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RE: **Testimony for the continuation hearing on the midwifery standard of care regulation, including the incorporation by reference of the modified standard of care text entitled "Standard of Care for California Licensed Midwives" (9/15/05 Edition)**

The California College of Midwives is a professional organization representing the legal and legislative interests of California licensed midwives. In the opinion of our members the proposed regulation satisfies the spirit and the letter of its authorizing legislation, SB 1950. The *Standard of Care for California Licensed Midwives* (9/15/05 Edition) facilitates midwifery practice that is both safe and competent and consistent with the history and tradition of midwifery in the US, as well as the midwifery model of care as practiced worldwide.

The 9/15/05 edition of the *Standard of Care* reflects the art and science of modern midwifery, balancing evidence-based practice parameters with the central role played by the practitioner's clinical judgment. In regard to the legal aspects, the 9/15/05 *Standard of Care* includes statutory and regulatory language or concepts excerpted from nineteen other states that have non-nurse midwife licensing laws. The informed consent / informed refusal policies identified in the standard of care and the regulatory language are consistent with documents on those topics as published in the American College of Obstetricians and Gynecologist Compendium of Policies, 2004 (see attachment #1, ACOG policies on Informed Refusal, submitted with CCM's original February 3, 2005 testimony).

The California College of Midwives believes that professional competence can be described and demonstrated and when consistently employed, it produces a consistent quality of care that preserves the fundamental health of childbearing women and protects mothers & babies from preventable complications. The 9/15/05 *Standard of Care* document does an excellent job of making the professionally competent practice of midwifery visible and understandable to the public, licensed midwives and state regulators and balancing the needs and often conflicting interests of all three major stakeholders:

- Public safety -- childbearing women and their unborn or newborn babies;
- The profession of community-based midwifery as licensed by the MBC
- The organizational needs of that regulatory agency -- the Medical Board of California

Continuation of Hearing – Additional Testimony

This written testimony is a continuation of comments submitted at the original November 2004 and February 2005 hearings. It is meant to build on that testimony and does not replace or negate earlier comments. The additional topics addressed in this supplemental document include:

1. A comparison of the original (Oct 2004) and the new (Sept 2005), modified text of the standard of care for LMs
2. The June 2005 prospective study in the British Medical Journal, identifying the safety of domiciliary midwifery (a quarter of its statistical data was from California LMs)
3. New information on VBAC policies from the American Academy of Family Practitioners
4. **Structure Dictates Behavior**: The unique legal situation generated by the parental decision not to contract for institutional care and the external management within an 'expert system' and to choose instead to labor in their own home under physiological conditions
5. The Midwifery Standard of Care, self-determination by healthy pregnant women and the concerns of organized medicine

1. Comparison of original and modified text of the Standard of Care for LM

At the November 2004 and February 2005 hearings, the midwifery standard of care identified and incorporated by reference was the original, October 2004 version of the California College of Midwives *Standard of Care*. The original regulation also recognized the legal right of self-determination of healthy women to decline the prophylactic (i.e., risk-reduction) medicalization of their pregnancy and, after appropriate written documentation, for the LM to continue to provide tradition (non-medical) midwifery care in non-institutional settings.

The current proposal is an abbreviated, 14 pages version of the same California College of Midwives' text. It includes the first 4 pages, with the addition of crucial text imported from other parts of the document, and the lists that delineated minimum practice requirements in regard to (1) criteria for client selection and consultation, referral, transfer of care, elective transport and emergency transport for all the areas of clinical practice – (2) antepartum, (3) intrapartum, (4) postpartum and (5) neonatal. New language of this proposed regulation likewise acknowledges the client's right to refuse optional, risk-reduction medical procedures and subsequently, under written informed refusal, the client's right to continue to receive standard midwifery care.

The abbreviated version of the original CCM document is unique in that the 9/15/05 version represents a *consensus between the three major midwifery organizations* – the California College of Midwives (CCM), the California Association of Midwives (CAM) and Californians Advocating Licensed Midwifery (CALM). In addition, this version is preferred by the America College of Obstetricians and Gynecologists (ACOG) and the DOL members of the Midwifery Task Force. This unanimous agreement removes a major stumbling block that had been preventing the Division of Licensing from bringing the regulation to a vote at the earlier hearings.

A few words of explanation about the two versions maybe helpful to DOL members.

The original version of the CCM *Standard of Care* was remarkable in that, for the first time in a credible public forum, it made the responsibilities of the licensed midwife visible. It did this by using an articulated format which delineated each of the LM's responsibilities in a community-based setting and then provided at least one, clear-cut way that each of those responsibilities could be competently met. Prior to this, I believe that neither ACOG and nor members of the MBC's Division

of Licensing were able to wrap their minds around the domiciliary practice of midwifery. Given the lack of experience with community-based midwifery that is the norm in our culture, this unfamiliarity is understandable. However, that lack of understanding led to the erroneous assumption by many that midwifery itself lacked a professional basis. This lead to a sense that it was the ethical duty of ACOG and Board members to restrict the practice of midwifery as much as possible. By eliminating this serious misunderstanding and providing a fact-based model for public review, the original CCM Standard of Care was a valuable contribution to everyone involved.

However, the CCM's identification of a specific way to meet each responsibility of the licensed midwife was in essence an 'example', meant to function as a floor and not a ceiling. It was never suppose to be the *one and the ONLY way* such responsibilities could competently discharged. The licensed midwives of California rightly feared that the CCM's "recommendations" could and eventually would be misinterpreted as mandated "requirements", thus triggering a cascade of non-meritorious prosecutions of LMs who had satisfied their responsibilities via other *equally competent but not necessarily enumerated* practices. This was the reason that the original version of the CCM standard engendered such opposition by members of other midwifery organizations.

The new consensus document is a neater, sleeker package that preserves an articulated definition of the professional discipline of midwifery and coordinates all the major principles of the original version, but does so in only 14 pages (instead of the original 51). By being less detailed, the midwives are ever so much less afraid it will be used against them. Also the reduction of specificity relieves the Medical Board of having to hold regulatory hearings for every update of the midwifery standard's evidence-based practice parameters. In regard to maintaining high standards, the consensus version functions as a pointer to published standards by state and national organizations, including the original 51-page CCM document, as well as all the original source materials, thus it still holds California LMs responsible for highly competent, evidence-based care. Last but not least, the consensus version will be easier to administer from the standpoint of the Medical Board.

The consensus edition (9/15/05) of the CCM *Standard of Care* also preserved the language of section B in the original 2004 regulation, which was added at Dr Fantozzi's request by Anita Scuri after the November regulatory hearing. This proposed language identified the licensed midwife's responsibility to recommend physician evaluation for clients with identified risk factors and if appropriate, transfer the client's primary care to an obstetrician. Section B also acknowledged the client's legal right of self-determination and written informed refusal of this advice, in which case the LM may, at her discretion, continue to provide care consistent with other aspects of the midwifery standard of care. This is protective of the consumer, without forcing the MBC into a paternalistic role or futile attempts to micro-manage the care of licensed midwives.

2. Peer-reviewed Study in BMJ on home birth

In June 2005 the **British Medical Journal** published a paper on the first large *prospective* study ever done on planned home birth (PHB) as attended by professionally-certified, direct-entry midwives in North America (BMJ 2005;330:1416–9; copy attached). The outcome of the study was consistent with earlier research on PHB and documented yet again the safety of home-based care by LM-CPMs practicing independently – that is, *without physician supervision*, direct medical oversight or even a close integration into the healthcare system at large. This study's positive findings are consistent with those of the Senate Office of Research's survey on California LMs, done in the fall of 2000 at Senator Figueroa's request.

The conclusion of the study as published in the BMJ stated that:

> "Planned home birth for low risk women in North America using certified professional midwives was associated with lower rates of medical intervention but similar intrapartum and neonatal mortality to that of low risk hospital birth in the United States."

Intrapartum and neonatal mortality, excluding deaths from life threatening congenital anomalies, was 1.7 per 1,000 planned home births (PHB), which was similar to rates in other studies of low risk births planned for homes and hospitals in North America. There were no maternal deaths. A total of 12.1% of women were transferred to the hospital, with failure to progress in the 1st stage of labor being the most frequently cited reason. Total medical intervention rates for the PHB cohort, including those transferred to hospital, were: 4**.**7 % epidural rate (average epidural rate for low-risk planned *hospital* birth is 63%), a 2**.**1% episiotomy rate (hospital cohort was 35%), a 1% forceps (hospital cohort 3%), a 0.6% vacuum extraction rate (hospital cohort 7%) and Cesarean section rate for PHB of 3.7% (hospital cohort 24%).

This study is considered to be remarkable both for its size - 5418 mothers who planned to deliver at home when labor began and 409 certified professional/LM midwives - and the fact that it is a "prospective" (*not* retrospective) review. It's also remarkable in that California LMs were included in the professional midwife cohort. The study's good outcomes are based in large part on births that I and other California LMs attended, as approximately ¼ of all contributors were California LMs. As one of the contributors to the study, I have included a copy of my individual practice stats for your information.

On July 15, 2005 **Ob.Gyn.News** published a report on the BMJ study entitled "**Planned Home Births Safe, Study Results Suggest**". Its conclusion stated that:

> "Not only are planned home births in North America safe for mother and baby, they are associated with a lower rate of medical intervention than are low-risk hospital births in the United States, results of the largest prospective analysis of such births suggest. The researchers compared outcomes in that group with outcomes among more than 3.3 million term, singleton vertex hospital births the same year in the United States.
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> Three infants died from fatal birth defects. There were five intrapartum fetal deaths and six* neonatal deaths [*author's note: three of the neonatal deaths were not related to pregnancy or birth -- two were diagnosed as SIDS deaths and one baby who was born in the hospital, was treated with antibiotics in the hospital but died of late onset GBS two weeks after discharge]
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> About 12% of the mothers were transferred to a hospital either intrapartum or post partum. Five of every six who went to a hospital did so before delivery**:** 51% went for failure to progress, pain relief, and/or exhaustion, according to the investigators. After delivery, 1.3% of mothers and 0.7% of newborns were transferred. The most common reasons mentioned were maternal hemorrhage (0.6% of total births), retained placenta (0.5% of total births), or respiratory problems in the infant (0.5% of total births). The midwives reportedly considered transfers urgent in 3.4% of cases. Transfers were four times more common among primiparous women (25%) than multiparous women (6%).

> As compared with low-risk hospital births**, planned home births** had a significantly **lower rate** of **induction** of labor (9.6% vs. 21%), **stimulation** of labor (9.2% vs. 18.9%), **episiotomy** (2.1% vs. 33%), **forceps** (1% vs. 2.2%), and **vacuum** extractions (0.6% vs. 5.2%). The rate of **cesarean section** for women transferred to a hospital was also **lower** than the rate among low-risk hospital births **(3.7% vs. 18%)."**

It should be noted that the dramatically *reduced* Cesarean rate associated with midwifery care and PHB is occurring simultaneously with a dramatic increase in the Cesarean rate for planned *hospital* delivery. In August (2005) Reuters reported that **1.2 million** Cesareans were performed, making it the number one hospital procedure, at a cost of **14.6 BILLION dollars** in 2003**.** As stated in earlier testimony, delivery via Cesarean surgery is associated with 33 unique 'route of delivery' complications – intra-operative, post-op, delayed or downstream -- as compared to 4 for vaginal birth. Downstream complications of Cesarean surgery include reproductive difficulties such as infertility, miscarriage or tubal pregnancy and post-cesarean sequelae in subsequent pregnancies, such as abnormal placentation, abruption and fetal demise. This is costly in personal suffering, as well as the economic expense to society.

To put into perspective the 14.6 billion dollar cost for Cesareans performed in 2003, the reader should note that the 2005 federal energy bill signed by President Bush this August was for only 14.**3** billion. The total cost for the 1989 Loma Prieta earthquake in the Bay area was estimated at only 6 billion dollars – a mere *5 months* worth of Cesarean surgery. During the last 30 years, Cesarean intervention has gone from one out of **twenty** to one out of **three** pregnancies, with **no reduction in the incidence of cerebral palsy or the rate of permanent, birth-related neurological damage**. However, the steep downward trend in maternal deaths for the entire 20th century stopped falling in 1982. Since 1996, there has been a slight rise in maternal mortality, primarily as a result of delayed and downstream complications of the sky-rocketing Cesarean rate. Any method that reduces Cesarean surgeries prevents maternal mortality, which is two to four times greater with a C-section that a normal birth. The recently published BMJ study amply documents that midwifery care and PHB dramatically reduce the incidence of Cesarean surgery, and therefore are protective of the lives of childbearing women.

3. New Wrinkle in the VBAC Controversy ~ AAFP Speaks Out

There has been an interesting development in the topic of vaginal birth after cesarean (VBAC). The language of the proposed regulation acknowledges that the right of self-determination by the childbearing women extends to those with identified risks factors such as VBAC. With appropriate documentation of the mother's informed refusal of elective hospitalization, licensed midwives may provide physiological support for spontaneous labor, and assuming the labor progresses normally, a normal vaginal birth at home. However, this provision is not without controversy from the obstetrical profession. ACOG's policies on vaginal birth after a previous cesarean effectively rule out elective VBAC unless the physician practices in a teaching hospital with 24/7 resident coverage or is willing to labor sit the entire time the mother is in the hospital. It is ACOG's opinion that their policy creates the equivalent of 'settled law' on the topic of VBAC and thus its restrictions should apply to all practitioners, including midwives and family practice physicians

This has negatively impacted the ability of family practice physicians to provide care for vaginal birth after cesarean. However, a recent public policy statement by the American Academy of Family

Practitioners (AAFP) took exception to ACOG's restrictive VBAC protocols. The AAFP pointed out that current ACOG policies are effectively denying women hospital care for a VBAC, thus forcing them to choose between medically unnecessary repeat Cesareans or unattended home births. Specifically, the AAFP noted that uterine rupture is just one of a small number of rare but catastrophic complications of labor -- notably placental abruption, cord prolapse, amniotic fluid embolism, etc. They pointed out that ACOG does not require the same risk-reduction measures for any of these other equally risky complications.

For example, use of the drugs prostaglandin for cervical ripening and Pitocin for labor induction and augmentation are known to be *drug-related causes of uterine rupture*. The product literature for Pitocin (by Parke-Davis) mirrors the language used in ACOG's VBAC policy, only in regard to the use of Pitocin. According to Parke-Davis, a physician capable of performed an emergency C-section is to be "immediately available" the entire time that Pitocin is being administered. However inductions are done routinely (23% of all hospital labors) without the presence or 'immediate availability' of an obstetrician being offered by the medical profession or required by hospital policies. Bottom line, the AAFP describes ACOG's restrictions on VBAC to be basically irrational and motivated *not* by science, but by rather by fear of malpractice litigation.

4. Structure Dictates Behavior – the basic reason that some families opt out of hospital-based maternity care

Dozens of well-conducted studies have validated the safety of community-based midwifery as provided to healthy women by professional midwives. Unfortunately, decades of positive reports in the scientific literature have not been able to reduce the resistance of organized medicine or solve what they refer to as the "midwife problem". The basic distinction between midwifery and medicine is the contrast between physiological management and the methods of contemporary obstetrics, which consist of a medically interventionist model universally applied. Proponents assert that their particular method is an effective strategy for reducing the natural risks of childbirth in healthy women with normal pregnancies. ACOG has historically maintained that they are right about their method, while midwives and the mothers who seek out midwifery care are obviously wrong.

However, the consensus of the scientific literature identifies only physiological management as an evidence-based model of maternity care that achieves the stated goal of predictable, cost-effective risk reduction. It is unlikely that anything said in this testimony will change opinions to the contrary, but I would like, at the very least, to identify the issue at its most basic level by borrowing a term from the architectural profession and that is: "structure dictates behavior".

Every architect knows that the design of a structure determines how the building will be used. At first glance this idea does not seem to have any connection with planned home birth and midwifery. But actually it identifies the fundamental reason why parents decide against the 'expert system' of institutionally-based obstetrical care and choose instead to labor in their own home, under physiological circumstances. Usually (but not always) their choice of non-medical management includes the support of a professional midwife.

It is a fact of life that the structure of institutions – physically, financially and politically -- dictates the behavior of all the parties, whether one is a hospital administrator, nurse or doctor. The structure and systems of hospital labor and delivery units also dictate the range of behavior possible or permitted of the childbearing woman herself. The characteristics and limitations of the hospital's

physical facility, its economic realities, legal obligations, government regulations and the complex interplay of personalities, will all predetermine the course of events with a force equal to or greater than the biology of uterine contractions and cervical dilatation.

Every obstetrician is faced with the peculiar realities of the institutions in which he or she practices. This includes the limitations of the physical space, department staffing patterns, hospital protocols and the over-arching influence of ACOG policies that define 'standard' obstetrical care. For the last 30 years the complex and interdependent systems of the modern hospital have been dominated by fear of litigation and risk-reduction protocols written by the hospital's lawyers. Labor patient and practitioner have both entered into a tightly choreographed dance with a centipede, and are obliged to keep thousands of legs moving in time to someone else's music.

The effect of hospital structure for a labor patient is just as predictable and as limiting as what a traveler finds upon entering a modern airport for purposes of boarding a plane. As an airline passenger, our behavior is predetermined by the demands of the airport systems (practical aspects as well as security regulations) and this limits us to a very narrow band of permitted activities. Failure to conform can cause the entire airport to be shut down for hours, get us arrested or even shot. In hospitals the issues are more subtle but like the airline passenger, one is still in someone else's 'house', without any inherent property rights and obliged to ask 'permission' before taking any action. In extreme cases, a parent's refusal to conform to the norms of that system will result in a refusal of obstetrical services or even reporting the parents to child protective services.

An example of this is a situation I encountered in which a healthy, intelligent and competent 4th time mother was electively transferred to the hospital as a precaution for pushing longer in 2nd stage than is typical for a 4th baby. There were no medical complications for mother or baby, either before or after hospital transfer. After giving birth normally to a healthy term neonate the parents wanted to return home. When the pediatrician came by a few hours later, the mother asked to be discharged with her baby. Without commenting, he left the room and went immediately to the nurse's station, where he instructed the clerk to report the parents to Child Protective Services.

CPS immediately called the local police station and they sent a police officer to sit in a chair in front of the door to their hospital room, with orders to detain the family until the social worker could come to the hospital and sort it all out. After 6 hours of this very upsetting drama, the nurses prevailed on the pediatrician to relent and give permission for the family to leave. But the message was clear -- the price will be steep for any behavior that is even remotely perceived as non-compliant with the dictates of the institutional structure, which is tightly organized around liability concerns.

What institutional systems do best is dispense high-tech medical and surgical care to victims of violent trauma and acute illnesses, to cancer patients and those who need complex diagnostic procedures and/or sophisticated treatment of debilitating chronic diseases such as diabetes or Parkinson's disease. Acute medical situations include women with complicated pregnancies or fragile, perhaps premature, newborns. But for healthy women with normal pregnancies, who are experiencing a normal labor and do not want or need labor accelerating drugs, narcotics or anesthesia, the behavioral restrictions of the hospital structure is a bad match. Just the price of the real estate alone limits the time and space available to each childbearing family. Immediately upon admission, the mother's labor is put on the institutional 'clock' and the whole family is excluded from any possibility of the privacy, freedom of movement, ability to control their experience and easy access to comforts that are both free and abundant in their own home, such as a place for the husband to nap

during a long night of slow (or no) labor, get a meal that doesn't come out of a vending machine, shave or attend to the older children.

However, the issue that most controls the conduct of medicalized childbirth and strictly dictates the behavior of the doctor is the peculiar nature of the common law contract between the hospitalized maternity patient and her physician. The shadow side of this unwritten contractual agreement is the professional liability of physician and institution. For the last 100 years, the obstetrical profession, in conjunction with the hospital industry, has publicly defined normal labor in healthy women as a risky medical condition for which physician care was a necessity. In the early decades of the 20th century, the frequent stories in the newspaper about the 'dangers of childbirth' were accompanied by the assurance that the obstetrical profession would dependably 'safeguard the mother and child'.

> "… we believe it to be the duty and privilege of the obstetricians of our country to safeguard the mother and child in the dangers of childbirth. The obstetricians are the final authority to set the standard and lead the way to safety. They alone can properly educate the medical profession, the legislators and the public."
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> Boston Medical and Surgical Journal, Feb. 23, 1911, page 261

As the "final authority" able "to set the standard and lead the way to safety", the obstetrical profession promised that medical management of normal labor in healthy women under the care of the hospital nursing staff, accompanied by the conduct of normal birth by a physician as a surgical procedure, could and would eliminate all the 'preventable' risks of childbearing. The medical profession and the lay public both assumed that the art and science of obstetrics would eventually bring childbirth-related death or disability almost to the vanishing point. In addition hospital-based obstetrical management was promised to eliminate the pain of labor and dramatically improved the mother's experience via narcotic medications and anesthesia. The routine use of episiotomy and forceps (made possible by anesthetizing the mother) was promoted as a dependable method to prevent pelvic floor complications later in woman's life.

The professional fee charged by the obstetrician and paid by the patient (insurance company or government) was to purchase access to this 'expert system', which came with a specified set of promises and matching "expectations" by both the patient and her doctor. Doctors expected women to comply with their medical advice and to present themselves to the 'system' as a hospitalized labor patient. As a hospital patient, the mother was expected to lie patiently and passively in a bed in a labor room and accede to the professional judgment of her medical caretakers, whatever that might be. In return, the childbearing family was to receive a healthy baby and the mother expected to be happy with her experience. While we are nearly a 100 years removed from the origins of this model, the exact same structure still defines the premise of 'modern' obstetrical care; the expectation of both parties (physician and family) remain identical in the first decade of the 21st century.

Statistically speaking, great expectations by the obstetrical profession for this medicalized system of maternity care did not come to fruition as hoped. While the US spends more money on birth-related medical care than any other country or society on earth, we are at the bottom end -- an unimpressive 22nd in perinatal mortality and 14th in maternal mortality out of 30 or so industrialized countries. The only place that the US shows up in the 'top five' is for Cesarean surgeries and other major interventions. The US ranks second in those areas. Unfortunately, we aren't getting our money's worth, as it turns out that the elective use of operative delivery – episiotomy, instrumental delivery – causes, rather than prevents, future pelvic floor damage and Cesarean delivery is not preventative.

The five countries that enjoy the best maternal infant outcomes all have something in common – a cost effective system that depends on physiological management for providing care to the 70% of healthy women with normal pregnancies. As documented by the BMJ study, physiological management has equally good perinatal outcomes, but uses *2 to 12 times fewer* expensive, potentially dangerous interventions. By comparison, our complex obstetrical system generates an unnaturally large number of iatrogenic complications. Even though it is an extremely expensive system, it also doesn't address the many social aspects of poor outcomes, which are the deleterious effects on maternal health caused by ignorance and poverty, a situation often associated with minority status.

An unfortunate combination of over treatment and under treatment means that our national statistics do not measure up to those of other developed countries. Unfortunately, this poor showing in maternal-infant health has done nothing to reduce the American public's unrealistic expectations of obstetrical care. When these unrealistic expectations are unable to be met at an individual level, the family files a law suit and the expert system is forced to bear the price of defending against malpractice litigation and if unsuccessful, pay out multi-million dollar awards. This further dictates how maternity care is configured and dispensed, producing even tighter limits on the behavior of all parties, while ever increasing the cost of care and diminishing satisfaction.

Over the last century the cumulative effect of these institutionalized structures has made it functionally impossible for an individual woman in labor to walk into a hospital L&D unit and receive physiologically management from the obstetrical system. Structure does dictate behavior and the behavior dictated by these structures is the *medical* management of labor and birth. In the present hospital structure, the normal activities associated with physiological management (many of which consist of *not* doing medical things, such as *not* keeping women in bed and *not* using continuous electronic monitoring), would at best constitute substandard care and at worst, incompetence and negligence. The obstetrician, who is unable to depend on physiological process, must instead routinely employ a host of medical interventions, thus creating an **asymmetrical burden of risk** that falls *directly and unfairly* on the childbearing woman. This risk-shifting and cost-shifting process reduces the litigious exposure of the physician by passing it along to the mother as the increased rate (and cost) of complications and the actual physical pain of invasive procedures or major surgery.

Until we have tort reform in the legislature *and* a policy revision by ACOG that acknowledges physiological management of childbirth in healthy women as an appropriate standard of care for board-certified obstetricians, there is nothing that an individual family can do to change the structure of the system or its limitations. However, if ACOG is interested in eliminating home birth, it should begin by changing its own policies and lobbying to reform the legal structures surrounding hospital-based maternity care. Were that to occur, midwives wouldn't be seen as a 'problem'.

For most childbearing families, the limitations of the hospital system are judged in relation to their experience of labor and birth. If the parents are committed to physiological management, their choice will be limited to an *out* of hospital setting. For a small but important subset of families this is a tough decision brought about by a pregnancy that has an identified risk factor, such as a previous cesarean delivery or a breech baby. Neither of these conditions is a mechanical block to normal labor and spontaneous vaginal birth. But at present, the obstetrical profession generally declines to provide care for a planned vaginal birth in these and similar situations. The issue is not the actual biological risk to mother or baby but rather the litigious risk to the physician. Institutional and /or organizational policies quite naturally are attempting to limit their liability in the face of enduring expectations by

the public that obstetrics can control all outcomes and prevent all 'adverse events'. The unfortunate result of this irrational expectation is an irreconcilable conflict of interest between the needs of the expert system and the right of self-determination of healthy, mentally competent adult women.

Whatever the individual reasons for opting out of the expert system, it dramatically changes the liability issue when a family chooses not to put their normal biological process under the control of medical experts. Their voluntary 'informed refusal' removes them from the conventional tort system, as one obviously cannot sue one's self for "permitting" oneself to have a normal labor and vaginal birth under physiological circumstances in a non-medical setting of one's choosing. Any potential liability associated with the mother's normal labor and birth will be uniquely different from that associated with a medically controlled process under the institutional care of medical experts. The decision-making process for the parents and professional attendant will include different parameters and frequently come to different conclusions.

Circumstances that would, in the 'expert system' of obstetrics, be judged as unacceptably risky (a term that applies to the physician or institution's risk of litigation as well as biological outcome), must be reassessed in light of the choice by the childbearing couple to depend, at least initially, on the normal biology and spontaneous physiology of childbirth instead of medical interventions. Any professional birth attendant associated with this situation – midwife or physician -- would be obligated, under the theory of 'due diligence', to provide full and scientifically valid information on currently available risk reduction measures and the potential consequences associated with their use and the decision *to decline*. But it must be the childbearing couple themselves, the people who will personally bear the burden and live with consequences of the decision, who make the ultimate choices about risk reduction (i.e., prophylactic) medicalization, especially in regard to Cesarean surgery, which doubles the likelihood of a maternal death and has a 13-fold increase in emergency hysterectomy (as compared with vaginal birth).

5. Midwifery Standards, Client Self-Determination and Objections by Organized Medicine

The heart of the remaining controversy between licentiate midwives, the Medical Board and organized medicine is the small cohort of families with an identified risk factor who, after being provided with appropriate informed consent information and reading materials, choose to decline professional advice for hospital-based risk reduction measures and instead plan to 'self-manage' the normal physiology of labor and spontaneous birth in their own home. There is a long-standing disagreement between organized medicine and childbirth activists over the principle of autonomy for the healthy, childbearing woman, her constitutional right to have control over the manner and circumstances of normal childbirth and whether there is any value to society in the mother's experience of normal birth.

It will come as no surprise that mothers and midwives believe that the functional autonomy of the healthy, mentally competent pregnant women is a compelling human rights issue that encompasses her right to decline risk-reduction protocols *even when that is an unusual or unpopular choice*. The reader may however be surprised to learn that the official polices of ACOG actually acknowledge and generally support the reproductive rights of women, except as it applies to midwifery and planned home birth. [See attachment "ACOG policy statements on Informed Refusal & Patient Choice and the Maternal-Fetal Relationship" in the February testimony and ACOG policy statement supporting elective abortion and their 1999 policy statement denouncing planned home birth]

During the last 3 1/2 years of MBC hearings, there has often been confusion between *standard* of practice and *scope* of practice. While the regulation mandated by SB 1950 was clearly about *standard* of care, many of the proposals by organized medicine were attempts to limit and thus rewrite the licensed midwife's scope of practice predicated on the idea of an identified risk factor. The crucial distinction here is that a risk factor is a potential circumstance, a small increase in the *rate* of complication but not the same thing as an actual, present tense complication.

We believe the confusion over the midwives' scope of practice represents a misunderstanding on the part of obstetricians, one that grows out of the issue of professional liability as it is linked to obstetrical practice within an expert system. Confusion between the dramatically different rules governing the non-medical, non-institutional model of midwifery and the tight restrictions of the hospital-based expert system is quite understandable. As discussed above, certain pregnancy-related circumstances are identified in the expert system of obstetrics as unacceptably risky to the physician or the institution. This reflects the earlier dictum of "Structure dictates behavior", meaning that within hospital systems, physiological management under certain circumstances is not 'permitted', as the potential liability to the hospital and physician is too great.

At fist glance it seems plausible that if an *obstetrician* (with 13 years of medical school!) could not, would not or should not attend a planned vaginal birth after previous cesarean or the normal vaginal birth of a breech baby, then surely it must be some form of forbidden activity for a licensed midwife (with only 3 years of midwifery school) to do so. But the root of this controversy is not childbirth, it's not the midwife, it's the choices of the childbearing family. It's about risks and risk-reduction in the context of a parental choice to decline, under informed refusal, to participate in the expert system and its medicalized risk-reduction measures, which often consist solely of 'prophylactic' cesarean section. The mother is not ill or unable to labor normally nor is the baby unable to be born safely through a normal vaginal birth. *The issue is obstetrical liability*. Once the parents decline (via informed refusal) to contract with the expert system, **the liability-based restrictions of the obstetrical profession become moot** and can no longer be used to deny the parents' the choice of a normal vaginal birth or to deny them access to professional midwifery services within a physiological model of care.

The midwifery scope of practice as defined in the LMPA authorizes the licensed midwife to attend 'normal birth'. Traditionally the discipline of midwifery has equated normal labor and birth with what is biologically natural -- that is, not artificially stimulated with drugs and not requiring the use of force, or mechanical devices such as forceps or vacuum extractors or surgery such as Cesarean. World-wide, the midwifery profession defines normal as referring to spontaneous physiological processes that are characteristic of the healthy reproductive biology of childbearing women and can reasonably be expected to lead to normal conclusions. Normal is associated with **a state of irreducible risk –** that is, **all other responses *add* rather than subtract risk.** Added risk would factor in the artificial risks and iatrogenic complications associated with the elective medicalization of normal labor or a medically (i.e., mechanically) unnecessary C-section. Functionally speaking, the midwifery definition may be distilled as follows:

> Normal as used in the LMPA would refer to a healthy pregnancy in a healthy woman that naturally advances to term with a live, growth-appropriate fetus/es in a vertical lie, culminating with a spontaneous labor that leads to the spontaneous live birth of a viable neonate, with conservation of the health and wellbeing of the mother and baby.

While the definition of 'normal' birth is not elaborated on by the LMPA, its inverse -- abnormal birth – certainly is. Any labor or delivery in which there is a need to use "artificial, forcible or mechanical means", (e.g. drugs to stimulate labor, obstetrical forceps, Cesarean delivery) is specifically prohibited (i.e., black letter law). The use of "artificial, forcible and mechanical means" (drugs and surgery) is also defined by other sections of Chapter five of the Business and Profession Code as the unauthorized practice of medicine.

All childbirth choices made by parents are associated with a specific risk of some sort – there is no choice, no risk reduction measure, no medical procedure, including elective Cesarean section -- that can provide zero risk. Therefore, risk reduction, which is for the benefit the childbearing family, must always be implemented *with the consent of the childbearing family*. For mentally competent women, there are legal principles of body integrity that already acknowledge their right to refuse medical treatments, procedures and surgery, even when doing so would benefit their child, such as donating an organ for transplant to a minor child. This holds true *even* when the decline of these interventions may, as perceived by medical authorities, disadvantage a fetus.

The following quote identifies contemporary case law precedent mandating maternal consent, even in the face of identified risks and possible adverse events or bad outcomes:

> "In 1990 District of Columbia Court of Appeals, in a strongly worded opinion, essentially *adopted the American College of Obstetricians and Gynecologists'* statement as law, holding that **the decision of the pregnant women must be honored in all but "extremely rare and truly exceptional" cases"**. [cited from ACOG policy statements on Patient Choice and the Maternal-Fetal Relationship]

OAL Ruling Acknowledging Variations in 'Normal' Birth Lawful Under the LMPA

In 1999 a disciplinary case was brought by the MBC against a licensed midwife for providing care to a mother whose baby was breech and who, with fully informed consent, declined the medical advice of her obstetrician to have a scheduled cesarean delivery. The mother-to-be discovered that none of the other obstetricians in her area would agree to, *or did not know how to,* deliver a breech baby vaginally. She instead found a licensed midwife who was specially trained and experienced in managing breech births. For reasons not associated with the baby's breech position, it was stillborn. Eventually this case came before Judge Roman in an administrative hearing.

His decision confirmed the right of the childbearing woman to decline the risk-reduction procedures of obstetrical care (in particular, to decline the elective performance of a cesarean section) and to choose physiological management under the care of a licensed midwife even when identified risk factors are present. The OAH decision also acknowledged that breeches and other variations of norm can be attended by LMs provided the midwife has appropriate 'informed consent/refusal, advanced training, additional experience and written protocols that included specific criteria for selection of such clients and specifies parameters of care, including referral and emergency transport arrangements. This was based on the recognition that these 'special circumstances' pregnancies are still normal and are anticipated to result in a normal childbirth.

The OAH judge's decision upheld as lawful the standard of care used by a California licensed midwife that included guidelines, protocols and special informed consent for healthy women with moderate risk situations. [see "OAL Decision by Judge Roman in the Alison Osborn case" in previous testimony]

Conclusions

The authorizing legislation (SB 1950) offered an important opportunity to identify in regulation the basic distinctions between the physiologically-based midwifery model of care, which addresses the normal biology of healthy childbearing women (as defined in SB 1479; Figueroa, 2000) and that of the medical model. Additionally, the regulation as proposed is:

1. Protective of consumer interests
2. Reduces the burden on the regulatory agency to investigate non-meritorious complaints
3. Helpful to midwives by assisting them to be in compliance with the LMPA
4. Meets or fulfills the legal criteria for regulations – that is, *Necessity, Authority, Consistency, Clarity, Non-duplication* and *Reference.*
5. In the consideration of all alternatives, there is no alternative which would either be more effective than or as effective as or less burdensome on affected private persons than the proposed language of Section 1379, as authorized by SB 1950

The 9/15/05 *Standard of Care* document supports the need for the licensing law to be stable, while remaining able to evolve as the scientific evidence and customs of society change. It notes the various professional obligations, guidelines, and minimum practice requirements necessary to meet the legal definitions of standard midwifery practice in California. The California licensed midwife who conforms to this standard would be judged to be competent. Furthermore, the members of the California College of Midwives believe that professional midwives owe a duty to their clients to make their professional standard of care known, so that the characteristics of it are plainly and publicly described and 'informed consent' can become a meaningful concept for all women receiving care from licensed midwives

The 9/15/05 *Standard of Care* document is protective of the consumer, protective of the professional status of the LM and protective of the regulatory agency, reducing the disciplinary burden by lowering the number of incidents that must be investigated and potentially prosecuted by the MBC. The achievement of these vital goals clearly establishes the functional quality of midwifery standards and guidelines to be an "appropriate" standard of care for the practice of midwifery in California. Therefore the membership of the California College of Midwives **supports the passage of this proposed regulation in its present form**.

Faith Gibson, LM, CPM
Executive Director, ACCM/
California College of Midwives

cc: Senator Figueroa's office

Enclosures: 1) Copy of BMJ paper: Outcomes of planned home birth with certified professional midwives: large prospective study in North American [BMJ 2005;330: 18 June]

(2) CPM Statistics Project 2000 – Publication – Midwives Individual Statistics; Detailed Statistics for Faith Gibson, CPM, planned home births in the year 2000 pages 1 to 5