Handling vacuum extraction cases requires an understanding of the use of the instrument and the consequences of its misuse. After discussing the warnings to physicians and midwives, the American College of Obstetrics and Gynecology and other literature, practical information and suggestions, including deposition excerpts, for representing those who may be injured will follow.

WARNING

On May 21, 1998, the FDA issued a public health advisory entitled, "Need For Caution When Using Vacuum Assisted Delivery Devices."[i] The Advisory stated that:

Vacuum assisted delivery devices may cause serious or fatal complications . . .

The Advisory went on to say that:

While no instrumental delivery is risk free, we are concerned that some health care professionals who use vacuum assisted delivery devices, or those who care for these infants following delivery, may not be aware that the device may produce life-threatening complications.

The FDA noted that it had received over the past four years reports of twelve (12) deaths and nine (9) serious injuries among newborns on whom vacuum assisted delivery devices were used. The types of complications that the FDA discussed were subgaleal hematomas[ii] and intracranial hemorrhages.

In Childbirth FDA Patient Safety News, June 2002, Problems After Vacuum-Assisted Childbirth, it is noted:

But the FDA has received reports of much more serious complications, including subgaleal
hematoma and intracranial hemorrhage. And although these are rare, they can be fatal.[iii]

Subgaleal hematoma (injury to the scalp with subsequent bleeding into the potential space between the galea aponeurotica and the pericranium[iv]) may be life threatening because “damage to the emissary veins may cause bleeding and result in a large proportion of the baby’s blood volume accumulating in this space.”[v] The relationship between subgaleal hematomas and vacuum extractors had been published in the medical literature before the FDA warning of 1998, evidenced in a 1995 article in The Journal of Family Practice which states, “The major reported risk factor for subgaleal hematoma is use of a vacuum extractor to assist with the delivery of the infant.”[vi]

In 1998, the Food and Drug Administration User Facility Reporting Bulletin[vii] discussed the FDA warning of May 21, 1998, and pointed to findings that would indicate a potential problem from the vacuum, including cerebral irritation, convulsions, lethargy, apnea, bulging fontanels, poor feeding, increased irritability, bradycardia and shock. It further pointed out that these symptoms were sometimes delayed until hours after birth. When a vacuum was used, it was important for those taking care of the newborn to watch for abnormal signs. Other signs that may be present at delivery from the use of a vacuum would include swelling, pallor, increased respiration rate and tachycardia.[viii] These might not be noticeable until hours after birth.

The Safe Medical Device Act of 1990 requires facilities to report deaths, serious illnesses and injuries to the FDA, as well as to the device’s manufacturer. This is done by using the Mandatory Reporting Form 3500A. There have been certain adverse reactions reported from the use of the vacuum extractor.

In September of 1998, ACOG issued a committee opinion. Among other things, the ACOG Committee On Obstetric Practices, stated that:

. . . As with any other obstetric procedure, obstetric care clinicians using vacuum-assisted delivery devices to effect operative vaginal deliveries should be appropriately trained and familiar with the indications and contra-indications for the use of the device, as well as with its proper application and traction procedure.[ix]

The Committee expressed concerns regarding the implications of the FDA Advisory, specifically given the decline in forceps use in the United States. They felt that the decrease in the use of the vacuum device resulting from the Advisory might result in a higher cesarean section delivery rate or the increased use of forceps by some who have not had adequate training.

In Childbirth FDA Patient Safety News, June 2002, Problems After Vacuum-Assisted Childbirth, it is noted:

But the FDA has received reports of much more serious complications, including subgaleal hematoma and intracranial hemorrhage. And although these are rare, they can be fatal.[x]

Diane Dwyer, BSN and Sonia Swayze, RNC in Nursing 2000, elaborated on the FDA warning by stating: “Intracranial hemorrhage may be subdural, subarachnoid, intraventricular, or, intraparenchymal. Signs and symptoms, which may not appear for several hours, include convulsions, lethargy, obtundation, tachypnea, a bulging fontanel, poor feeding, increasing irritability, tachycardia and shock.”[xi]

The FDA has recommended that in cases where vacuums were used, the caregivers of the newborn be instructed to watch for several days for possible problems as set forth above, and recommend that the fact that a vacuum was used be clearly listed in the patient’s chart.[xii]
It is therefore important to carefully review the newborn records to determine whether or not any abnormal signs were present. These may include bogginess of the scalp, increased size of the head, pallor and other indications of a baby that was not neurologically intact. If caught at an appropriate time, an expanding subgaleal hemorrhage can be appropriately treated. If left unattended, it will lead to the baby's demise. When doing discovery in these cases, inquiries should be made of the health care professionals who were in the delivery room and those who took care of the newborn. This should include whether or not they were familiar with the FDA warning and if so, how it had been implemented.

To learn more about Andrew Greenwald's experience with medical malpractice and how he can help victims of medical malpractice, you can visit www.dcbirthinjurylawyer.com.


[vii] Sue Ann Smith, M.D., supra at 569.


[viii] Id.
ACOG Committee on Obstetric Practice Opinion, Number 208, September 1998.

