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November 25, 2012

Rohno Geppert, Program Manager, Office of Special Licensing
Arizona Midwifery Scope of Practice Advisory Committee
150 N 18th Ave, 4th Floor
Phoenix, AZ 85007

Re: Out-of-Hospital Births
Vaginal Birth after Cesarean (VBAC)

Dear Mr. Geppert,

My comments concerning the above-cited topic are submitted at the request of the Arizona Section of the American College of Obstetricians and Gynecologists. By way of introduction, I served as chair of the Expert Panel for the National Institutes of Health Consensus Development Conference entitled *Vaginal Birth after Cesarean: New Insights* which was held in Bethesda in 2010. These conferences are sponsored by a number of agencies within the NIH, and preparations and research for each one span about two years and include an exhaustive review of the medical and scientific literature. Thus, objective data are used for analysis of evidence-based outcomes that are incorporated into the summary and recommendations arrived at by the Panel. The final meeting of *The VBAC Conference* included scholarly testimony from invited national experts. The meeting was widely advertised and it was open to the public with time set aside for comments from attendees. The meeting culminated in the Panel drafting its final statement, and after committee revisions by conference calls, the findings were distributed.

Because a primary objective of a consensus conference is a thorough review of objective data, during the first year, the Panel spent many hours analyzing studies reviewed and summarized by experts who researched literally thousands of publications. These reports were derived from respected search engines that included that of the National Library of Medicine. The Panel adhered closely to conference guidelines to grade the level of scientific evidence that accompanied conclusions or recommendations.

Regarding the current subject, it is my understanding that the Arizona Midwifery Scope of Advisory Committee has been requested to add "VBAC" to a list of approved procedures for direct entry midwives to perform when attending out-of-hospital births. As stated above, my comments regarding this proposed change were requested by the Arizona Section of ACOG and can be summarized as follows:

1. In the Panel's report, we state that there is a paucity of data to assess outcomes *except in tertiary-care settings*, and that hospitals with these high volumes overall have correspondingly better outcomes. Because the majority of outcomes—both both good and bad—are from larger hospitals, most of our discussion in the report, as well as recommendations and conclusions we reached, were limited to these types of facilities. Importantly, simply because we did not address out-of-hospital births in detail, this **cannot** be taken as *de facto* endorsement of their application in those settings. Quite the contrary, the report summarizes an imposing list of life-threatening complications to both mother and baby that will inevitably be encountered even in women who choose to undertake a “safe” trial of labor in a high-volume, fully staffed Labor & Delivery Unit.

2. This litany of serious complications for women and their unborn babies furthermore are for the most part unpredictable for any individual labor. For the mother, complications include uterine rupture, hemorrhage requiring blood transfusions, hysterectomy, and at the worst, maternal death. For the baby, complications are stillbirth, and in some survivors, neurological disabilities including cerebral palsy with mental retardation. For example, in a report in *Obstetrics & Gynecology*, Bujold and colleagues described a multicenter study from 10 centers in metropolitan Montreal in which there were 89 cases of uterine rupture during a trial of labor. And even in these well-equipped and staffed units in which emergency cesarean delivery was performed, 6 infants were stillborn and a third of the surviving infants had a very low 5-minute Apgar score and/or were acidotic by objective biochemical measurements. Certainly not all of these latter infants will subsequently have neurological disabilities, but they are at high risk for such. Most important, these emergent complications encountered in laboring women mandate immediate operative intervention to mitigate horrific maternal and fetal morbidity and mortality. Because of the inability to perform such emergency surgical procedures, the serious drawbacks of out-of-hospital births are obvious even to the most enthusiastic of supporters of such practices.

3. The American College of Obstetricians and Gynecologists has an abiding interest and concerns about the risks and benefits of a trial of labor to attempt VBAC in carefully selected women. Indeed, the Consensus Conference in March was attended by both the President and Executive Vice President of ACOG. And subsequent to this, ACOG issued its revised Practice Bulletin *Vaginal Birth after Previous Cesarean Delivery*. Their recommendations, in agreement with those of our Panel, clearly state that a trial of labor should be undertaken at facilities capable of performing emergency deliveries. Continuous electronic fetal monitoring is also recommended. The facility must be ready to perform an emergent cesarean delivery which would necessitate a team consisting of surgeons, anesthesia personnel, surgical nurses, and operating rooms as well as blood transfusions if needed and appropriate postoperative care. Thus, the lack of these safeguards stresses the wisdom that precludes the practice of attempting a trial of labor to achieve a VBAC in out-of-hospital births. Moreover, in such situations, there would be an unacceptable delay imposed by transfer of the laboring woman to a suitable facility, as well as preoperative evaluation and preparation upon arrival to that facility.

From the foregoing, it should be apparent that selected women with a prior cesarean delivery, and who are judged to be at low risk for complications, can relatively safely undergo a trial of labor to attempt a vaginal birth. The caveat is that such labors should only be conducted in well-

equipped facilities that can emergently handle dangerous complications that inevitably will arise. And even with these safeguards, there are still real and devastating complications that can accrue.

I hope that the Board finds these remarks useful in its deliberations.

Sincerely,

F. Gary Cunningham, M.D.
Professor
Holder, Beatrice and Miguel Elias Distinguished
Chair in Obstetrics and Gynecology

FGC/cau

EC: Maria Manriquez, M.D.

F. Gary Cunningham, M.D.
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August 16, 2010

The Board of Direct Entry Midwifery
Oregon Health Licensing Agency (OHLA)
700 Summer St., NE, Suite 320
Salem, OR 97301-1287

Re: Out-of-Hospital Births
Vaginal Birth after Cesarean (VBAC)

To Whom It May Concern:

My comments concerning the above-cited topic are submitted at the request of the Oregon Section of the American College of Obstetricians and Gynecologists. By way of introduction, I served as chair of the Expert Panel for the National Institutes of Health Consensus Development Conference entitled *Vaginal Birth after Cesarean: New Insights*. Sponsored by a number of agencies within the NIH, preparations and research for such conferences span about two years and include an exhaustive review of the medical and scientific literature. Thus, objective data are used for analysis of evidence-based outcomes that are used to underpin the summary and recommendations arrived at by the Panel. The final meeting of what was termed *The VBAC Conference* was held on the NIH campus in Bethesda in March 2010 and included scholarly testimony from invited national experts. The meeting was widely advertised and it was open to the public with time set aside for comments from attendees. The meeting culminated in the Panel drafting its final statement, and after committee revisions by conference calls, the findings were distributed via a number of sources.

Because a primary objective of a consensus conference is a thorough review of objective data, during the first year, the Panel spent many hours analyzing studies reviewed and summarized by experts who researched literally thousands of publications. These reports were derived from respected search engines that included that of the National Library of Medicine. The Panel adhered closely to conference guidelines to grade the level of scientific evidence that accompanied conclusions or recommendations.

Regarding the current subject, it is my understanding that the Oregon Board of Direct Entry Midwifery is considering adding "VBAC" to a list of approved procedures for direct entry midwives to perform when attending out-of-hospital births. As stated above, my comments

regarding this proposed change were requested by the Oregon Section of ACOG and can be summarized as follows:

1. In the Panel's report, we state that there is a paucity of data to assess outcomes *except in tertiary-care settings*, and that hospitals with these high volumes overall have correspondingly better outcomes. Because the majority of outcomes--both good and bad--are from larger hospitals, most of our discussion in the report, as well as recommendations and conclusions we reached, were limited to these types of facilities. Importantly, simply because we did not address out-of-hospital births in detail, this **cannot** be taken as *de facto* endorsement of their application in those settings. Quite the contrary, the report summarizes an imposing list of life-threatening complications to both mother and baby that will inevitably be encountered even in women who choose to undertake a "safe" trial of labor in a high-volume, fully staffed Labor & Delivery Unit.

2. This litany of serious complications for women and their unborn babies furthermore are for the most part unpredictable for any individual labor. For the mother, complications include uterine rupture, hemorrhage requiring blood transfusions, hysterectomy, and at the worst, maternal death. For the baby, complications are stillbirth, and in some survivors, neurological disabilities including cerebral palsy with mental retardation. For example, in a recent report in *Obstetrics & Gynecology*, Bujold and colleagues described a multicenter study from 10 centers in metropolitan Montreal in which there were 89 cases of uterine rupture during a trial of labor. And even in these well-equipped and staffed units in which emergency cesarean delivery was performed, 6 infants were stillborn and a third of the surviving infants had a very low 5-minute Apgar score and/or were acidotic by objective biochemical measurements. Certainly not all of these latter infants will subsequently have neurological disabilities, but they are at high risk for such. Most important, these emergent complications encountered in laboring women mandate immediate operative intervention to mitigate horrific maternal and fetal morbidity and mortality. Because of the inability to perform such emergency surgical procedures, the serious drawbacks of out-of-hospital births are obvious even to the most enthusiastic of supporters of such practices.

3. The American College of Obstetricians and Gynecologists has an abiding interest and concerns about the risks and benefits of a trial of labor to attempt VBAC in carefully selected women. Indeed, the Consensus Conference in March was attended by both the President and Executive Vice President of ACOG. And subsequent to this, ACOG recently issued its revised Practice Bulletin *Vaginal Birth After Previous Cesarean Delivery*. Their recommendations, with which our Panel agreed, clearly state that a trial of labor should be undertaken at facilities capable of performing emergency deliveries. Continuous electronic fetal monitoring is also recommended. The facility must be ready to perform an emergent cesarean delivery which would necessitate a team consisting of surgeons, anesthesia personnel, surgical nurses, and operating rooms as well as blood transfusions if needed and appropriate postoperative care. Thus, the lack of these safeguards stresses the wisdom that precludes the practice of attempting a trial of labor to achieve a VBAC in the vast majority of out-of-hospital births. Moreover, in such situations, there would be an unacceptable delay imposed by transfer of the laboring woman to a suitable facility, as well as preoperative evaluation and preparation upon arrival to that facility.

From the foregoing, it should be apparent that selected women with a prior cesarean delivery, and who are judged to be at low risk for complications, can relatively safely undergo a trial of labor to attempt a vaginal birth. The caveat is that such labors should only be conducted in well-equipped facilities that can emergently handle dangerous complications that inevitably will arise. And even with these safeguards, there are still real and devastating complications that can accrue.

I hope that the Board finds these remarks useful in its deliberations.

Sincerely,

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EC: Stella Danta, M.D.
Randy Everitt