased. Yet, rather than a profound statement about electronic fetal monitoring's lack of efficacy in labor rooms and courtrooms, both defaulted to the vapid "more research is needed." The International Task Force perfectly summarized both task forces' lack of allegiance to their patients facing unnecessary cesarian sections and to their colleagues facing junk science experts 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].... [S]uch recommendations will have to await further research on...the ability of monitoring as a means of avoiding outcomes by prompting obstetric action." $^{\!\!\!\!\!^{45}}$

"More research" has been the mantra of most articles and workshops from electronic fetal monitoring's beginning until now despite the long acknowledged fact that there was no scientific evidence to support the contention that intervention based on any single electronic fetal monitoring pattern or pattern combinations prevented cerebral palsy or any other neurologic injury.⁴⁶ Through the years, only a very few souls have been willing to challenge electronic fetal monitoring orthodoxy.⁴⁷ But even those souls were unwilling to say it was time to abandon electronic fetal monitoring dogma and start over. Until now.

Back to the Future

Recently a prestigious group of maternal fetal medicine scholars acknowledged that an evolving maternal fetal medicine consensus exists regarding electronic fetal monitoring: "It is time to start over and establish some common language, standard interpretation, and reasonable management principles and guidelines" because "there has never been a standard hypothesis to test dealing with interpretation and management of abnormal [electronic fetal monitoring] patterns."⁴⁸

This admission comes 5 years after the American College of Obstetricians and Gynecologists-Maternal Fetal Medicine Society's 2008 Workshop reclassified electronic fetal monitoring into a more workable, "user-friendly" 3-tier system and, of course, concluded with the ubiquitous "more research was needed."49 This admission is made in the face of scores of how-to articles concerning the 3-tier system's clinical efficacy.⁵⁰ Finally, a group of thought leaders recognize that electronic fetal monitoring cannot be rescued even by changing its classification system. This recognition is 40 years too late, but it is a recognition nonetheless. What is missing from the call to start over, however, is the same reality missing from American College of Obstetricians and Gynecologists' Practice Bulletin 106 adopting the 3-tier approach.⁵¹ In that Bulletin, the American College of Obstetricians and Gynecologists, like the maternal fetal medicine scholars, never said electronic fetal monitoring is unreliable.

Another difficulty with maternal-fetal medicine's call to start over is the fact that what follows is an effort to "fix" electronic fetal monitoring so it can continue in clinical use. Maternal fetal medicine, while acknowledging the absence of scientific evidence to support interventions based on any single or combination of electronic fetal monitoring patterns, proposes continued electronic fetal monitoring clinical use based on their unique algorithm which, they acknowledge, lacks scientific evidence of effectiveness.⁵² The solution that should follow these acknowledgements is a declaration by the American College of Obstetricians and Gynecologists and birth-related professional organizations that electronic fetal monitoring is useful for the limited purpose of serving as a labor-serving device, but its efficacy in predicting outcome is still under investigation and therefore electronic fetal monitoring is unreliable, is not the standard of care, and is not the arbitrator for labor-delivery decisions in labor rooms or courtrooms.

The 40-year unsuccessful effort to fix electronic fetal monitoring paralleled another effort to indirectly save electronic fetal monitoring—reforming the tort system. These reforms and cures ignored cerebral palsy lawsuits' real cause, electronic fetal monitoring, and have been unsuccessful.

Tort Reform/No-Fault Solutions

For almost as long as electronic fetal monitoring has propelled cerebral palsy lawsuits to mega verdicts, there have been articles, editorials, and books advocating that the only cure for medical malpractice in general and birth injury litigation in particular is either tort reform or scrapping the tort system and instituting a no-fault system.⁵³ Cerebral palsy-birth injury lawsuits were singled out as deserving of their own separate, special tort reform/no-fault/dedicated courts.⁵⁴ And the calls for cerebral palsy-birth injury to be separated from general malpractice through creation of special courts and birth no-fault systems continues even today.⁵⁵ The reason for these continued pleas is that in the past 40 years changes in cerebral palsy-birth injury trial law have been anemic to nonexistent. Legislators have ignored special status for cerebral palsy-birth injury suits. And tort reform has not and will not solve the problem of the cerebral palsy-birth injury mega verdict.

Tort reform legislation almost universally limits pain and suffering awards (noneconomic damage) to some amount like \$250,000–\$500,000 but does not limit full damages for past and future medical and life care expenses, and economic damages like loss of income. Thus, in states with tort reform, cerebral palsy–birth injury mega verdicts are still on a par with non–tort reform states because life care plans for severe cerebral palsy often exceed \$20 million, \$30 million, and higher, grossly illegitimate figures offered to compassionate jurors by so-called life care experts solely to drive up verdicts and settlements.⁵⁶

Only 2 states have ever isolated cerebral palsy–birth injury claims, Virginia in 1986 and Florida 2 years later. Much has been written about these pioneering efforts, the majority of which is negative.⁵⁷ Recently, New York established a birth injury program because of the continuing crisis in insurance availability and expense of obstetrical malpractice insurance.⁵⁸ And the effort to change the cerebral palsy–birth injury litigation scenario is not limited to just the United States. There has been a worldwide push to alter the court system for cerebral palsy–birth injuries.⁵⁹ The reasons are the same: the tort system is unpredictable, unjust, costly, inefficient, lengthy, encourages defensive medicine, and benefits only a few cerebral palsy children and their families.⁶⁰

The point is, despite a plethora of books, articles, editorials, studies, government commissions, hearings, and reports, all calling for cerebral palsy–birth injury reform, virtually nothing has changed in the cerebral palsy–birth injury lawsuit industry since electronic fetal monitoring appeared in the first cerebral palsy case. Why?

There is simply no clear answer.

Obviously, trial lawyers have a great influence as discussed, but remaining factors are elusive. What is obvious is this: legislatures the world over have been uninterested in the plight of cerebral palsy kids and the physicians, midwives, and nurses who deliver them. If the past pleas and calls for action have been unheard, it is doubtful current and future pleas will spur any meaningful action.⁶¹

What Can Be Done?

There is a solution. To apply the solution requires an understanding of the current lawsuit system, the role of expert witnesses, and an understanding of courtroom junk science that should be thrown out under the famous *Daubert* case and its progeny. *Daubert* extends beyond the United States to include many other countries with comparable evidence procedures.⁶² Simply stated, the beginning of the end of cerebral palsy–birth injury litigation starts with recognition of the ethical quagmire involved in continued electronic fetal monitoring use, proceeds with honest, plain declarative-language education of physicians and the public about the myths of the birth journey and its rare connection to cerebral palsy, and ends with professional societies officially labeling electronic fetal monitoring unreliable for labor rooms and courtrooms.

Finding the Answer

Drs Barrett Robinson and Latasha Nelson reviewed the 2008 three-tier electronic fetal monitoring guidelines. They observed that, despite the lack of demonstrated fetal or neonatal benefit from electronic fetal monitoring, "the medicolegal climate in the United States requires obstetricians to integrate continuous intrapartum surveillance [electronic fetal monitoring] into their care."⁶³ This sentence contains an extraordinary admission but also captures most physicians' ill-informed thoughts when it comes to the medicolegal process.

The admission is that despite the knowledge that a medical modality has no benefit but great potential for harm, it should continue to be used to protect doctors from lawsuits. Ignoring for the moment the gross disregard of the "do no harm" principle, this statement is a revealing look at physicians' unrequited hope that if things go wrong somehow, an electronic fetal monitoring strip magically confers protection from a lawsuit or jury verdict. In reality, the direct opposite is true, as has been pointed out for years in the medical and legal literature.⁶⁴ Nevertheless, obstetricians generally continue to believe that electronic fetal monitoring's "own ubiquity suggests that it is the exclusive standard of care" 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."65 Physicians' continued belief in electronic fetal monitoring as a savior from being sued may just turn out to be a medical imbroglio as famous as the century-long miasma versus germ theory of disease.

The failure to understand a basic malpractice principle standard of care—also leads to the false notion that the "medicolegal climate" requires electronic fetal monitoring use. What physicians fail to understand is that in most courts the world over physicians' testimony—from the defendant and

world over physicians' testimony—from the defendant and expert witnesses—is the only evidence of the standard of care for any individual case.⁶⁶ Thus, if birth-related professional organizations had declared electronic fetal monitoring not to be the standard of care, the cerebral palsy litigation lottery would have been dead decades ago.

What Is Standard of Care?

A physician is negligent-guilty of malpractice-when he or she does not do those things that the reasonable, prudent physician practicing in the same specialty would do taking into account the same or similar circumstances faced by the defendant physician. Lawyers often refer to the negligence concept by the phrase "standard of care." Thus, these 2 terms are synonymous. Importantly, only physicians can testify what actions constitute negligence or a breach of a standard of care. Negligence does not mean a deviation from perfection. It means deviation from what ordinary, reasonable physicians do-a community standard that has morphed into a more national or at least regional standard today. Recently, many courts worldwide have begun to focus more heavily on evidence-based guidelines, also called practice parameters, as standard of care evidence.⁶⁷ As we will see, this emphasis on evidence-based guidelines is salvation for courtroom cerebral palsy-birth injury defendants, if only the professional societies would act.

As noted, only physicians can testify what conduct constitutes standard of care. A malpractice suit cannot proceed without a physician witness testifying that the defendant practiced below the standard of care (i.e., was negligent) and caused the plaintiff's injury or death.⁶⁸ Thus, the primary cause of medical malpractice lawsuits, unrecognized by most physicians, is the defendant's colleagues.⁶⁹ Generally, the parties to a cerebral palsy–electronic fetal monitoring lawsuit each call experts to support their arguments. Presumably, each expert has a polar opposite electronic fetal monitoring opinion. Each expert articulates his or her opinions and the juror must decide whom to believe. But, based on what? Who looks better? Who they liked the best? Who dressed the best? Which expert's slides and props were more entertaining? In effect, jurors are reduced to being judges in a beauty contest.

Determining how juries decide which witness is believable has been the subject of much study.⁷⁰ The reality is that believability is unrelated to the soundness of the medical opinions. Thus, the expert beauty contest can be greatly assisted by official professional society pronouncements regarding the efficacy of procedures and modalities. In the case of electronic fetal monitoring, no matter how poorly the defendant electronic fetal monitoring expert was perceived, an official pronouncement by recognized professional organizations, particularly those pronouncements articulated in plain, declarative language understandable to everyday jurors and judges, would provide defendants with a firm foundation that the other side lacks. Is it a guarantee? No. But it is a very powerful tool that has been unavailable to courtroom defendants for the last 4 decades.

Experts and Standard of Care

Professional societies have attempted to deal with spurious courtroom testimony by punishing members for spewing junk science. This had little impact as evidenced by the continuing cerebral palsy–electronic fetal monitoring verdicts and settlements increasing year to year for 40 years. Moreover, professional society punishment has recently encountered several court cases that portend difficulties for punishment related to standard of care opinions.⁷¹ And just as sanctions failed to blunt cerebral palsy–electronic fetal monitoring mega verdicts and settlements, public exposure of the small number of physicians who typically act as plaintiff expert witnesses in US birth injury litigation also failed. One published study found that 71 physicians, 89% of the sample, participated in 738 cases which paid \$2.9 billion in compensation.⁷²

Thus multiple efforts to deal with cerebral palsy–electronic fetal monitoring mega verdicts and settlements over the last 4 decades have failed almost as dramatically as the yearly effort to change electronic fetal monitoring terminology and interpretation and attempt to place a scientific patina on an illegitimate and decidedly unscientific device. What should be done with the floundering electronic fetal monitoring ship?

Abandon Ship

Bluntly stated, electronic fetal monitoring "harms women," wastes "money and time," and "offers no lasting benefit to children." "[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."⁷³ It is past time to abandon the "we can fix EFM with more study" ship. Continuing electronic fetal monitoring as the standard of care is like rearranging the Titanic's deck chairs: it looks like much is being done but in the end the ship will still sink. And so it is with birth injury lawsuits as long as electronic fetal monitoring is allowed to masquerade as science.

Because all other efforts to change the birth injury malpractice system have failed, how can cerebral palsy–electronic fetal monitoring be stopped? The answer is by admitting the obvious electronic fetal monitoring is unhelpful and unscientific—and officially declaring that electronic fetal monitoring not only is unreliable but also is not the standard of care. Why would this stop the cerebral palsy–electronic fetal monitoring lottery? Because it would finally link electronic fetal monitoring to the *Frye-Daubert* family and the long feud between science and the courts.

Frye, Daubert, and Other Strange Names

The history of medical malpractice scientific expert testimony dates back to 1767 and the English case of *Slater vs. Baker &*

Stapleton.⁷⁴ In the intervening years, considerable effort was expended by courts in the industrial world grappling with the ever-increasing complexities of scientific advancements, almost all of which eventually were proffered as evidence in the world's courtrooms. These challenges were handled one at a time on an individual basis, resulting in a multitude of disparate opinions concerning what was and was not admissible. Finally, it was the polygraph—the lie detector—that was at the heart of one of the first cases to establish a universal guiding principle for admission into evidence of scientific opinion. The famous 1923 Frye case established one of the better known standards for admission of scientific evidence still viable today-general acceptance in the particular field in which it belongs.⁷⁵ Frye endured until the 1970s, when court-made restrictive and for the most part conservative evidence law was supplanted by expansive, liberalized evidence codes favoring admission of any evidence a trial court deemed relevant. And crafty trial lawyers took full advantage.

These expansive evidence codes-along with expanding liability concepts like product liability, mass tort actions, class actions, vicarious liability, and the like-ushered in an era of unprecedented jury verdicts. Trial lawyers put expert witnesses on the world's witness stands to testify about alleged scientific opinions based on little more than personal beliefs and unpublicized personal data untested by peer review or the scientific method. The era of junk science-"trust me, I'm a doctor"-resulted in mass tort cases where billions were paid to alleged victims-and primarily their lawyers-based on nothing more than experts' causation opinions that, when finally tested, were found to be not only erroneous but unscientific. Among dozens of examples are breast implants; Bendectin; pertussis; thimerosal; and measles, mumps, and rubella (MMR) vaccine allegedly causing autism.⁷⁶ This hit-or-miss justice based on novel scientific theories espoused by "experts" prompted one contemporary observer to write: "Junk science verdicts, once rare, are now common. Never before have so many lawyers grown so wealthy peddling such ambitious reports and the science of the things that aren't so."77

It was mere coincidence that electronic fetal monitoring became clinically popular at the exact same time that the tort-evidence revolution began. Coincidence or not, defendant physicians, midwives, and nurses suffered the courtroom consequences and still suffer the consequences, unlike breast implants; Bendectin; pertussis; thimerosal; and measles, mumps, and rubella, all of which have now been proven not to have caused the medical maladies the trial lawyers and their experts alleged.

Daubert and Her Children

The famous *Daubert* opinion did not actually change any evidence codes. *Daubert* simply implemented a procedure whereby trial judges became scientific gatekeepers—amateur scientists in one judge's words.⁷⁸ *Daubert* was a Bendectin lawsuit. Plaintiffs' expert witnesses did their own experiments, animal studies, and data reanalyses, concluding, contrary to all published data, that Bendectin caused birth defects. The Supreme Court rejected this expert evidence, imposing a non-exclusive checklist that trial judges were to use to assess prof-fered scientific expert testimony: (1) Can the theory be tested and challenged in an objective scientific study? (2) Has the theory been subjected to peer review and publication? (3) Does the theory or technique have a known or potential error rate? and (4) Is the theory generally accepted?⁷⁹

The *Daubert* criteria today are actually an amalgamation of a trilogy of Supreme Court cases, including a 1997 opinion holding expert testimony is excluded when there is too great an analytical gap, that is, the expert unjustifiably extrapolates from an accepted premise to an unfounded conclusion, and a 1999 decision applying *Daubert* criteria to all expert testimony, not just scientific testimony.⁸⁰

Twenty years after the Daubert opinion, Daubert and her children and grandchildren number in the thousands. The crux of Daubert et al is that scientific evidence must be relevant and scientifically reliable. The myriad factors explicated by Daubert et al focus on the principles and methodology the expert used to arrive at the proffered opinion. The factor especially applicable to electronic fetal monitoring opinions is methodological reliability or, as expressed by the courts, the analytical gap qualifier. That qualifier says that an expert's principles and methods must be reliable, and the conclusions necessarily logically follow therefrom. If the expert reaches conclusions other experts have not reached, then no matter how reliable the principles or methods used, there is reason to suspect the expert has extrapolated from an acceptable premise to an unreliable, unscientific conclusion, leaving too great an analytical gap between the data and the ultimate opinion.⁸¹

Excluding Unscientific Opinions

Daubert-related opinions, analyses, and other resources are now legion. Type "Daubert" into Google: 4,900,000 results in 0.17 seconds. And almost all countries and jurisdictions have slight-to-major application differences, but the basic approach is the same—ban junk science from courtrooms. Much easier said than done because, as we will see, individual judges also have a substantial impact how scientific gatekeeping functions.

Nevertheless, there are certain *Daubert* themes common to jurisprudence in almost all the world's courts. The essence of *Daubert* is that every expert, no matter the subject matter, is potentially subject to a challenge that their testimony is unreliable and therefore inadmissible into evidence. In legal terminology, the expert is "struck"—not allowed to testify. In essence, reliable scientific evidence requires some objective, independent validation of its reliability and/or the expert's methodology. No matter how impressive the expert's CV, no matter the number of editorships, the number of lectures or articles written, an expert's bare assurance of reliability—the expert's ipse dixit—is no longer a substitute for proof of an actual, generally accepted, scientific methodology supporting the opinion. The correctness of the opinion itself is not the issue. The court is charged to determine whether the expert's evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist.⁸² In other words, is the testimony based on a reliable scientific foundation?

Electronic Fetal Monitoring Should Meet Daubert

Daubert or its equivalent may have met electronic fetal monitoring somewhere in the world's courtrooms, but if so, the meeting has not been well publicized. This meeting, however, must take place if medicine hopes to see the beginning of the end of the cerebral palsy–electronic fetal monitoring litigation lottery.

The commonly expressed plaintiff expert opinion in cerebral palsy–electronic fetal monitoring lawsuits is that electronic fetal monitoring demonstrates clear signs of fetal oxygen compromise at a time when the compromise is reversible. The reversing agent is an immediate cesarean or assisted delivery that prevents the child's cerebral palsy or other neurologic deficit. As noted previously, this opinion is nonscientific, contrary to research and consensus statements on cerebral palsy causation. It is a rogue opinion lacking any recent published research support.⁸³ So why do courts the world over still allow these rogue opinions into evidence in virtually all cerebral palsy cases?

The answer is that electronic fetal monitoring has been unchallenged.⁸⁴ But challenging electronic fetal monitoring's reliability and a plaintiff's expert's causation opinion based on electronic fetal monitoring technology is an undertaking requiring a defense witness to explain the electronic fetal monitoring paradox: electronic fetal monitoring is used in 85% of all births in the United States; hundreds of books and articles have been published explaining electronic fetal monitoring clinical interpretations and when to intervene; thousands of cesarian sections are done around the world based on perceived ominous electronic fetal monitoring patterns; dozens of meetings and seminars are held yearly to improve electronic fetal monitoring interpretation; and hundreds of cerebral palsy verdicts and settlements occur yearly, all based on electronic fetal monitoring technology and its interpretation; but on the other hand, the medical literature is filled with 40 years of electronic fetal monitoring studies demonstrating electronic fetal monitoring's scientific impotency and its potential harm. In other words, what is true? Is electronic fetal monitoring efficacious because it is used to assist in hundreds of daily deliveries or is it merely a crude crutch for risk-averse physicians seeking to avoid lawsuits?

What is missing is a comprehensive plain-language, declarative, unified, professional society voice summarizing current electronic fetal monitoring research and distinguishing the stale, outdated books, articles, and opinions relied on by plaintiffs' experts published long before consensus statements on cerebral palsy causation⁸⁵ and before the even more recent genetic research and the growing body of evidence strongly suggesting that diverse genetic abnormalities play a major role

in most cases of cerebral palsy.86 An electronic fetal monitoring Daubert challenge today requires a judge to decide between 2 experts, each citing studies and papers from electronic fetal monitoring's 4 decades of use, but without professional societies' pronouncements concerning electronic fetal monitoring's efficacy. Recall, judges as gatekeepers are deciding on the reliability of the methodology used to reach the opinion, not whether the expert's opinion is correct. Judges faced with several hundred articles and books, some favoring and some opposing, will virtually always choose the easy ruling, which is to allow the expert's testimony. Judges are not medically trained or oriented, nor are they inclined to wade through articles and books. Nor are all judges equal in their dedication to judging. If, however, professional societies would declare electronic fetal monitoring unreliable and publish bulletins, evidence-based guidelines, and other standard of care publications demonstrating electronic fetal monitoring's unreliability, judges' decisions would become more predictable. The decisions would become automatic if these pronouncements were written in plain, declarative language understandable to judges, jurors, the public, and especially physicians.

What Should Birth-Related Professional Organizations Do and Say?

Professional societies must first begin educating their own members to the reality that despite electronic fetal monitoring's ubiquity, electronic fetal monitoring is ineffectual, prone to interpretative errors, has a 99% false positive prediction of fetal distress, has not reduced the incidence of cerebral palsy, has increased cesarian sections, and is no better a screening test for absence of injury than is a coin toss.⁸⁷ At the same time, birthrelated professional organizations must come to the realization that electronic fetal monitoring is a misnomer. It is not a monitor at all. Long ago, the point was made that electronic fetal monitoring is merely a heart-beat recorder,⁸⁸ recording data that must be interpreted. Interpretation is an art, subjective at its very best, and in electronic fetal monitoring's case, difficult to standardize and is poorly reproducible.⁸⁹ Subjective interpretation always leaves room for human bias. Any test dependent on human interpretation will also be subject to the pressures exerted on the individual making the interpretive decisions and that individual's motivations and, in the electronic fetal monitoring case, fears-in particular, fears of litigation.90 "Decisions based on fear are not rational."91 The interpreter's self-interest will likely be the decisive factor in the interpretation, creating a huge medical and ethical Gordian Knot.

Birth-related professional organizations must undo this knot—first by an official declaration that the standard of care does not require electronic fetal monitoring monitoring in low-risk pregnancies, and second, by an official declaration that electronic fetal monitoring is still under clinical investigation and its use cannot yet be construed as scientifically reliable, either in labor rooms or courtrooms.

These pronouncements would be most effective if made in a fashion similar to the International Consensus Statement on cerebral palsy—an amalgamation of worldwide experts from many countries and worldwide professional societies. A consensus statement should be accompanied by literature analysis weeding out the past unscientific literature and explaining why electronic fetal monitoring use and interpretation must go "back to the future" and, through appropriate clinical testing, be reborn. It really is time to abandon ship and start over.⁹²

Can Birth-Related Professional Organizations Change the Standard of Care?

The first objection will be, "We can't just change the standard of care; plaintiff lawyers will accuse us of being self-serving."

Yes, medicine can change the standard of care; it's done every day. One only need read the latest journals to see that medicine changes evidence-based diagnoses and treatments frequently. Electronic fetal monitoring is no different. Admittedly, it has taken 40 years to evaluate the evidence, but that is no reason to duck the issue. Some will say that electronic fetal monitoring is a sacrosanct standard of care, but there is a case study that proves that argument's fallaciousness. In 2008, United Kingdom's National Institute for Health and Care Excellence recommended no continuous electronic fetal monitoring for uncomplicated, low-risk pregnancies. They also recommended no routine fetal heart auscultation. Why? Because there was no evidence to support routine monitoring, even by auscultation.⁹³ In an instant, UK 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 electronic fetal monitoring monitoring is not required in healthy pregnancies.

Physicians set the standard of care, both in labor and delivery rooms and in courtrooms. Is a publication, even a worldwide Consensus Statement, automatic proof of the standard of care? No. Nothing is guaranteed. An evidence-based guideline, however, well-written and reasoned, in plain declarative language that even judges and jurors can understand, is certainly more persuasive than any testimony or document available today. Evidence-based guidelines do provide the legal standard in some of the world's courts, and in others are highly persuasive evidence.⁹⁴ Depending on the jurisdiction, such evidence-based guidelines could be admissible in evidence or at the very least be admissible for oral discussion on both direct and cross-examination.

In similar fashion, a detailed analysis of the current and past electronic fetal monitoring literature would be highly beneficial and shed light upon the many nonpersuasive studies that still populate the literature and that are relied upon by plaintiff experts. Unsophisticated judges and jurors cannot distinguish good from bad literature. Such a reanalysis will be essential to helping establish the unreliability of the opinion of any expert who might be relying on stale, outdated writing.

Conclusion

Cerebral palsy is real and heartbreaking for its victims and their parents. Electronic fetal monitoring was a noble attempt to solve the cerebral palsy mystery. Despite its noble beginnings, however, birth-related professional organizations allowed trial lawyers to hammer electronic fetal monitoring from a plowshare into a gun perpetually pointed at obstetricians and the myriad health care providers routinely caring for birth asphyxia babies. Each birth has the potential to be the one resulting in years of litigation, multiple defendants each pointing the finger of blame at each other, and the very real possibility that at the end there will be a career-damaging, headline-making jury verdict. It is little wonder that most physicians choose a quick cesarian section as the only choice whenever the machine indicates even a slight possibility of a birth problem. Far better to choose early cesarian section with its complications for mother and baby than risk being sued for acting slowly. This electronic fetal monitoring decision dilemma occurs every day. It is a decision that has created an ethical nightmare. Birth decisions are made based on fear-the fear of being sued-and decisions made out of personal consequences fear are neither rational nor ethical.

It is far past time for birth-related professional organizations to confront electronic fetal monitoring reality, abandon the electronic fetal monitoring ship, and start over. Birth-related professional organizations must come to grips with the undeniable evidence that electronic fetal monitoring is an epic medical ethical dichotomy—it harms mothers and babies in direct opposition to the long-made promise not to do so. The time to act is now. If not now, when?

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Notes

- O'Connell J, Robinette CJ. A Recipe for Balanced Tort Reform. Durham, NC: Carolina Academic Press; 2008:87-121; Sloan FA, Chepke LM. Medical Malpractice. Cambridge, MA: MIT Press; 2008:85-105.
- E.g., MacLennan AH. A "no-fault" cerebral palsy scheme would benefit all Australians. *Aust NZ J Obstet Gynecol* 2011;51:479-484; Johnson SL, Paed D, Blair E, Stanley FJ. Obstetric malpractice litigation and cerebral palsy in term infants. *J Forensic Legal Med.* 2011; 18:97-100; Farrell AM, DeVaney S, Dar A. No-fault compensation schemes for medical injury: a review. Scottish Government Social Research 2010 www.scotland.gov.uk/resource/ 0039/00394407.pdf (accessed August 10, 2013) (also available for download at http://www.academia.edu/1764851/no-fault_compensation_schemes_for_medical_injury_A_review); MacLennan AH, Hankins G, Speer M. Only an expert witness can prevent cerebral

palsy. *Obstet Gynecol.* 2006;8:28-30; MacLennan A, Nelson KB, Hankins G, Speer M. Who will deliver our grandchildren. *JAMA*. 2005:294:1688-1690; Banta JV. Medical liability crisis, an international problem. *Dev Med Child Neurol.* 2003;45:363-366.

- 3. Sources cited supra note 2. See also Hankins G, MacLennan AH, Speer ME, et al. Obstetric litigation is asphyxiating our maternity services. *Obstet Gynecol.* 2006;107:1382-1385; Domin S. Where have all the baby-doctors gone? Women's access to healthcare in jeopardy: Obstetrics and the medical malpractice crisis. *Cath Univ L Rev.* 2004;53:499-517; Rosenblatt RA, Weitkemp G, Lloyd M, et al. Why do physicians stop practicing obstetrics? The impact of malpractice claims. *Obstet Gynecol.* 1990;76:245-250.
- 4. Sartwelle TP. Electronic fetal monitoring: a bridge too far. J Legal Med. 2012;33:313-379 (see 323 "The EFM age: 1968-2012" and in particular note 51 for extensive citations to the literature on defensive medicine especially in obstetrics).
- 5. Id., 321-325 and sources cited notes 41-51.
- Sources cited supra note 2; see also, Ellenberg JH, Nelson KB. The association of cerebral palsy with birth asphyxia: a definitional quagmire. *Dev Med Child Neurol.* 2013;55:210-216; Badawi N, Keogh JM. Causal pathways in cerebral palsy. *J Paediatr Child Health.* 2013;49:5-8; Constantine MM, Saade GR. The first caesarian: role of "fetal distress" diagnosis. *Semin Perinatol.* 2012;36:379-383.
- 7. Sartwelle, supra note 4 at 317-334.
- 8. E.g., O'Callaghan M, MacLennan A. Cesarean delivery and cerebral palsy: a systematic review and meta-analysis. Obstet Gynecol. 2013;112:1169-1175 (C-section not associated with reduced risk of CP); Main EK, Morton CH, Hopkins D, et al. Cesarean deliveries, outcomes, and opportunities for change in California: toward a public agenda for maternity care safety and quality. California Maternal Quality Care Collaborative, Palo Alto, CA, 2011 (available at www.cmqcc.org) (accessed July 25, 2013), (cesarian section thought of as safer option when it actually has greater risks and complications than vaginal birth); Villar J, Carroli G, Zavaleta N, et al.; World Health Organization 2005 Global Survey on Maternal and Perinatal Health Research Group. Maternal and neonatal individual risk and benefits associated with caesarean delivery: multicenter prospective study. Br Med J. 2007;335:1025-1036 (nonemergency cesarian sections have double the risk of complications, even death, compared to vaginal birth); Nelson KB. Can we prevent cerebral palsy? N Engl J Med. 2003;349:1765-1769 at 1768 (no evidence cesarian section based on electronic fetal monitoring indications prevents cerebral palsy but is associated with increased morbidity risks). See also Neu J. The pre- and early post-natal microblome: relevant to subsequent health and disease. Neo Rev. 2013;14:e592-e599, available at http://neoreviews.aappublications.org/content/14/12/e592 (accessed December 12, 2013) (intestinal microbiota could alter brain function; cesarian section versus vaginal delivery could contribute to enterocolitis, lateonset sepsis, and altered brain motor activity and anxiety-like behavior).
- Spilka S. Chudacek V. Janku P. et al. Analysis of obstetricians' decision making on CTG recordings. *J. Biomed Informatics* (2014), http://dx.doi.org/10.1016/j.jbi.2014.04.010 (accessed 5 June 2014); Clark SL Nageotte MP Garite TJ et al. Intrapartum

management of category II fetal heart rate tracings: toward standardization of care. *Am. J. Obstet. & Gynecol.* 2013; 209(2): 89-97; Blackwell SC Grobman WA Antoniewicz L et al. Interobserver and intraobserver reliability of NICHD 3-tier fetal heart rate interpretation system. *Am. J. Obstet. & Gynecol.* 2011; 205(4): 378. e1-5; deCampos DA, Bernardes J. Twenty-five years after FIGO guidelines for the use of fetal monitoring: time for a simplified approach? *Int. J. Gynecol.* Obstet. 2010; 110(1): 1-6; Sartwelle supra note 4 at 326-329 and sources cited notes 65-75.

- Sartwelle TP. Defending a neurologic birth injury: asphyxia neonatorum redux. J Legal Med. 2009;30:181-247, 195-206.
- Halmgren CM, Esplin MS, Jackson M, et al. A risk stratification model to predict adverse neonatal outcome in labor. *J Perinatol*ogy. 2013;33:914-918; Tan S. Fault and blame: insults to the perinatal brain may be remote from time of birth. *Clin Perinatol.* 2014;41:105-117; available at http://dx.doi.org/10.1016/j.clp. 2013.10.006 (accessed December 20, 2013). Sartwelle, supra note 4, 325-333.
- E.g., Constantine, supra note 6; MacLennan et al. Only an expert witness can prevent cerebral palsy, supra note 2; Clark S, Hankins G. Temporal and demographic trends in cerebral palsy—fact and fiction. *Am J Obstet Gynecol.* 2003;188:628-632.
- 13. See sources cited supra notes 2, 6, 11, 12.
- 14. See sources cited supra notes 1 and 2.
- Natale R, Dodman N. Birth can be a hazardous journey: electronic fetal monitoring does not help. *J Obstet Gynecol Can.* 2003;25: 1007-1009.
- Mohr JC. American medical malpractice litigation in historical perspective. *JAMA*. 2000;283:1731-1737, quoting a physician's 1878 survey of medical malpractice litigation in Maine, 1733-1734.
- E.g., Mohr, supra note 16; Bal SB. An introduction to medical malpractice in the United States. *Clin Orthop Relat Res.* 2009; 467:339-347; deVille KA. Medical malpractice in twentieth century U.S.: the interaction of technology, law and culture. *Int J. Technol Assess Health Care.* 1998;98:99-103; Mohr JC. *Doctors and the Law: Medical Jurisprudence in Nineteenth-Century America.* New York, NY: Oxford University Press; 1993; deVille KA. *Medical Malpractice in Nineteenth Century America: Origins and Legacy.* New York, NY: New York University Press; 1990.
- Johnston JC, Sartwelle TP. The expert witness in medical malpractice litigation: through the looking glass. *J Child Neurol*. 2013;28:484-501.
- 19. Id.
- DeVille KA. Medical malpractice in nineteenth-century America, supra note 17.
- 21. Mohr, supra note 16.
- 22. Id.
- Laine C, Davidoff F. Patient centered medicine. A professional evolution. JAMA. 1996;275:152-156.
- 24. Danzon PM. The frequency and severity of medical malpractice claims: new evidence. *Law Contemp Probl.* 1986;49:57-62.
- 25. Sloan and Chepka, supra note 1 at chapter 76: Compensating plaintiffs' attorneys.
- 26. O'Connell and Robinette, supra note 1 at 181: The time is ripe.

- 27. DiVenere L. ACOG's push for medical liability reform: what's the latest? *Obstet Manage*. 2013;25:36-47 (DiVenere is government affairs senior director at the American College of Obstetricians and Gynecologists; her conclusion: medical liability reform ... remains beyond our reach.... Ibid. at 47).
- DeVille KA, supra note 17; see deVille KA. The historical origins of medical malpractice litigation. Ethics & Health Care Newsletter, Department of Medical Humanities, East Carolina University. 1999; 2(2). Available at http://www.ecu.edu/cs-dhs/medhum/ newsletter/v2 n 2.csm/deville volume 2 number 2 fall 1999 (accessed August 11, 2013).
- 29. Sartwelle, supra note 4 at 323-324, notes 46-51 and 359-360, notes 239-244.
- Quilligan EJ, Paul RN. Fetal monitoring: is it worth it? *Obstet Gynecol.* 1975;45:96-99.
- Haverkamp AD, Thompson HE, McFee JG, Cetrulo C. The evaluation of fetal heart rate monitoring in high risk pregnancy. *Am J Obstet Gynecol.* 1976;125:310-315; see Freeman RK. Intrapartum fetal monitoring—a disappointing story. *N Engl J Med.* 1990;322:624-628.
- 32. Thacker SB, Stroup DF, Peterson HB. Efficacy and safety of intrapartum electronic fetal monitoring: an update. *Obstet Gynecol.* 1995;86:613-620.
- Scheller JM, Nelson KB. Does caesarean delivery prevent cerebral palsy or other neurologic problems in childhood? *Obstet Gynecol.* 1994;83:624-630.
- Nelson KB, Dambrosia JM, Ting TY, Grether JK. Uncertain value of electronic fetal monitoring in predicting cerebral palsy. *N Engl* J Med. 1996;334:613-619.
- 35. Sartwelle, supra note 4, 326-329.
- 36. See sources cited, supra notes 2, 4, 8, 12. From time to time studies appear that challenge the known fact that physicians, nurses, and midwives are a rare cause of cerebral palsy during birth. See several studies cited and discussed in Sartwelle, supra note 10 at 234-237 and notes 308-325, and Sartwelle, supra note 4 at note 325. Recently a Norwegian retrospective study of birth asphyxia and cerebral palsy between 1994 and 2008 concluded human error was a frequent reason for substandard care and inadequate fetal monitoring occurred in 50% of deliveries where birth asphyxia was the cause of subsequent neurological sequela resulting in compensation. Andreasen S, Backe B, Olan P. Claims for compensation after alleged birth asphyxia: a nationwide study covering 15 years. Acta Obstet Gyunecol Scand. 2014;93:152-158. Among the many criticisms that can be leveled at the authors' conclusions, the most obvious is the total lack of any citation to or discussion of the last 40 years of fetal monitoring literature. The authors merely conclude fetal monitoring revealed birth asphyxia and the birth asphyxia caused neurologic sequela.
- Greene MF. Obstetricians still await a deus ex machina. N Engl J Med. 2006;355:2247-2248.
- Benson RC, Shubeck F, Deutschberger J, Weiss W, Berendes H. Fetal heart rate as a predictor of fetal distress: a report from the collaborative project. *Obstet Gynecol.* 1968;32:259-266.
- 39. Sartwelle, supra note 4 at 336 and sources cited note 107.
- 40. Sartwelle, supra note 4, 334-344.

41. Id., 338-342.

- 42. Nat'l Inst. Child Health & Human Development Research Planning Workshop, Electronic fetal heart rate monitoring: research guidelines and interpretation. *Am J Obstet Gynecol.* 1997;177: 1385-1389 at 1385. (See summary of efforts to formalize electronic fetal monitoring interpretation in the article's background section.)
- 43. MacLennan AH. A template for defining a causal relation between acute intrapartum events and cerebral palsy: international consensus statement. *Br Med J.* 1999;319:1054-1057 (hereinafter "Consensus Statement"); see Sartwelle, supra note 10 at 202-203 for a discussion of the Consensus Statement details.
- 44. Am. Coll. Obstet. Gynecol. and Am. Acad. Pediatricians, Neonatal encephalopathy and cerebral palsy: defining pathogenesis and pathophysiology (2003); see Sartwelle, supra note 10 at 204-205 for a discussion of the report's details.
- 45. Consensus Statement, supra note 43 at 1057.
- 46. E.g., Clark, supra note 9.
- 47. Sources cited note 2 and note 9 supra.
- 48. Clark et al, supra note 9 at 89. To their credit, two of the authors, Clark and Hankins, in 2003 published a landmark electronic fetal monitoring article labeling electronic fetal monitoring absurd and as possibly having done more harm than good. The article was "landmark" because for almost the first time in electronic fetal monitoring history, medical professionals abandoned medicalspeak for plain language, abandoned euphemisms for concrete expression, and abandoned passive acceptance of status quo for medical accountability. See Clark and Hankins, supra note 12. See also American College of Obstetricians and Gynecologists for Maternal-Fetal Medicine. Safe prevention of the primary cesarean section. Am J Obstet Gynecol. 2014;123:179-193 at 187 (unnecessary cesareans for abnormal electronic fetal monitoring tracings attributed to "limited knowledge about the ability of the patterns to predict neonatal outcomes and the lack of rigorous science to guide clinical response to the patterns.") (hereinafter American College of Obstetricians and Gynecologists-Society for Maternal-Fetal Medicine Consensus). Electronic fetal monitoring is not the only obstetric orthodoxy to be second-guessed after multiple years in clinical use. Recently the management of labor and the historical understanding of normal labor progress over time have been challenged as being flawed and based on an analytic flaw in the historic labor data. Cahill AG, Tuuli MG. Labor in 2013: the new frontier. Am J Obstet Gynecol. 2013;209:531-534.
- 49. Macones GA et al. The 2008 National Institute of Child Health and Human Development Workshop report on electronic fetal monitoring. *Obstet Gynecol.* 2008;112:661-667. See extensive discussion in Sartwelle, supra note 4 at 348-350.
- 50. Berkowitz RL, D'Alton ME, Goldberg JD, et al. The case for an electronic fetal heart rate monitoring credentialing examination. *Am J Obstet Gynecol.* 2014;210:204-207.; *Am Coll Obstet Gynecol.*, Practice Bulletin 116, Management of intrapartum fetal heart rate tracings (2010) (conceding optimal time frame for delivery of fetus demonstrating category III tracing, the most ominous, is absent; suggested management: do the best you can); see also Sartwelle, supra note 4 at 350-352.

- 51. *Am Coll Obstet Gynecol.*, Practice Bulletin No. 106, Intrapartum fetal heart rate monitoring: nomenclature, interpretation and general management principles (July 2009).
- 52. Clark et al, supra note 9 at 95-96.
- 53. E.g., sources cited supra note 1; see also Havighurst CC, Taneredi LR. "Medical Adversity Insurance": A no-fault approach to medical malpractice and quality assurance. *Milbank Mem Fund Q Health Soc.* 1973;51:125-168; O'Connell J. An alternative to abandoning tort liability: elective no-fault insurance for many kinds of injuries. *Minn Law Rev.* 1976;60:506-509; Schaefer M. Medical malpractice tort reform across America: an overview. *Forum.* 2003; 23-33; Sartwelle, supra note 4 at 324, note 51 and sources cited beginning with Albany law professor Allen Reddick's analysis of the 1974-1976 medical malpractice crisis and subsequent "legislative panic."
- 54. E.g., Sartwelle, supra note 4, note 51 and sources cited.
- 55. See sources cited supra notes 2, 6; Freeman RK. Medical and legal implications of necessary requirements to diagnose damaging hypoxia-ischemic encephalopathy leading to cerebral palsy. *Am J Obstet Gynecol.* 2008;199:585-586 (calling for specialized courts and expert witnesses retained by the court rather than the lawyers). See also American College of Obstetricians and Gynecologists–Society for Maternal-Fetal Medicine Consensus, supra note 48.
- 56. Life care planners are now a cottage industry. The training of those testifying runs the gamut from physiatry-physical medicine, to general pediatrics, to nursing, to any college graduate. For example, the University of Florida Continuing Education division offers online courses leading to a Life Care Planning certificate. Many other similar programs are offered on the Internet. The paradox is that evidence-based studies of the lifetime costs associated with the wide variety of cerebral palsy are rare. Those that do exist place the lifetime costs of cerebral palsy. *Dev Med Child Neurol.* 2009;51:622-628. Even if a multiplier of 4, 6, 8, or 10 is used, the costs are a far cry from \$50 million and many of the other figures routinely put forth by plaintiffs' life care witnesses.
- 57. E.g., Women's Health & Education Center, Healthcare Policies & Women's Health: Medical Liability; Tort Reform, WHEC Practice Bulletin and Clinical Management Guidelines for healthcare providers. August 23, 2011, at 4. Available at http://www.womenshealthsection.com/content/heal/heal020.0hp3 (accessed September 7, 2013).
- Goldsmith JP. Programs offer alternative to malpractice suits when newborns suffer neurologic injury. *AAP News*. 2012;33: 10-11.
- 59. E.g., sources cited supra note 2; see Badawi, supra note 6; Tomizuka T, Matsuda R. Introduction of no-fault obstetric compensation (Japan). Health Policy Monitor. October 2009. Available at http://www.hpm.org/survey/jp/a14/4 (accessed October 12, 2013); Kennedys Law LLP. No-fault scheme for Scotland. Feb. 22, 2013, available at http://www.Kennedys-law.com/article/ nofaultcompensationforscotland/ (accessed December 3, 2013).
- 60. E.g., sources cited supra note 2.
- 61. DiVenere, supra note 27.

- 62. See, e.g., *R. v. Mohan* (1994) 2 S.C.R. 9 and *R. v. J.L.-J.* (2000) 2 S.C.R. 600 (*Daubert* standard adopted by Supreme Court of Canada); §79(1) Uniform Evidence Law [Evidence Act] (Australia adopting a *forme fruste* of *Daubert* upheld by the High Court in various cases including *Dasreef v. Hawchar* (2011) 277 ALR 611, 85 ALJR 694; [2011] HCA 21; BC201104304; §23 Evidence Code 1999 (commentary on New Zealand judgments referring to non-exhaustive guidelines of *Daubert* in assessing the reliability of scientific evidence). See, generally, R. Beran, ed. *Legal and Forensic Medicine*. Berlin: Springer-Verlag; 2013 (international legal medicine compendium includes discussion of evidence laws in various jurisdictions).
- Robinson B, Nelson L. A review of the proceeding from the 2008 NICHD workshop on standardized nomenclature for cardiotocography. *Rev Obstet Gynecol.* 2008;1:186-192 at 186 and 192.
- 64. Sartwelle, supra notes 4, 10; Lent M. The medical and legal risks of the electronic fetal monitor. *Stanford Law Rev.* 1999;51:807-837; Sachs BP. Is the rising rate of caesarean sections a result of more defensive medicine?, in Rostow VP, Bulge RJ, eds. *Professional Liability and the Delivery of Obstetrical Care*. Washington, DC: National Academies Press, 1989; at 31 (Table 2); Friedman EA. The obstetrician's dilemma: how much fetal monitoring and cesarean section is enough? *N Engl J Med.* 1986;315: 641-643.
- 65. Lent M, supra note 64 at 830-831, 835.
- 66. Johnston and Sartwelle, supra note 18 at 493-494. There are exceptions, as in the United Kingdom, where the courts are not necessarily bound by expert opinions.
- 67. Ibid. Medicine and lay people are also emphasizing use of clinical guidelines. E.g., Pronovost PJ. Enhancing physicians' use of clinical guidelines. JAMA. 2013;320:2501-2502; Montori VM. The optimal practice of evidence-based medicine. JAMA. 2013;310: 2503-2504; O'Malley AC. Preventing a return to twilight and straitjackets: using the Patient Protection and Affordable Care Act as a starting point for evidence-based obstetric reform in the United States. Northwestern J. Law Social Policy. 2012;8:295-324.
- 68. Sartwelle TP. Electronic fetal monitor: a defense lawyer's view. *Rev Obstet Gynecol.* 2012;5:e121-e125.
- 69. E.g., MacLennan et al. Only an expert witness can prevent cerebral palsy, supra note 2; MacLennan et al. Who will deliver our grandchildren, supra note 2.
- 70. Sartwelle, supra note 4 at 346-347 and sources cited. The issue whether a jury of 6-to-12 ordinary citizens without training or discernment in things of medicine and science should be the ultimate decision makers is another argument altogether. The argument for and against juries has gone on for decades if not a century or more. So far the jury proponents have carried the day and it seems likely they will continue to win for the foreseeable future. E.g., Curriden M. Power of 12. *Am Bar Assoc J.* 2001;87:36-41.
- 71. Johnston and Sartwelle, supra note 18 at 498-499.
- 72. Kesselheim AS, Studdert DM. Characteristics of physicians who frequently act as expert witnesses in neurologic birth injury litigation. *Obstet Gynecol.* 2006;108:273-279. See also MacLennan et al. Only an expert witness can prevent cerebral palsy, supra note 2; MacLennan et al. Who will deliver our grandchildren, supra note 2.

- Grimes DA, Peipert JF. Electronic fetal monitoring as a public screening program: the arithmetic of failure. *Obstet Gynecol.* 2010;116:1397-1399.
- 74. Johnston and Sartwelle, supra note 18.
- 75. Id. at 485-487.
- 76. Id.; Huber PW. Galileo's revenge: junk science in the courtroom. New York, NY: Basic Books; 1993 (recounting multiple dozens of junk science courtroom scams); Offit P. Deadly Choices. New York, NY: Basic Books 2010; Offit P. Autism's False Prophets. Columbia University Press; 2010; Mnookin S. The Panic Virus. Simon & Schuster; 2011; Angell M. Science on trial: The clash of medical science and the law in the breast implant case. New York: Norton; 1997; Green MD. Bendectin and birth defects: The challenge of mass toxic substances litigation. Philadelphia: University of Pennsylvania Press: 1998.
- 77. Huber, supra note 76 at 4.
- 78. Johnston and Sartwelle, supra note 18 at 487 (the thought being that most judges, untrained in science, lacked the scientific literacy to effectively carry out the gatekeeper role).
- 79. Id. at 488. There are many more criteria articulated by courts but those listed capture the *Daubert* essence. Not all courts use the *Daubert* criteria. Some still rely on the *Frey* test. The aim, however, is the same: exclude junk science.
- 80. Id.
- 81. Id. at 490.
- 82. Id. at 489-491. See Spechler IS. Physicians at the gates of *Daubert*: a look at the admissibility of differential diagnosis testimony to show external causation in toxic tort litigation. Rev. of Litigation 2007; 26:739 (a discussion of the use of differential diagnosis in the general causation and specific causation elements in medical liability-medical products-device cases).
- E.g., MacLennan et al. Only an expert witness can prevent cerebral palsy, supra note 2 and sources cited supra notes 4, 6, 10, 12 and 15.
- 84. Sartwelle, supra note 4 at 316 note 15, and in particular at 355-357 with the discussion of obstetricians' poor state of cerebral palsy causation knowledge and continuing belief in eighteenth century birth myths.
- Am. Coll. Obstet. & Gynecol. & Am. Acad. Peds. supra note 44; Consensus Statement supra note 43.
- 86. E.g., Tollanes MC, Wilcox AJ, Rolv TL, et al. Familial risk of cerebral palsy: population based cohort study. Brit. Med. J. 2014; 349:g4294 (available at http://www.bmj.com/content/349/bmj. g4294 (accessed 17 July 2014); Rosenbaum P. What causes cerebral palsy? (Editorial). Brit. Med. J. 2014;349:g4514 (available at http://www.bmj.com/content/349/bmj.g4514 (accessed 17 July 2014); McIntyre S, Blair E, Badawi N, Keogh J, Nelson K. Antecedents of cerebral palsy and perinatal death in term and late preterm singletons. Obstet Gynecol. 2013;122:869-877; Streja E, Miller JE, Beck BH, et al. Congenital cerebral palsy and prenatal exposure to self-reported maternal infections, fever, or smoking. Am J Obstet Gynecol. 2013;20:332.e1-332.e10; MacLennan AH. Cerebral palsy-is it in your genes? Genetic susceptibility and environmental risk factors. Oral presentation to 4th International cerebral palsy Conference, Pisa, Italy, October, 2012; Moreno-De-Luca A, Ledbetter DH, Martin CL. Genomic insights

into the causes and classification of the cerebral palsies. Lancet Neurol. 2012;11:383-292; Wu D et al. The association of genetic polymorphisms with cerebral palsy: a meta analysis. Dev Med Child Neurol. 2011;53:217-225; Moreno-De-Luca A, Helmers SL, Mao H, et al. Adaptor protein complex-4 (AP-4) deficiency causes a novel autosomal recessive cerebral palsy syndrome with microcephaly and intellectual disability. J Med Genet. 2011;48: 141-144; Gibson CS, Maclennan AH, Dekker GA, et al. Candidate genes and cerebral palsy: a population-based study. Pediatrics. 2008;122:1079-1085; see also Neu, supra note 8. Genetic abnormalities are not the only causative factors thought to play a role in cerebral palsy causation. Among many others are oxidative injury also known as "free radical disease of the newborn." E.g., Tonni G, Leoncini S, Signorini C, et al. Pathology of perinatal brain damage: background and oxidative stress markers. Arch Gvnecol Obstet. 2014;290:13-20.

87. Constantine MM et al, supra note 6, at 381. Constantine et al are not the only practitioners concerned with the growing knowledge of mortality and morbidity associated with cesareans and repeat cesareans. The concern over too many cesareans, many promoted by electronic fetal monitoring tracings, has again become the focal point of workshops and articles not only in the United States but a number of other countries as well: E.g., American College of Obstetricians and Gynecologists–Society for Maternal-Fetal Medicine Consensus, supra note 48; Rossignol M, Moutquin JM, Boughrassa F, et al. Preventable obstetrical interventions: how many caesarean sections can be prevented in Canada? J Obstet Gynecol Can. 2013; 35:434-443; Helal AS, Abdel-Hady ES, Warda O, Goda H, Sherief L. Rising rate

of caesarean delivery at Mansoura University Hospital: a reason for concern. Gynecol Obstet. 2013;3:146; Wang CPY, Tan WC, Kanagalingam D, Tan HK. Why we do caesars: a comparison of the trends in caesarean section delivery over a decade. Ann Acad Med Singapore. 2013;42:408-412; Spong CY, Berghella V, Wenstrom KD, Mercer BM, Saade GR. Preventing the first cesarean delivery: summary of a joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, and American College of Obstetrics and Gynecologists workshop. Obstet Gynecol. 2012;120:1181-1193; Rafique S, Raana G. Changing trends in caesarean section rate and indications. Pakistan J Surg. 2012;28:60-64. For a brief history of caesarean section, its popularity, the decades-long debate over how many is too many, and its relationship to electronic fetal monitoring, see Sartwelle, supra note 4 at 329-331 and accompanying notes.

- Jenkins HML. Thirty Years of Electronic Intrapartum Fetal Heart Rate Monitoring: Discussion Paper. *Royal Soc Med.* 1989; 82: 210-214, at 211, citing a 1974 electronic fetal monitoring critique.
- 89. Greene, supra note 37 at 2247.
- 90. Constantine, supra note 6 at 380.
- 91. Ibid.
- 92. Clark et al, supra note 9.
- 93. NHS NICE, Anetanatal Care, Routine Care for the Healthy Pregnant Woman, NICE Clinical Guideline 62 at 36, available at http://www.nice.org.uk/cg62 (accessed September 15, 2013). For a perspective on NICE see Rawlins MD. NICE moving forward. N Engl J Med. 2013;369:3-5.
- 94. Johnston and Sartwelle, supra note 18 at 493-495.