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How Does a Physician Avoid Prescribing Drugs and Medical Procedures That Have Reproductive and Developmental Risks?

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In 1967 I published an article titled the "Medicolegal Aspects of Teratology" in which I predicted the epidemic in malpractice litigation. This speculation was based on an influx of requests to evaluate the merits of what I characterized as nonmeritorious malpractice cases involving birth defects [1]. Even in the 1960s teratologists were aware that only a small percentage of birth defects were caused by drugs, chemicals, and physical agents [2–8]. In 2007 even more information is available to confirm this viewpoint (Table 1) [9–11]. Birth defects caused by drugs, chemicals, and physical agents account for a very small percentage of birth defects (see Table 1).

In the United States the medicolegal climate has changed considerably in the past 50 years. When I was appointed to the faculty at the Jefferson Medical College in Philadelphia in 1957, my malpractice premium was $50.00 per year. I am certain it is hard for many young obstetricians and perinatologists to believe that fact. But the climate has changed dramatically. Two reports of congenital malformations can put a historical perspective on the present malpractice climate in the United States.

The philosophy of some members of the legal profession and of the public is that someone must be responsible for personal damages that have been incurred. Historically, the father or mother of a malformed infant was open to ridicule, criticism, or even persecution [12–14]. Folklore and superstition dominated the field, and the causes of malformations were attributed to evil spirits, fornication with animals, lewd thoughts, or other immoral acts. Certainly, in the 1600s no one could have thought of receiving compensation for the birth of a malformed child. The following case presentation highlights

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Table 1
Causes of human congenital malformations observed during the first year of life

Suspected cause	Percentage of total
Unknown	65–75
Polygenic	—
Multifactorial (gene–environment interactions)	—
Spontaneous errors of development	—
Synergistic interactions of teratogens	—
Genetic	15–25
Autosomal and sex-linked inherited genetic disease	—
Cytogenetic (chromosomal abnormalities)	—
New mutations	—
Environmental	10
Maternal conditions: alcoholism; diabetes; endocrinopathies; phenylketonuria; smoking and nicotine; starvation; nutritional deficits	4
Infectious agents: rubella, toxoplasmosis, syphilis, herpes simplex, cytomegalovirus, varicella-zoster, Venezuelan equine encephalitis, parvovirus B19	3
Mechanical problems (deformations): amniotic band constrictions; umbilical cord constraint; disparity in uterine size and uterine contents	1–2
Chemicals, prescription drugs, high-dose ionizing radiation, hyperthermia	<1

Data from Brent RL. Utilization of developmental basic science principles in the evaluation of reproductive risks from pre- and postconception environmental radiation exposures. Teratology 1999;59:182–4.

the ignorance and superstition that surrounded the birth of a malformed offspring in the seventeenth century:

At a General Court held at New Haven on March 2, 1641, it transpired that on the preceding February 14,

> John Wakeman a planter and member of this church acquainted the magistrates that a sow of his which he had lately bought of Henry Browning, then with pigge, had now brought among divers liveing and rightly shaped pigs, one prodigious monster, which he then brought with him to be viewed and considered. The monster was come to the full growth as the other piggs for ought could be discerned, butt brought forth dead. Itt had no haire on the whole body, the skin was very tender and a reddish white collour like a childs; the head most straing, itt had butt one eye in the middle of the face, and thatt large an open, like some blemished eye of a man; over the eye the bottome of the foreheade which was like a childes, a thing of flesh grew forth and hung downe, itt was hollow, and like a man's instrument of generation. A nose, mouth and chinne deformed, butt nott much unlike a childs the neck and eares had also such resemblance.

This description is that of a typical cyclopean monster. The record continues,

> [A] strange impression was allso upon many that saw the monster, (therein guided by the neare resemblance of the eye) that one George Spencer, late

> servant to the said Henry Browning, had beene actor in unnatureall and abominable filthynes with the sow–.

(It came out during the proceedings that Spencer actually had not been in the service of Browning at the critical time!)

> The aforementioned George Spencer so suspected hath butt one eye for use, the other hath (as itt is called) a pearle in itt, is whitishy Y deformed, and his deformed eye being beheld and compared together with the eye of the monster, seamed to be as like as the eye in the glass to the eye in the face.

There is little doubt that George Spencer had a cataract in one eye. That he ''had beene formerly notorious in the plantation for a prophane, lying scoffing and lewd speritt'' surely did not help his situation.

Although professing innocence, he was committed to prison on February 24. In jail he was visited by some of the magistrates and other fellow-Puritans and under their strong moral suasion admitted to being guilty of the suspected crime but almost immediately revoked his confession. There followed, up to the final day of the drama, a succession of admissions and revocations; but although he impudently and with desperate imprecations ''against himselfe denyed all thatt he had formerly confessed,'' witnesses testified in court to his former admissions, and their word was accepted as evidence. The court then ''judged the crime cappitall, and thatt the prisoner and the sow, according to Levit, 20 and 15, should be put to death—.'' And so, on April 8, 1642, ''The sow being first slaine in his sight, he ended his course here. God opening his mouth before his death, to give him the glory of his rightousness, to the full satisfaction of all them present, butt in other respects leaving him a terrible example of divine justice and wrath'' [15,16].

Spencer's case is a cruel example of injustice. Injustices continue to occur, although they may not be as extreme as the case of George Spencer. In a recent time, however, when injustice occurs, it trends to favor the afflicted or the malformed. The following case, which was decided in the 1960s, is a good example of up-to-date injustice. A pregnant woman was involved in an automobile accident and claimed that the accident was responsible for her child's having Down syndrome. In *Sinkler v Kneal*, ''The plaintiffs filed a complaint containing four counts. In the first count plaintiff Nancy D. Sinkler claimed in her own right $100,000 damages for lacerations and contusions and shock to her nervous system which resulted in the birth of a Mongoloid child, Rebecca'' [17]. The majority opinion of the court pertaining to the third count was reported September 26, 1960, several years after the genetic aspects of Down syndrome had been clarified [18–20]. The majority opinion clearly devoted its entire discussion to the question of whether an injured unborn had the right to recover damages in a negligence suit [17,21].

The majority decision did not address the important question whether the malformation and the automobile accident involving a pregnant woman were related. There is no question that the majority decision was accurate

and sound with regard to the biologic concept that the fetus is a separate organism. The court, however, was grossly negligent in taking for granted an etiologic relationship between a pregnant woman's automobile accident and the subsequent birth of a child who had Down syndrome. It is obvious that a turnabout has occurred. The "malformed" offspring and his parents are no longer accused. On the contrary they have become the plaintiffs, seeking recompense and justice for the malformation and the "injured" family, when, in the eyes of a lawyer and his medical consultants, the mother or infant has been treated negligently during the pregnancy.

Along with cancer, psychiatric illness, and hereditary diseases, reproductive problems have been viewed throughout history as diseases of affliction (Fig. 1). Inherent in the reactions of most cultures is that these diseases represent punishments for misdeeds [12–14]. Regardless of the irrationality of this viewpoint, these feelings do exist. Ancient Babylonian writings recount tales of mothers being put to death because they delivered malformed infants. As previously cited, George Spencer was slain by the Puritans in New Haven in the seventeenth century, having been convicted of fathering a cyclopean pig because the Puritans were unable to differentiate between George Spencer's cataract and the malformed pig's cloudy cornea [21]. In modern times, some individuals who have reproductive problems reverse the historical perspective and blame others for the occurrence of their congenital malformations, infertility, abortions, and hereditary diseases [22]. They place the responsibility for their illness on environmental agents dispensed by their health care provider or used by their employer.

Reproductive problems alarm the public, the press, and some scientists to a greater degree than most other diseases. In fact, severely malformed children are disquieting to health care providers, especially those not experienced in dealing with these problems. No physician is comfortable informing a family that their child has been born without arms and legs. The objective evaluation of environmental causes of reproductive diseases is clouded by the emotional climate that surrounds these diseases, resulting

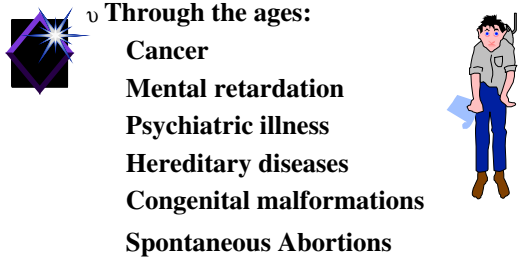

Fig. 1. Through the ages these diseases have been interpreted or considered by multiple cultures to be stigmatizing; punishments for misdeeds or sins. In modern times, environmental factors are thought to cause these diseases. Converting the guilt of the past into anger that is projected on others in our society sometimes leads to litigation.

in the expression of partisan positions that either diminish or magnify the environmental risks. These nonobjective opinions can be expressed by scientists, the laity, or the press [23]. It is the responsibility of every physician to be aware of the emotionally charged situation that is created when a family has a child with a birth defect. The inadvertent comment by a physician, nurse, resident, or student in attendance at the time of the child's delivery can have grave consequences for the physician and the family. Comments such as, "Oh, you had an X-ray during your pregnancy," or "You did not tell me that you were prescribed tetracycline while you were pregnant," can direct the patient's family to an attorney rather than to a teratology or genetic counselor.

How serious is the malpractice situation?

From the perspective of the perinatologist and the obstetrician, the answer is, "Very serious."

There were more than 210,000 closed claims reported to the data-sharing project of the Physician Insurer Association of America during a recent 20-year period [24]. Of the 28 medical specialties, the highest percentage of closed claims in which indemnity payments were made was ascribed to dentists, at 43%, with an average claim payment of $15,000.00. Obstetricians had the second-highest percentage of indemnity payments, at 36%, but the average claim payment was $110,000.00. Pediatricians account for 2.97% of these claims, making pediatrics the tenth among the 28 specialties in terms of the number of closed claims and sixteenth in terms of indemnity payment rate (28.13%). These figures include both settlements and lost lawsuits. The average cost to try a malpractice lawsuit is greater than the average settlement costs. Many nonmeritorious lawsuits are settled because it is cheaper for the insurance company to settle a case than to enter the courtroom and win.

Being a defendant in a malpractice lawsuit is an enervating, anxiety-provoking, time-consuming, and lengthy process. Some of these lawsuits last for years before they reach their conclusion [25]. The burden of the lawsuit can affect collegial relationships and the obstetrician's family life as well as his or her ability to carry out the practice of medicine. In many instances, the defendant feels like he or she is being treated like a criminal. Accusations and badgering in the deposition and even the courtroom can be distressing. It is an experience that every physician would rather avoid.

How does the obstetric community avoid product liability litigation?

The simple answer would be that the obstetrician can avoid product liability litigation by not prescribing drugs that have reproductive risks for the mother or developmental risks for the developing embryo or fetus. Table 2

Table 2
Proven human teratogens or embryotoxins: drugs, chemicals, milieus, and physical agents that have resulted in human congenital malformations

Reproductive toxin	Alleged effects
Aminopterin, methotrexate	Growth retardation, microcephaly, meningomyelocele, mental retardation, hydrocephalus, and cleft palate
Androgens	Masculinization of the developing fetus can occur from androgens and high doses of some male-derived progestins
Angiotensin-converting enzyme inhibitors	Fetal hypotension syndrome in second and third trimester resulting in fetal kidney hypoperfusion and anuria, oligohydramnios, pulmonary hypoplasia, and cranial bone hypoplasia. No effect in the first trimester.
Antidepressants	Recent publications have implicated some of the SSRIs administered in the last trimester with postnatal neurobehavioral effects that are transient and whose long-term effects have not been determined. First-trimester exposures to some SSRIs have been reported to increase the risk of some congenital malformations, predominantly congenital heart disease. The results have not been consistent, but warnings have been issued.
Antituberculous therapy	Isoniazid and paraaminosalicylic acid have an increased risk for some CNS abnormalities.
Caffeine	Moderate caffeine exposure is not associated with birth defects; high exposures are associated with an increased risk of abortion but the data are inconsistent.
Chorionic villous sampling	Vascular disruption malformations (ie, limb-reduction defects)
Cobalt in hematemic multivitamins	Fetal goiter
Cocaine	Vascular disruptive type malformations in very low incidence; pregnancy loss
Corticosteroids	High exposures administered systemically have a low risk for cleft palate in some studies, but the epidemiologic studies are not consistent.

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Table 2 (*continued*)

Reproductive toxin	Alleged effects
Cyclophosphamide and other chemotherapeutic agents and immunosuppressive agents (eg, cyclosporine, leflunomide)	Many chemotherapeutic agents used to treat cancer have a theoretical risk for producing malformations in the fetus when administered to pregnant women, especially because most of these drugs are teratogenic in animals, but the clinical data are not consistent. Many of these drugs have not been shown to be teratogenic, but the numbers of cases in the studies are small. Caution is the byword.
Diethylstilbestrol	Administration during pregnancy produces genital abnormalities, adenosis, and clear cell adenocarcinoma of vagina in adolescents. The last has a risk of 1:1000 to 1:10;000, but the other effects, such as adenosis, can be quite high.
Ethyl alcohol	Fetal alcohol syndrome consists of microcephaly, mental retardation, growth retardation, typical facial dysmorphogenesis, abnormal ears, small palpebral fissures.
Ionizing radiation	Radiation exposure above a threshold of 20 rad (0.2 Gy) can increase the risk for some fetal effects such as microcephaly or growth retardation, but the threshold for mental retardation is higher.
Insulin shock therapy	Insulin shock therapy, when administered to pregnant women, resulted in microcephaly, mental retardation.
Lithium therapy	Chronic usage for the treatment of manic-depressive illness has an increased risk for Ebstein's anomaly and other malformations, but the risk seems to be very low.
Minoxidil	This drug's promotion of hair growth was discovered because administration during pregnancy resulted in hirsutism in newborns.
Methimazole	Aplasia cutis has been reported to be increased in mothers administered this drug during pregnancy[a].
Methylene blue intra-amniotic instillation	Fetal intestinal atresia, hemolytic anemia, and jaundice in neonatal period. This procedure is no longer used to identify one twin.
Misoprostol	A low incidence of vascular disruptive phenomenon, such as limb-reduction defects and Mobius syndrome, has been reported in pregnancies in which this drug was used to induce an abortion.

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Table 2 (*continued*)

Reproductive toxin	Alleged effects
Penicillamine (D-penicillamine)	This drug results in the physical effects referred to as "lathyrism," the results of poisoning by the seeds of the genus *Lathyrus*. It causes collagen disruption, cutis laxa, and hyperflexibility of joints. The condition seems to be reversible, and the risk is low.
Progestin therapy	Very high doses of androgen hormone–derived progestins can produce masculinization. Many drugs with progestational activity do not have masculinizing potential. None of these drugs have the potential for producing nongenital malformations.
Propylthiouracil	This drug and other antithyroid medications administered during pregnancy can result in an infant born with a goiter.
Radioactive isotopes	Tissue- and organ-specific damage depends on the radioisotope element and distribution (ie, high doses of Iodine-131 administered to a pregnant woman can cause fetal thyroid hypoplasia after the eighth week of development).
Retinoids	Systemic retinoic acid, isotretinoin, and etretinate can cause increased risk of CNS, cardioaortic, ear, and clefting defects such as mMicrotia, anotia, thymic aplasia, other branchial arch and aortic arch abnormalities, and certain congenital heart malformations.
Retinoids, topical	Topical administration is very unlikely to have teratogenic potential, because teratogenic serum levels cannot be attained by topical exposure to retinoids.
Streptomycin	Streptomycin and a group of ototoxic drugs can affect the eighth nerve and interfere with hearing; it is a relatively low-risk phenomenon. Children are less sensitive than adults to the ototoxic effects of these drugs.
Sulfa drugs and vitamin K	These drugs can produce hemolysis in some subpopulations of fetuses.
Tetracycline	This drug produces bone and teeth staining, it does not increase the risk of any other malformations.

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Table 2 (*continued*)

Reproductive toxin	Alleged effects
Thalidomide	This drug results in an increased incidence of deafness, anotia, preaxial limb-reduction defects, phocomelia, ventricular septal defects, and gastrointestinal atresias. The susceptible period is from the twenty-second to the thirty-sixth day after conception.
Trimethorpin	This drug was used frequently to treat urinary tract infections and has been linked to an increased incidence of neural tube defects. The risk is not high, but it is biologically plausible because of the drug's effect on lowering folic acid levels, which has resulted in neurologic symptoms in adults taking this drug.
Vitamin A	The malformations reported with the retinoids have been reported with very high doses of vitamin A (retinol). Dosages to produce birth defects would have to be in excess of 25,000 to 50,000 units/d.
Vitamin D[a]	Large doses given in vitamin D prophylaxis may be involved in the etiology of supravalvular aortic stenosis, elfin faces, and mental retardation.
Warfarin and warfarin derivatives	Early exposure during pregnancy can result in nasal hypoplasia, stippling of secondary epiphysis, intrauterine growth retardation. Central nervous system malformations can occur in late pregnancy exposure because of bleeding.
Anticonvulsants	
Diphenylhydantoin	Treatment of convulsive disorders increases the risk of the fetal hydantoin syndrome, consisting of facial dysmorphology, cleft palate, ventricular septal defect, and growth and mental retardation.
Trimethadione and paramethadione	Treatment of convulsive disorders with these drugs increases the risk of characteristic facial dysmorphology, mental retardation, V-shaped eyebrows, low-set ears with anteriorly folded helix, high-arched palate, irregular teeth, CNS anomalies, and severe developmental delay.
Valproic acid	Treatment of convulsive disorders with this drug increases the risk of spina bifida, facial dysmorphology, and autism.
Carbamazepine	Treatment of convulsive disorders with this drug increases the risk facial dysmorphology.

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Table 2 (*continued*)

Reproductive toxin	Alleged effects
Chemicals	
Carbon monoxide poisoning	Central nervous system damage has been reported with very high exposures, but the risk seems to be low[a].
Lead	Very high exposures can cause pregnancy loss; intrauterine teratogenesis is not established at very low exposures below 20 μg/% in the serum of pregnant mothers.
Gasoline addiction embryopathy	Facial dysmorphology, mental retardation
Methyl mercury	Minamata disease consists of cerebral palsy, microcephaly, mental retardation, blindness, and cerebellum hypoplasia. Other epidemics have occurred from adulteration of wheat with mercury-containing chemicals that are used to prevent grain spoilage. Present environmental levels of mercury are unlikely to represent a teratogenic risk, but reducing or limiting the consumption of carnivorous fish has been suggested to avoid exceeding the maximum permissible exposure recommended by the Environmental Protection Agency, an exposure level far below the level at which the toxic effects of mercury are seen
Polychlorinated biphenyls	Poisoning has occurred from adulteration of food products (" Cola-colored babies," CNS effects, pigmentation of gums, nails, teeth, and groin; hypoplastic deformed nails; intrauterine growth retardation; abnormal skull calcification). The threshold exposure has not been determined, but it is unlikely to be teratogenic at the present environmental exposures.
Toluene addiction embryopathy	Facial dysmorphology, mental retardation
Embryonic and fetal infections	
Cytomegalovirus infection	Retinopathy, CNS calcification, microcephaly, mental retardation
Rubella	Deafness, congenital heart disease, microcephaly, cataracts, mental retardation
Herpes simplex	Fetal infection, liver disease, death
HIV	Perinatal HIV infection
Parvovirus infection, B19	Stillbirth, hydrops
Syphilis	Maculopapular rash, hepatosplenomegaly, deformed nails, osteochondritis at joints of extremities, congenital neurosyphilis, abnormal epiphyses, chorioretinitis
Toxoplasmosis	Hydrocephaly, microphthalmia, chorioretinitis, mental retardation

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Table 2 (*continued*)

Reproductive toxin	Alleged effects
Varicella zoster	Skin and muscle defects; intrauterine growth retardation; limb reduction defects, CNS damage (very low increased risk)
Venezuelan equine encephalitis	Hydranencephaly; microphthalmia; destructive CNS lesions; luxation of hip
Maternal disease states	
Corticosteroid-secreting endocrinopathy	Mothers who have Cushing's disease can have infants with hyperadrenocortism, but anatomic malformations do not seem to be increased.
Iodine deficiency	Can result in embryonic goiter and mental retardation
Intrauterine problems of constraint and vascular disruption	These defects are more common in multiple-birth pregnancies, pregnancies with anatomic defects of the uterus, placental emboli, or amniotic bands. Possible birth defects include club feet, limb-reduction defects, aplasia cutis, cranial asymmetry, external ear malformations, midline closure defects, cleft palate and muscle aplasia, cleft lip, omphalocele, and encephalocele)
Maternal androgen endocrinopathy (adrenal tumors)	Masculinization
Maternal diabetes	Caudal and femoral hypoplasia, transposition of great vessels, and other malformations
Maternal folic acid in reduced amounts	An increased incidence of neural tube defects
Maternal phenylketonuria	Abortion, microcephaly, and mental retardation; very high risk in untreated patients
Maternal starvation	Intrauterine growth restriction, abortion, neural tube defects (Dutch famine experience)
Tobacco smoking	Abortion, intrauterine growth restriction, stillbirth
Zinc deficiency[a]	Neural tube defects[a]

Abbreviation: CNS, central nervous system.
[a] Controversial.

describes the known agents that increase reproductive and developmental risks [9–11,26]. Unfortunately, the situation is not so straightforward. In many lawsuits alleging that congenital malformations were the result of a drug exposure, the allegation was incorrect (Box 1).

Progestational drugs

The largest number of product liability congenital malformation lawsuits that involved the obstetric community erroneously alleged that progestational

Box 1. Agents erroneously alleged to have caused human malformations

Bendectin: Alleged to cause numerous types of birth defects including limb-reduction defects, heart malformations, and many other malformations
Diagnostic ultrasonography: No significant hyperthermia, therefore no reproductive effects
Electromagnetic fields: Alleged to cause abortion, cancer, and birth defects
Progestational drugs: Alleged to cause numerous types of nongenital birth defects, including limb-reduction defects, heart malformations, and many other malformations

drugs were responsible for the occurrence of congenital malformations. Frequently, obstetricians were the physician defendants in these cases. Numerous lawsuits were filed or went to trial involving the progestational drugs, alleging that they were responsible for the occurrence of congenital heart disease or limb-reduction defects. In 1977 the Food and Drug Administration (FDA) placed a black box warning in the label of progestational drugs indicating that these drugs were associated with the occurrence of congenital heart disease and limb-reduction defects [27]. The warning was placed because several publications reported an association of progestational drugs and limb-reduction defects, congenital heart disease, and a few other malformations [28–37]. In 1999, 22 years after the black box warning, the FDA removed the warning [38,39].

Many of the lawsuits were decided in favor of the plaintiffs, although the majority of the lawsuits was decided in favor of the defendants. Irresponsible experts were one of the key contributors the plaintiffs' success in some of these lawsuits [23]. Obstetricians had to sit through lengthy trials, away from their family and practice, to defend themselves against an allegation that was totally erroneous. In 1977 extensive literature indicated that it was most unlikely that progestational drugs could produce nongenital malformations. In 1981 Wilson and Brent [40] published an extensive review and analysis of the allegation that progestational drugs could produce nongenital malformations and concluded that the allegation was incorrect. Other publications were in agreement [41,42], but 22 years elapsed before the warning was removed [27,39].

Bendectin

Another drug, Bendectin, was prescribed commonly by obstetricians for the treatment of nausea and vomiting of pregnancy. Thousands of lawsuits

alleged that Bendectin was a teratogen, although Bendectin was the only drug approved by the FDA for the treatment of nausea and vomiting of pregnancy. During the 1970s, when Bendectin was used most frequently, it was prescribed to 30% of pregnant women. There are approximately 4,000,000 births each year in the United States, and the background incidence of major birth defects is 3% (Table 3). Therefore expected background incidence of birth defects would be 120,000; 36,000 newborns who had congenital anomalies would have been exposed to Bendectin each year. This prevalence was a bonanza for some plaintiff attorneys, because a jury might interpret these numbers as representing an epidemic of birth defects. The 36,000 birth defects, however, is exactly the expected background incidence of birth defects in the Bendectin-exposed group. This medication was studied extensively, and the allegation had no merit [43–53]. After 20 years of litigation, not a single Bendectin lawsuit was decided on behalf of the plaintiffs [49,50,53]. The medication was removed from the market in 1982, however, because the cost of litigation and negligence insurance was greater than the gross sales of the medication. The frequency of hospital admissions for nausea and vomiting of pregnancy doubled because Bendectin was not available, and physicians were reluctant to prescribe any medication for fear of litigation [51–53]. The numerous negative aspects of the Bendectin saga included (1) the loss of an approved medication for the treatment of nausea and vomiting of pregnancy, (2) the reluctance of many obstetricians to use any medication to treat nausea and vomiting of pregnancy, (3) the increase in hospital admissions for the treatment of nausea and vomiting of pregnancy [52], and (4) the waste of time and expenses to the courts of litigating nonmeritorious lawsuits.

Table 3
Frequency of reproductive risks in the human

Reproductive risk	Frequency
Immunologically and clinically diagnosed spontaneous abortions per 10^6 conceptions	350,000
Clinically recognized spontaneous abortions per 10^6 pregnancies	150,000
Genetic diseases per 10^6 births	110,000
Multifactorial or polygenic (genetic–environmental interactions)	90,000
Dominantly inherited disease	10,000
Autosomal and sex-linked genetic disease	1200
Cytogenetic (chromosomal abnormalities)	5000
New mutations	3000
Major congenital malformations per 10^6 births	30,000
Prematurity per 10^6 births	40,000
Fetal growth retardation per 10^6 births	30,000
Stillbirths/10^6 pregnancies (>20 weeks)	2000–20,900
Infertility	7% of couples

This plethora of litigation did have one major beneficial outcome, however. The Supreme Court rendered the famous Daubert decision as part of the litigation activities. It permitted jurists to disqualify the testimony of expert witnesses who used methodologic procedures that are not accepted and approved by the scientific community to reach their opinion [48]. The courts rejected the testimony of several of the plaintiffs' experts involved in the Daubert decision. This small group of irresponsible medical and scientific experts contributed negatively to the welfare of the obstetric patients in the United States [23,49,54].

This review of the progestational drug and Bendectin litigation is a reminder that lawsuits on behalf of a child who has congenital malformations can be instituted regardless of whether the allegation has scientific or medical merit. There are, however, drugs that can harm the developing embryo if administered at a sensitive period of embryonic development and at exposures high enough to affect the developing embryo or fetus deleteriously. This extensive list of potential embryo toxic agents is listed in Table 2. Box 1 lists some of the agents that have been involved in litigation that have not been demonstrated to affect the embryo deleteriously at their acceptable exposure.

These tables are simply lists that can be misused if one does not pay attention to the importance of timing and dose. For example, thalidomide is a known and proven teratogen, but if 1 mg were administered during the sensitive period of development, rather than the usual dose of 50 mg or greater, there would be no effect on the exposed embryo. Likewise, 50 mg of thalidomide administered during the sixth month of gestation never would result in the malformations observed in the typical thalidomide syndrome, because the sensitive period is so limited (Table 4).

Table 4
Developmental stage sensitivity to thalidomide-induced limb-reduction defects in the human

Days from conception for induction of defects	Limb-reduction defects
21–26	Thumb aplasia
22–23	Microtia, deafness
23–34	Hip dislocation
24–29	Amelia, upper limbs
24–33	Phocomelia, upper limbs
25–31	Preaxial aplasia, upper limbs
27–31	Amelia, lower limbs
28–33	Preaxial aplasia, lower limbs; phocomelia, lower limbs; femoral hypoplasia; girdle hypoplasia
33–36	Triphalangeal thumb

Data from Brent RL, Holmes LB. Clinical and basic science lessons from the thalidomide tragedy: what have we learned about the causes of limb defects? Teratology 1988; 38:244.

Anticonvulsants

Another example pertains to the administration of anticonvulsants to pregnant women because of the frequency with which anticonvulsants are administered. Diphenylhydantoin, when administered throughout pregnancy, increases the risk of congenital malformations that include facial dysmorphogenesis, microcephaly, decreased cognition, digital hypoplasia, and ventricular septal defects [55]. These malformations do not occur frequently, and the physician administering the drugs often is faced with a dilemma as to whether to continue the medication, reduce the medication, or discontinue use of the anticonvulsant during pregnancy. If, for example, a pregnant woman is in an automobile accident and sustains a head injury, the consulting neurosurgeon might prescribe one dose of 200 mg of phenytoin. It is unlikely that this single dose will result in the phenytoin embryopathy. This future mother, however, has a 3% risk of delivering a baby with congenital malformations. One can imagine how an irresponsible expert might testify if this mother delivers a child who has congenital malformations.

It is impossible to discuss each of the drugs in Table 2 and describe the circumstances when the embryo is or is not at risk. Publications dealing with the subject of teratogenic drugs, chemicals, and physical agents and the genetic causes of congenital malformations can be useful to clinicians for evaluating the risks of environmental toxicants [9–11,26,56–62].

Principles of counseling obstetric or perinatology patients about the risks of pregnancy and the therapy that may be necessary for the patient's care

Predicting the developmental risks of a pregnancy

Patients frequently ask obstetricians or perinatologists whether a particular preconception or postconception environmental exposure represented a risk for their developing embryo or fetus. For example, a pregnant patient might ask whether the chest radiograph that occurred early in her pregnancy could result in a newborn who had birth defects. The most appropriate answer would be:

> A chest radiograph does not expose the embryo to a harmful dose of radiation. The radiation exposure is so low that even the same exposure to your uterus would not increase your risk for having a child with birth defects. You must realize, however, that even if you have no personal or family history of reproductive or developmental problems, you began your pregnancy with a 3% risk for birth defects and a 15% risk for miscarriage.

This information should be communicated verbally and also be noted in the patient's medical chart. The obstetrician and perinatologist must be careful not to provide verbal guarantees concerning the outcome of the pregnancy (eg, ''You have nothing to worry about''; ''The baby will be fine.''). In an effort to quell the patient's anxiety, the physicians may provide

misinformation, because physicians cannot prevent the background incidence of developmental problems.

Understanding the principles of teratology to determine developmental risks

Five principles of teratology are useful for evaluating reproductive and developmental risks. These principles can assist clinicians in evaluating risks and in determining the significance of developmental effects in newborns and children that they have delivered [9–11,26]. When evaluating studies dealing with the reproductive effects of any environmental agent, important principles should guide the analysis of human and animal reproductive studies. Paramount to this evaluation is the application of the basic science principles of teratology and developmental biology [9–11,63]. These principles are as follows:

1. Exposure to teratogens follows a toxicologic dose–response curve. There is a threshold below which no teratogenic effect will be observed; as the dose of the teratogen is increased, both the severity and frequency of reproductive effects increase (Table 5).
2. The embryonic stage of exposure is critical in determining what deleterious effects will be produced and whether any of these effects can be produced by a known teratogen. Some teratogenic effects have a broad and others have a very narrow period of sensitivity. The most sensitive

Table 5
Stochastic and threshold dose-response relationships of diseases produced by environmental agents

Relationship	Pathology	Site	Diseases	Risk	Effect
Stochastic phenomena	Damage to a single cell may result in disease	DNA	Cancer mutation	Some risk exists at all dosages; at low exposures the hypothetical risk is below the spontaneous risk.	The incidence of the disease increases with the dose, but the severity and nature of the disease remain the same.
Threshold phenomena	Multi-cellular injury	High variation in etiology, affecting many cells and organ processes	Malformation, growth retardation, death, chemical toxicity, and others	No increased risk below the threshold dose	Both the severity and incidence of the disease increase with dose.

Data from Brent RL. The irresponsible expert witness: a failure of biomedical graduate education and professional accountability. Pediatrics 1982;70:754–62.

stage for the induction of mental retardation from ionizing radiation is from the eighth to the fifteenth week of pregnancy, a lengthy period. Thalidomide's period of sensitivity is approximately 2 weeks (see Table 4) [64].
3. Even the most potent teratogenic agent cannot produce every malformation.
4. Most teratogens have a limited group of congenital malformations that result after exposure during a critical period of embryonic development. This limited group of malformations is referred to as the syndrome that describes the agent's teratogenic effects.
5. Although a group of malformations may suggest the possibility of certain teratogens, they cannot confirm the causal agent definitively, because some teratogenic syndromes mimic genetic syndromes. On the other hand, the presence of certain malformations can eliminate the possibility that a particular teratogenic agent was responsible because those malformations have not been demonstrated to be part of the syndrome or because the production of that malformation is not biologically plausible for the particular alleged teratogen.

Determining whether an environmental agent has developmental or reproductive effects at the exposure to which the population is exposed

Evidence supporting or refuting the allegation that an environmental agent has reproductive or developmental effects at the typical human exposures comes from several areas of investigation [40,49,65]:

1. Consistency. Consistent findings in a number of epidemiologic studies in which statistical associations for a spectrum or group of developmental effects or specific reproductive effects are found in several studies
2. Secular trend analysis. Secular trend analysis can be used when a large percentage of the population has been exposed as with the progestational drugs or Bendectin. Changes in exposure caused by a reduction or cessation of prescribing may or may not alter the incidence of developmental or reproductive effects.
3. Animal reproductive studies. These studies are very useful in determining whether findings in epidemiologic studies can be confirmed in animal reproductive or developmental studies. Every environmental agent that has been confirmed to be a human teratogen or reproductive toxin has been found to be teratogenic in an animal model. When this confirmation cannot be accomplished, reproductive and developmental scientists are somewhat concerned about the validity of the causal relationship in the epidemiologic studies.
4. Dose–response relationships and pharmacokinetic studies comparing human and animal metabolism. One important aspect of modern preclinical testing protocols is that serum and/or tissue levels of the drug or chemical are determined in both the animal model and in humans. If reproductive and developmental effects occur in the animal model

at serum or tissue levels that occur in humans, there should be concern about the safety of the drug or chemical.

5. Biologic plausibility. This concept is important, because in some instances scientific considerations can support or refute an allegation of the reproductive or developmental toxicity. For example, the original epidemiology studies involving progestational drugs reported that epidemiologic studies showed an increased incidence of congenital heart disease but no increase in the incidence of limb-reduction defects. In other studies there was an increased incidence of limb-reduction defects but no increase in the incidence of congenital heart disease. Those findings, in themselves, should have refuted the allegation. Second, progestational drugs function by attaching to sex steroid receptors. Early in embryonic development there are no sex steroid receptors in the developing heart and limb buds. Biologic plausibility involves consideration of
   a. Mechanisms
   b. Receptor studies
   c. Nature of the malformations
   d. Mechanism of action
   d. Teratology principles

It should be apparent that determining the reproductive risks of an exposure during pregnancy or the origin of a child's congenital malformations is not a simple process. It involves a careful analysis of the medical and scientific literature pertaining to the reproductive toxic effects of exogenous agents in humans and animals as well as an evaluation of the exposure and biologic plausibility of an increased risk or a causal connection between the exposure and a child's congenital malformation. It also involves a review of the scientific literature pertaining to genetic and environmental causes of the malformations in question. An abridged or superficial evaluation based on incomplete analyses is not acceptable.

What circumstances stimulate negligence lawsuits?

Certain circumstances seem to stimulate negligence lawsuits in cases of birth defects [1,23,25,51,66]:

1. A plaintiff who generates sympathy, a defense expert who frequently is unable to be certain of the cause of the child's birth defect, and a plaintiff expert who is certain
2. Neurobehavioral effects, mental retardation, cerebral palsy
3. Miscarriage
3. A high proportion of exposures in the population at risk
4. A scientific topic that has attracted junk scientists as experts
5. Jurisdictions or geographic areas that are known to favor plaintiff verdicts
6. A litigation subject that has become attractive to number of law firms

7. A new area (drug) for which little data are available and therefore hypotheses without data can be generated
8. Vaccinations given during pregnancy

Clinical situations in which the obstetrician or perinatologist is the primary provider and the therapy and/or diagnostic tests may represent potential or hypothetical reproductive and developmental risks

It is impossible to discuss all the medications and pre- and postconception therapies that obstetricians might use to care for their patients. The following is a short list of categories of therapy for which patients have filed lawsuits alleging that the obstetrician's or perinatologist's treatment resulted in harm to the fetus:

1. Nausea and vomiting of pregnancy
2. Treatment of hypertension
3. Treatment of psychiatric problems (depression, anxiety)
4. Exposure to various forms of "radiation"
5. Medications and therapy to manage premature labor
6. Treatment of infections
7. Immunizations
8. Diagnostic radiologic studies
9. Diagnostic ultrasonography

Treating nausea and vomiting of pregnancy

In the 1960s there was an increase in the number of lawsuits involving malformed children and their families as plaintiffs [1]. Many of the lawsuits involved an antinausea medication, such as meclizine. The first meclizine lawsuit with which I was acquainted occurred in the late 1960s and involved a child who had ectrodactyly, ectodermal dysplasia, and cleft palate—EEC syndrome, which is a genetic disease. Scientists from a prestigious university and the from National Institutes of Health testified that meclizine caused this child's defect; of course, the defect, in fact, was present at the time of conception, before there was any exposure to the medication.

Bendectin containing doxylamine succinate, dicyclomine, and pyridoxine was listed as appropriate for the treatment of nausea and vomiting of pregnancy. The FDA approved labeling for Bendectin as the only drug formerly recommended for the treatment of nausea and vomiting in pregnant women.

Benefits of effective treatment

It is obvious that clinical, psychologic, and social benefits result from any effective therapy that reduces the symptoms of nausea and vomiting in pregnant women. The benefits include

1. Symptomatic improvement and comfort
2. Preventing the progression of symptoms to necessitate hospitalization

3. Optimal nutrition for mother and fetus
4. Decreased risk of some pregnancy complications
5. Psychologic benefits
6. Decrease absenteeism for working mothers
7. Decreased difficulty in managing the home and family

Medical risks of therapeutic intervention

The medical risks of any therapy have two implications. The first is that the therapy may be unacceptable to the patient or may represent a medical risk that is unacceptable to the physician and the patient. In other circumstances the theoretic risk of a new therapy could be more significant than the benefit of relieving the nausea and vomiting. Some of these risks, if they occur, could lead to litigation. The most serious medicolegal risk is the occurrence of embryonic and fetal malformations.

Legal risks of therapeutic intervention

Because many of the therapies for nausea and vomiting of pregnancy are relatively new, there are minimal data on which to base an evaluation of the risk of reproductive effects. Unfortunately, attorneys can be creative in generating hypotheses and obtaining witnesses who are willing to support hypotheses that implicate the therapy as having teratogenic potential [23,25]. Even when therapies such as acupressure, hypnosis, psychotherapy, or psychologic conditioning seem to be very unlikely to harm the fetus, that unlikelihood does not prevent a lawsuit from being initiated if a severely malformed fetus results from a pregnancy. Therefore, the best protection for the patient, the physician, the manufacturer of a drug, or the developer of a therapeutic technique is to have abundant data that indicate that the therapy has no measurable harmful effects on the developing embryo or fetus or on pregnant women. Unfortunately, only one therapy that fits these criteria, and that is Bendectin (10 mg each of doxylamine succinate and pyridoxine). Twelve cohort studies and numerous case-control studies, involving more than 13,000 patients, indicate that Bendectin does not represent a measurable risk to the developing mother or fetus. Furthermore, the animal studies and in vitro studies support this conclusion [49,50,53]. No other treatment of nausea and vomiting during pregnancy has the demonstrated low-risk record of Bendectin. Unfortunately, this medication is no longer sold in the United States, but it is sold in Canada under a proprietary name [67]. It has the same constituents as Bendectin (10 mg of pyridoxine and 10 mg of doxylamine succinate).

In 1999 the FDA published a statement in the Federal Register that summarizes the FDA's opinion on the lack of teratogenicity of Bendectin [68]. In summary:

> The Food and Drug Administration has determined that the drug product Bendectin, a tablet composed of pyridoxine hydrochloride, 10 mg, and doxylamine succinate, 10 mg, for the prevention of nausea during pregnancy,

was not withdrawn from sale for reasons of safety or effectiveness. This determination will permit FDA to approve abbreviated new drug applications for the combination product pyridoxine hydrochloride, 10 mg, and doxylamine succinate, 10 mg, tablets.

Treatment of hypertension during pregnancy

Toxemia of pregnancy, renal hypertension, lupus hypertension, idiopathic "essential" hypertension, and other causes of hypertension represent serious medical problems during pregnancy. Fortunately, there are numerous excellent medications to treat high blood pressure. Two classes of medications, however, have serious, deleterious effects on fetal development [69–72]. Fetal exposure during the second and third trimester to angiotensin-converting enzyme inhibitors or the angiotensin II receptor blockers may produce severe fetal hypotension, oligohydramnios, pulmonary hypoplasia, fetal and neonatal renal failure, and decreased calcification of the skull. If the fetus survives, death can occur postnatally from renal or pulmonary failure. Some children survive after renal transplantation. Animal studies support the clinical impression that the second and third trimester are the vulnerable period when the drugs do their damage and that exposure during early organogenesis does not seem to have any detrimental effect from. A recent article by Cooper and colleagues [73] indicates that there is an increased risk of congenital malformations with first trimester exposures, but the animal studies and other epidemiologic studies do not support these findings.

Treatment of psychiatric problems (depression, anxiety) during pregnancy

Many drugs that are used for the treatment of psychiatric disorders demonstrate transient behavioral effects in newborns whose mothers received these medications before delivery of the infant. Transient irritability, jitteriness, and depression may be manifested, depending on the primary effects of the medication. Very few of these drugs have been reported to be associated with reproductive or developmental effects, although some of the anticonvulsants that have psychopharmacologic therapeutic effects (eg, diphenylhydantoin, valproic acid, carbamazepine, phenobarbital) have been associated with an increased risk of birth defects (see Table 2).

Recently the selective serotonin receptor reductase inhibitors (SSRIs) have been studied for first-trimester teratogenic effects, and paroxetine was reported to be associated with an increased risk of congenital heart disease [74,75]. These findings have not been consistent, however, because there are studies that do not confirm these findings [76,77]. The few animal studies that have been reported do not find teratogenic effects [78]. The increased teratogenic risks following first-trimester exposure to SSRIs has yet to be

resolved, although the FDA and the companies involved have issued warnings about the potential teratogenicity of SSRIs.

Radiation exposures

The public and some health care providers have concerns about new diagnostic radiation modalities using radiographs and radionuclides. Some physicians and many patients assume that these new procedures involve much higher exposures and much higher risks. It is important that all the new procedures and their embryonic risks be placed in proper perspective. These procedures include

CT scans and positron emission tomograph scans
MRI studies (Many patients believe that X-rays are involved in these studies, which is not true. The electromagnetic fields used in MRI studies are non-ionizing forms of radiation.)
Diagnostic scans using radionuclides for studying the location of a pulmonary embolus, the presence of gallbladder disease, cardiac perfusion, cardiac stress test, areas of bone inflammation or injury, thyroid function, liver function, renal perfusion, lung perfusion, and other conditions

There are misconceptions concerning the reproductive and developmental risks of low exposures of ionizing radiation from occupational exposures and airplane travel, especially the magnitude of the risk from solar flares. Health care providers who work in medical or research fields have exaggerated concerns about the reproductive or developmental risks of their on-the-job exposures. Among the most common concerns are those of dental technicians who perform the dental radiographic examinations in a dentist's office and nurses and operating room assistants who are in proximity to fluoroscopes or brachytherapy procedures in the operating room.

Pregnant patients receiving radiation therapy for the treatment of cancer or other serious diseases are in a special category. If the fetus is in the therapeutic beam, it is likely that the treatment will be harmful to the developing embryo. The developmental risks also can be increased in pregnant women receiving therapeutic doses of radionuclides.

Concern about the risk of infertility or genetic disease in their children from preconception radiation exposure of the ovaries or testicles has been increasing among patients contacting the Health Physics Ask the Expert Website.

The public and some health care providers have old and new concerns about the risks of harm to the embryo from non-ionizing "radiation" because of misconceptions about the risks that can be ascribed to the many forms of non-ionizing radiation. Although addressing these issues may seem unnecessary, these exposures can generate as much concern and anxiety as the exposures to ionizing radiation that do represent a real risk to the embryo. These concerns have been communicated frequently to the Health Physics Society Website, Ask The Expert [66,79–82]. Matters of concern include

Diagnostic ultrasound procedures that expose the embryo or expose other parts of the body of a pregnant woman
Exposure to electromagnetic fields from power lines, house appliances, electric commuter trains
Exposure to or proximity to microwave communication antennae for fire departments, police departments, ambulance services, or cellular telephone communications
Exposure to personal cellular telephones (birth defects in their embryo and cancer in themselves)
Visiting a tanning salon while pregnant
Laser hair removal from the abdomen or thigh of pregnant patients
Use of an ultrasound sonicator for preparing tissue or cleaning jewelry
Use of a hair dryer, computer, cellular telephone, or microwave oven
Working in an office or other site in proximity to a microwave dish
Walking through a metal detector scanner at any security monitoring site
The possibility that a suitcase and its contents will become radioactive after passing through an airport X-ray scanner
Exposure to ultraviolet light for treating certain skin disease
Exposure to intense light and dermatologic chemicals for the treatment of acne
Eating food that has been sterilized by exposure to ionizing radiation

Other concerns of pregnant women in regard to radiation exposure include inadvertently being in a room when a radiograph was taken and being near a patient who has received external radiation therapy or who has been given a radionuclide for diagnostic or therapeutic purposes.

One must realize that families have grave concerns about having a child who has a birth defect, having a miscarriage, or having a child who has neurologic problems, mental retardation, or cancer following ''radiation'' exposures. Counselors must address these fears, even though many of them have no scientific basis. Discussion of all these matters in a compassionate and erudite manner can be of great benefit to concerned parents [66,81,82].

Clinical situations when a consultant is the primary prescriber of medications or therapies for diseases for which the obstetrician or perinatologist is not an expert

A proportion of obstetric and perinatology patients have medical problems that require special skills and training. Many of these special patients require medical care beyond the prenatal care and delivery services of an obstetrician or perinatologist. Many of these patients may need special medications, and it is important to review these medications with the medical consultant to make certain that the patient has been informed of any reproductive or developmental risks associated with these medications and whether alternative medications can be selected that do not reproductive

or developmental risks. The patient's medical record should note the interaction with the consultant concerning the medications and that the information has been shared with the patient. Some perinatologists have been trained to care for diabetic pregnant patients or patients who have other complicated medical problems. It is advantageous for the perinatologist who is caring for pregnant patients who have complicated medical diseases to require that the patient's medical care be provided by the medical consultant. Diseases that necessitate the use of medications that may have reproductive or developmental risks include diabetes, malignancies, autoimmune disease, some infections, asthma or hyperactive airway disease, and any form of pulmonary or cardiac decompensation.

The perinatologist or obstetrician may not be an expert in many of these complicated medical diseases but can be very helpful to the medical consultant in selecting medications that are necessary for the patient that have either no increased risk or the least increased risk for reproductive or developmental problems.

How should a physician in respond to a citation that he or she is being sued for malpractice?

I have been a defense expert for many obstetricians, and on one occasion I was a plaintiff expert in an egregious case of malpractice that was settled before the trial began. I have the following suggestions for the defendants:

1. Immediately notify your insurance carrier, the hospital (if it is a hospital case), your partners, and appropriate members of your family.
2. Recognize that any competent attorney can study the medical aspects of the case and know more than you do at the time of the depositions and trial. Therefore, the three most important aspects of being a defendant are "preparation, preparation, and preparation."
3. Make certain that you have an excellent attorney and law firm. You have the right to request new counsel if you detect delays and incompetence.
4. Make certain that you have the best expert witnesses with absolutely no academic or ethical skeletons in their closet.
5. **Do not:**
   A. Go to the record room on the day you receive your citation and sign out the chart. You can look at your office records, but stay away from the record room until you have competent legal representation who will obtain the records in a proper manner.
   B. Call the plaintiff's attorney, even if you are friends or belong to the same organization or club.
   C. Call the plaintiff. Inform the patient that you are transferring her records to another physician. Your lawyer should supervise this correspondence.

D. Contact other defendants or potential defendants in the case without advice from your attorney. If contact is made, your attorney should be present.

6. Be prepared for a lengthy process that is enervating, exhausting, and possibly anxiety-provoking. You will need the support of family, partners, attorney, and noninvolved colleagues.

What measures can scientists and physicians initiate to diminish the litigation epidemic?

Bendectin litigation is the prototype of nonmeritorious litigation, and the issues involved explain in part the epidemic of litigation brought before juries in this country. A lawsuit is filed because it may be won, regardless of whether it has merit [1,25,66,82]. A few changes could reduce the negligence litigation crisis and the excessive amount of nonmeritorious litigation in the United States.

The first suggestion is to eliminate the contingency-fee system for attorney compensation, a system that is practically nonexistent in the rest of the world. It is unlikely that this suggestion is going to be adopted for a long time in the United States, because the members of the law profession dominate the state and federal legislatures and have an undue influence on a significant proportion of the legislators [1,25].

The second suggestion is to put a cap on the size of the awards, especially on punitive damages. This suggestion has reduced litigation in some venues, but it will not solve the crisis.

The third suggestion is to eliminate the use of plaintiff and defense expert witnesses and rely on expert scientific panels that are "friends of the court." I discussed this matter many years ago [1]. I found out, however, that many of the plaintiff and defense attorneys want to use experts whom they select. Attorneys do not want a panel of court-assigned experts.

The fourth and most important suggestion is to have the loser pay the court costs. This measure would reduce dramatically the number of nonmeritorious lawsuits. It would discourage plaintiffs from filing nonmeritorious lawsuits and would encourage insurance companies to defend their clients rather than settle the nonmeritorious lawsuits, which is one of the large item costs in handling malpractice lawsuits. Assessing the court costs to the loser would change in the number of negligence lawsuits radically.

As physicians and scientists, we must recognize that the only area of litigation over which science and medicine can have legitimate control is in the performance of expert witnesses. Most nonmeritorious cases would not proceed if the attorneys could not find a physician or scientist who is willing to say that a nonmeritorious case has merit. Therefore, although we may be displeased with some attorneys and may blame them for the epidemic of litigation, the fact is that unscrupulous scientists and physicians have an important role in promoting nonmeritorious actions. Because we are not able to modernize

the legal system, our best initiative is to alter drastically the activities of the irresponsible expert by raising the quality of expert-witness testimony [23,54,66,82]. We must strengthen the guidelines of universities and professional organizations in the United States to train and encourage scientists and physicians to perform as scholars and to monitor their contributions to the courts. If they do not provide competent and scholarly testimony, they should be criticized or expelled by their universities or their professional scientific and medical organizations.

Summary

Although some aspects of this discussion may seem to be critical of the legal profession, it is important to place this criticism into perspective. Physicians, as a group, tend to be hypercritical of the legal profession because of the escalation of malpractice litigation and malpractice insurance premiums. Recommendations from the medical community to modify the law to reduce the frequency of nonmeritorious litigation and the size of the awards have been minimally successful, primarily because lawyers dominate the legislatures. Furthermore, many attempts by physicians to change the law are naive. My suggestions in the past have urged the medical community to focus their attention on junk scientists and their junk science, because they are problems that emanate from the medical community, over which physicians should have some authority [1,23,25].

More importantly, we should respect the importance and accomplishments of the legal profession and admire its accomplishments, because it is the foundation of any thriving democracy. Without the law, we could never have rid ourselves of a sitting president or protect all rights bestowed on individuals in our Constitution. A very small percentage of attorneys exploiting the power of the law to their own advantage does not mean that the legal system must be replaced or eliminated. It is to everyone's advantage to have a functioning legal system with its benefits and risks. Remember that many nonmeritorious lawsuits could not proceed without the testimony of a junk scientist who appears before a judge and testifies that the case has merit. Many of these junk scientists are obstetricians and pediatricians as well as other members of the clinical and scientific community [49–51].

Will the situation improve? I cannot predict the future of malpractice litigation, but we are not doing our job by allowing irresponsible expert witnesses to participate in matters of litigation without being censured by their university or professional organizations [47,49–51].

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