



“No-fault” insurance that covers a pregnancy and birth

➤ The author envisions one-child-at-a-time policies that will blunt the OB malpractice crisis. Could it work?

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The practice of obstetrics is in crisis because of the ever-rising cost of malpractice insurance. Premiums have become so burdensome in many states that they discourage physicians from providing OB care.

And matters grow worse: Many insurance companies are discontinuing liability coverage altogether. With providers unable to afford or obtain insurance, we seem doomed to see a repeat of the loss of OB services that led to harm to patients in the past.^{1,2}

But if we can discern a crisis at hand, isn’t it reasonable to act to develop a solution that prevents, or solves, the problem? In the past, we waited until the system collapsed—to the detriment of patients, their infants, and physicians. In earlier crises in some states, good solutions ultimately allowed for the return of OB care.^{3,4}

Experience has taught that, sadly, state legislatures usually act only *after* the system collapses; then, they may opt for the easiest (often temporary) solution instead of the best one.

In this article, I offer a solution to the malpractice insurance crisis that is *easy* and that may also be the *best* one possible. The solution covers three areas of concern:

- **payment** (including who pays for the policy)

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Can “no-fault” OB liability insurance work? What could stand in the way of its success?

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- 5. Impaired glucose tolerance.
- 6. Reduced response to metyrapone test.

E. CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY

Long-term continuous administration of estrogen, with and without progestin, in women with and without a uterus, has shown an increased risk of endometrial cancer, breast cancer, and ovarian cancer. (See **BOXED WARNINGS, WARNINGS** and **PRECAUTIONS**.)

Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver. (See **BOXED WARNINGS, CONTRAINDICATIONS, and WARNINGS** sections.)

In a 24 month oral carcinogenicity study in mice dosed with 10 mg/kg/day drospirenone alone or 1 + 0.01, 3 + 0.03 and 10 + 0.1 mg/kg/day of drospirenone and ethinyl estradiol, 0.24 to 10.3 times the exposure (AUC of drospirenone) of women taking a 1 mg dose, there was an increase in carcinomas of the hardier gland in the group that received the high dose of drospirenone alone. In a similar study in rats given 10 mg/kg/day drospirenone alone or 0.3 + 0.003, 3 + 0.03 and 10 + 0.1 mg/kg/day drospirenone and ethinyl estradiol, 2.3 to 51.2 times the exposure of women taking a 1 mg dose, there was an increased incidence of benign and total (benign and malignant) adrenal gland pheochromocytomas in the group receiving the high dose of drospirenone. Drospirenone was not mutagenic in a number of *in vitro* (Ames, Chinese Hamster Lung gene mutation and chromosomal damage in human lymphocytes) and *in vivo* (mouse micronucleus) genotoxicity tests. Drospirenone increased unscheduled DNA synthesis in rat hepatocytes and formed adducts with rodent liver DNA but not with human liver DNA. (See **WARNINGS** section.)

F. PREGNANCY

ANGELIQ should not be used during pregnancy. (See **CONTRAINDICATIONS**.)

G. NURSING MOTHERS

Estrogen administration to nursing mothers has been shown to decrease the quantity and quality of the milk. Detectable amounts of estrogens have been identified in the milk of mothers receiving this drug. Caution should be exercised when **ANGELIQ** is administered to a nursing woman.

After administration of an oral contraceptive containing drospirenone about 0.02% of the drospirenone dose was excreted into the breast milk of postpartum women within 24 hours. This results in a maximal daily dose of about 3 mcg drospirenone in an infant.

H. PEDIATRIC USE

ANGELIQ is not indicated in children.

I. GERIATRIC USE

There have not been sufficient numbers of geriatric patients involved in clinical studies utilizing **ANGELIQ** to determine whether those over 65 years of age differ from younger subjects in their response to **ANGELIQ**.

In the Women's Health Initiative Memory Study, including 4,532 women 65 years of age and older, followed for an average of 4 years, 82% (n = 3,729) were 65 to 74 while 18% (n = 803) were 75 and over. Most women (80%) had no prior hormone therapy use. Women treated with conjugated estrogens plus medroxyprogesterone

acetate were reported to have a two-fold increase in the risk of developing probable dementia. Alzheimer's disease was the most common classification of probable dementia in both the conjugated estrogens plus medroxyprogesterone acetate group and the placebo group. Ninety percent of the cases of probable dementia occurred in the 54% of women who were older than 70. (See **WARNINGS, Dementia**.)

ADVERSE REACTIONS

See **BOXED WARNINGS, WARNINGS, AND PRECAUTIONS**.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

The following are adverse events reported with **ANGELIQ** occurring in >5% of subjects:

Table 4: Adverse Events Regardless of Drug Relationship Reported at a Frequency of >5% in a 1-year Double-blind Clinical Trial

ADVERSE EVENT	E2 1 MG (N=226) n (%)	ANGELIQ (N=227) n (%)
BODY AS A WHOLE		
Abdominal pain	29 (12.8)	25 (11)
Pain in extremity	15 (6.6)	19 (8.4)
Back pain	11 (4.9)	16 (7)
Flu syndrome	15 (6.6)	16 (7)
Accidental injury	15 (6.6)	13 (5.7)
Abdomen enlarged	17 (7.5)	16 (7)
Surgery	6 (2.7)	12 (5.3)
METABOLIC & NUTRITIONAL DISORDERS		
Peripheral edema	12 (5.3)	4 (1.8)
NERVOUS SYSTEM		
Headache	26 (11.5)	22 (9.7)
RESPIRATORY SYSTEM		
Upper respiratory infection	40 (17.7)	43 (18.9)
Sinusitis	8 (3.5)	12(5.3)
SKIN AND APPENDAGES		
Breast pain	34 (15.0)	43 (18.9)
UROGENITAL		
Vaginal hemorrhage	43 (19.0)	21 (9.3)
Endometrial disorder	22 (9.7)	4 (1.8)
Leukorrhea	14 (6.2)	3 (1.3)

The following additional adverse reactions have been reported with estrogen and or estrogen/progestin therapy:

1. Genitourinary system

Changes in vaginal bleeding pattern and abnormal withdrawal bleeding or flow; breakthrough bleeding, spotting, dysmenorrhea, increase in size of uterine leiomyomata, vaginitis, including vaginal candidiasis, change in amount of cervical secretion, changes in cervical ectropion, ovarian cancer, endometrial hyperplasia, endometrial cancer.

2. Breasts

Tenderness, enlargement, pain, nipple discharge, galactorrhea, fibrocystic breast changes, breast cancer.

3. Cardiovascular

Deep and superficial venous thrombosis, pulmonary embolism, thrombophlebitis, myocardial infarction, stroke, increase in blood pressure.

4. Gastrointestinal

Nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, increased incidence of gall bladder disease, pancreatitis, enlargement of hepatic hemangiomas.

5. Skin

Chloasma or melasma, which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, pruritus, rash.

6. Eyes

Retinal vascular thrombosis, intolerance to contact lenses.

7. Central nervous system

Headache, migraine, dizziness, mental depression, chorea, nervousness, mood disturbances, irritability, exacerbation of epilepsy, dementia.

8. Miscellaneous

Increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, arthralgias, leg cramps, changes in libido, anaphylactoid/anaphylactic reactions including urticaria and angioedema, hypocalcemia, exacerbation of asthma, increased triglycerides.

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- description of the policy (i.e., the benefits provided)
- regulations and contracts involved (to optimize medical care and minimize medical costs).

A proposal to create “no-fault” pregnancy insurance

I believe that a good solution to the impending crisis in OB medical liability is a form of **no-fault, mutual insurance in which policies are written for one pregnancy at a time**—just as air travel insurance is written for one flight at a time. A policy would be designed to protect a mother and baby while improving the quality of OB care.

This innovation would provide for continued availability of OB care when the current

medical liability system collapses. The physician could pay the premium for the one-pregnancy policy, or it could be paid for directly by the mother's health insurer, which is paying for the rest of her health care (i.e., an enterprise medical liability solution, which provides a financial incentive for the insurer to help provide excellent, not just the cheapest, OB care).⁵

I call this solution **Mothers Mutual Medical Liability Insurance**. Here, I refer to it as “3MLI.”

Keeping patients safe

No question: Medical errors that harm patients are far too common in our current system.⁶ But malpractice litigation as a deterrent to medical mishap? That has been a failure. Patients, after all, sue their physician to be made whole after they have suffered an

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Mothers Mutual Medical Liability Insurance (3MLI) has its benefits

Several features make a 3MLI system appealing—to all parties.

Such a system:

- preserves a patient’s right to sue
- offers a no-fault settlement option as an alternative to litigation
- avoids blame and punishment, which are demonstrably ineffective at minimizing medical errors
- links to a system to optimize the standard of care and record keeping
- guarantees health care and ancillary services for as long as needed by the patient and family
- covers case management services, life insurance, and ongoing legal advocacy
- includes ACOG accreditation to assure clinical excellence and minimize the risk of adverse outcome
- creates a database of adverse obstetric outcomes that add to our knowledge about causes and possible preventions

- offer a no-fault option sufficiently attractive that most patients would prefer it to the uncertainties of a lawsuit
- create a structure in which payers, patients, providers, lawyers, and government are **on the same side**, with the potential for increased financial efficiencies and improved health-care outcomes
- provide the full spectrum of services—possibly lifelong—that an injured infant may require
- avoid costly, lengthy, often futile litigation.

How would the system work?

Coverage comes one pregnancy at a time. A 3MLI policy covers an individual pregnancy. In the event of an adverse outcome, the patient preserves her right to sue. The policy provides liability insurance to cover the cost of a lawsuit and payment for an adverse outcome **or** a system to assist a disabled infant and its family.

Quality assurance is built in. For a pregnancy to be covered, the system requires a guideline-based, quality assurance system to optimize **1) the quality of care and 2) record keeping.** Only OB providers who agree to participate in all aspects of the 3MLI system would have medical liability coverage—coverage that includes full participation in case reviews for adverse outcomes as well as use of record systems and appropriate guidelines for OB care.

It offers an attractive no-fault option. When a disabled infant is born or other adverse outcome of an insured pregnancy occurs, 3MLI provides parents with a no-fault settlement option as an alternative to filing a malpractice suit. Medical care needed by the infant or mother as a result of complications to pregnancy, a congenital defect, or perinatal misadventure not otherwise covered by primary insurance or a government agency would be covered by 3MLI for as long as needed—in some cases, for life. Women who choose this option forego the right to sue, with all the delays and uncertainties that malpractice lawsuits typically involve.

Enhanced coverage is part of the policy. Women covered by a 3MLI policy are provided with

injury—but not for any punitive purpose.

As the Institute of Medicine (IOM) said in its landmark report on medical errors: “When an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.”⁷ What is needed instead, according to the IOM, is creation of an environment “conducive to encourage healthcare professionals and organizations to identify, analyze, and report errors without the threat of litigation and without compromising patients’ rights.”

That is the environment that 3MLI could bring about.

This way to a better way

An ideal 3MLI system for providing OB care would have to:

- ensure continued availability of services
- allow for the care of **all infants** who need help, with expanded opportunities for families to obtain needed medical, economic, and legal assistance
- establish an objective, critical evaluation of the quality of care, with built-in incentives for continuous quality improvement
- end battles over tort reform
- preserve victims’ right to sue



A 3MLI policy covers an individual pregnancy. In the event of an adverse outcome, the patient’s right to sue is preserved.



support services they need to obtain access to medical services (including transportation, if needed) during prenatal care. In an adverse outcome, additional services (such as home nursing care and other appropriate domestic assistance) are included, and are coordinated whenever possible with existing coverage provided by patients' health insurance or by government programs. Rehabilitation and physical therapy are initiated at the earliest appropriate time to minimize long-term disability.

It provides case management. The no-fault policy also includes the services of a case worker to advocate for mother and child. The case worker coordinates the involvement of the primary health insurance company, HMO, government agencies, and other third-party payers, as well as charities, community support groups, and other agencies—all in the interest of providing the best and most effective care possible.

The case worker receives legal assistance to mobilize resources and assistance in a timely manner, thereby promoting a good medical outcome. Case management services continue to be available for a disabled child, even after the death of parents and other family members. Note that these services can be utilized during the pregnancy (coordinated with the OB provider) to help prevent adverse outcomes, as well as after delivery.

It offers life insurance and legal advocacy. The no-fault settlement option includes life insurance for the mother and offspring and pays for legal counsel to advocate for the rights and benefits of the pregnant woman during pregnancy and the injured or disabled party (if any) afterwards. This lawyer could not serve as a plaintiff attorney, and would be paid for services rendered—not on contingency. Legal tasks could include:

- working with the case worker to secure appropriate and timely care when red tape and bureaucracy threaten to deny or delay it
- helping to prevent further adverse outcomes
- designing trusts for the long-term maintenance and care of a disabled infant.

It promotes quality improvement. The settlement benefit of 3MLI provides for a complete and open review of the circumstances associated with the adverse outcome. Because no lawsuit and no adversarial relationship would exist, it becomes possible to compile cases and promote true quality improvement.

Bad outcomes that arise from a poor system of care, physician error or negligence, government regulation (such as bureaucratic delay in initiating care or regulations that prevent optimal OB care), or any other cause are objectively categorized, and recommendations for improvement are made. Case reviews are undertaken by national professional organizations, such as the Society for Maternal-Fetal Medicine and the American College of Obstetricians and Gynecologists (ACOG), and local committees.

These reviews are then fed into a central database that permits objective understanding of the magnitude, and possible causes, of infant disability. The impact of such studies would be to prevent similar problems, when possible, and to provide the most appropriate care, when necessary. Individual practices and physicians are accredited by ACOG or the American Board of Obstetrics and Gynecology (ABOG) before being allowed to participate in this program.

In addition:

The insurer is a nonprofit, mutual insurance company. Each policyholder has a voice in how the system functions. 3MLI must be a mutual company that maintains long-term potential value to the patient who owns the policy. It must never be allowed to demutualize, so to speak, or to be run by a for-profit company.

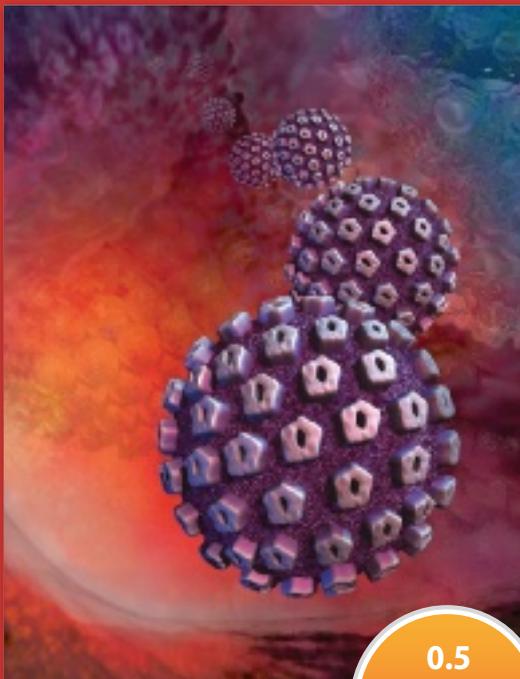
The policy has a specified life. A 3MLI policy lasts from the time it is purchased, in pregnancy, until the child reaches 21 years of age (unless, in the case of a bad outcome, the lifetime medical and support benefit is activated). At some time, it is possible that the policy could be converted to another form of mutual health insurance for children who do not have a disability.

Coverage. Questions about which infants need assistance and how disability is defined can be resolved by families, physicians, and

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A 3MLI policy lasts from the time it is purchased, in pregnancy, until the child reaches 21 years of age (unless the lifetime medical and support benefit is activated)

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legal counsel available to each family as part of this plan. Note that no large financial payment occurs under the no-fault settlement option, so a financial incentive for fraud by the family of the disabled child does not exist.

The 3MLI system is a mutual insurance system with potential benefits (such as dividends or paid-up insurance) to the mothers and families only if money is left in the system. This motivates systemic efficiency and appropriate use of resources, and encourages improving OB care from the patient population point of view.

What is the foundation of such a system?

3MLI would be structured as one, or more, insurance companies set up to provide the services that I’ve outlined. Rather than directly providing all health-care funding for disabled infants, 3MLI would obtain access to, and help maintain, existing health insurance policies and draw on other resources, when available. These could include, as needed, Medicaid, SCHIP, charity and government-run early-intervention programs, and private providers. In short, it would use collateral sources of health care and other resources in fulfilling its mission.

A 3MLI insurance system might also arise from physician-owned mutual medical liability companies or from self-insured medical liability systems, such as the ones found in large hospital systems. HMOs or health insurance companies could develop a 3MLI system as well. Government-related institutions and universities or state health departments with a need to find OB care for indigent populations could also develop 3MLI insurance systems. Initial funding could also come through demonstration projects underwritten, in part, by government or foundations.

Who wins with 3MLI?

Everyone, I believe.

Patients win. The continued availability of high-quality OB care—threatened now by the loss of affordable malpractice insurance—is the most important benefit for patients. In the event of an adverse outcome, parents who choose the settlement option have guaranteed access to immediate health care and other assistance, for as long as they need it.

So do physicians. Participation in 3MLI allows physicians to continue practicing OB after they are priced out of the market by the cost of standard medical liability insurance.

Professional organizations win. Participation by organizations like ACOG is a way to support their physician-membership and their members’ patients. In addition, participation ensures that professional organizations have access to databases and that they be able to assist in creating practice

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guidelines that evolve from their participation.

The states. Many low-income families depend on state assistance for OB care and for the care of disabled children. So, state governments have a substantial stake in the continued availability of OB care and in providing long-term care for the disabled. Many states (New York, for example) already provide a comprehensive system of care for persons who have a significant neurologic disability. 3MLI is designed to coordinate with such state-run systems, thereby increasing their efficiency and effectiveness.

Hospitals. When a significant number of staff physicians participate in a 3MLI system, the hospital benefits from a drop in medical liability claims and suits. Hospitals and hospital systems may find it to their advantage to help initiate or support a 3MLI system.

Attorneys. New, key roles for lawyers will be created in helping to prevent poor medical outcomes before they occur. For example, prenatal care that includes the need for prolonged maternal rest may need legal assistance in a disability dispute. Lawyers also give lifelong assistance to disabled infants and their family.

Lawyers would be paid for these important services without having to participate in litigation. Litigation would continue to be an option if needed or desired by the injured party.

No reason to wait

The progressive severity of the obstetrics liability crisis provides a window of opportunity to propose, consider, and then construct a solution like Mothers Mutual Medical Liability Insurance. Above all, we must consider the needs and well-being of our patients. The time to do this is now—before the loss of OB services places women and their babies at risk. ❗

References

1. Women's access to health care hurt by medical liability crisis [news release]. Washington, DC: American College of Obstetricians and Gynecologists; November 3, 2006.
2. "Catch 22" for New York's obstetricians: failing state insurance system leaves OBs no options [news release]. Albany, NY: American College of Obstetricians and Gynecologists District II; May 21, 2009.
3. Medical Injury Compensation Reform Act (MICRA), Cal Civ Code §3333.2(b) (1975).
4. Florida Birth-Related Neurological Injury Compensation Plan, Fla Stat Ann §766.301-766.316 (1988).
5. Sage WM, Hastings KE, Berenson RA. Enterprise liability for medical malpractice and health-care quality improvement. *Am J Law Med.* 1994; 20:1-28.
6. Ogburn PL Jr, Julian TM, Brooker DC, et al. Perinatal medical negligence closed claims from the St. Paul Company, 1980-1982. *J Reprod Med.* 1988;33:608-611.
7. Kohn LT, Corrigan JM, Donaldson MS, eds; Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System. Executive Summary.* Washington, DC: National Academy Press; 2000:1-16.