Insurer's "Spin Defense" to Bile Duct Transection

By: Thomas T. Dunbar

All agree that a common bile duct transection arising from a gallbladder surgery can be a devastating injury, life-threatening, and cause life-long consequences.

This article is an attempt to alert the public including those injured of the "Spin" defenses being advanced in the defense of medical negligence claims for the very serious damage caused by negligent transection of the common bile duct during laparoscopic gallbladder surgery. Transecting the wrong bile duct in a laparoscopic gallbladder surgery has been the most prevalent source of surgical malpractice claims over the last 15 years. Over the last few years, there has been a campaign whose purpose is to mislead the public (and potential jurors and judges) about the frequency and cause of common bile duct injuries and the damages suffered by the patient. The transection (cutting across the wrong duct) of a common bile duct is entirely preventable if careful and proper technique is employed. Lack of attention, refusal to convert when it is difficult to see, and/or excessive speed are two principal reasons for this surgical error. Amazingly, the current "spin" defense is that the surgical error is a "recognized complication of a laparoscopic gallbladder surgery". (Or restated, "A recognised risk of this surgery is medical malpractice.)

Over the last few years, this Defense, designed to mislead, has been advanced in both medical publications and by Defense "experts" who rely on articles written for defense of these cases. The "Defense Community" has promoted and written articles stating that transection injuries of the common bile duct are a "recognized complication of a laparoscopic gallbladder surgery." The purpose of these misleading articles is to influence jurors and to support experts hired by Defendants to testify in defense of a common bile duct transection. Experts hired by the Defendant surgeon can "rely" on the articles in support of their opinion at trial. The expert then can testify, "... the Plaintiff just unfortunately fell within that percentage of patients who bear the inherent risk of this surgical procedure, given the best of surgical techniques."

Corruption of the medical literature is not new. It is now well-known that for years, drug companies have influenced and funded researchers to publish biased studies in the medical literature. Less well-known is that members of the American College of Obstetrics and Gynecology (ACOG) have been doing the same thing. These physicians have created ***litigation* literature** and published it in obstetrical and pediatric literature disguising it as scientific literature. (The Litigation Literature", by Joel Cunningham, Esquire, Washington State Trial Lawyers Association, Volume 39-2 October 1, 2003) Litigation literature is designed to support the defense of obstetricians in court. It is designed to give credibility to the expert opinions, and the literature in support of the "no negligence" expert opinions, and to meet Daubert objections, it became important that medical literature be "peer-reviewed". So, through litigation literature the defense has taken "Junk Science" to a new level, under the guise of peer-reviewed medical literature so that the articles can be "relied upon" by defense experts. General surgeons have

now joined obstetricians in publishing misleading articles. See “Causes and Prevention of Laparoscopic Bile Duct Injuries- Analysis of 252 Cases from the Human Factors and Cognitive Psychology Perspective “ Vol. 237, Number 4 , pages 460-469 , *Annals of Surgery* , April 2003. (Misperception like an “optical illusion” is cause of bile duct transections though the theme directly contradicts author Dr. Way’s written conclusions from 1992).

In the early 1990's, common bile duct transections occurred because surgeons were inexperienced as the new technique of laparoscopic cholecystectomy (closed, minimally invasive surgery) was introduced across the United States of America. Journal articles were published and seminars given explaining the proper technique to prevent common duct transections during laparoscopic cholecystectomy. The incidence of common bile duct transections decreased markedly after these journal articles were published and surgeons received additional training. Yet overconfidence and “being in a hurry” continue to cause common bile duct transections needlessly. Rather than converting to an open procedure on those occasions when a surgeon can’t see (so that the biliary anatomy is readily touched, felt, manipulated and distinguished), the surgeon continues forward laparoscopically and transects the wrong duct. Then when he is sued, the surgeon says that he was not negligent, and that the injury is a “recognized complication”. Experts hired by Defendants then attempt to defend the failure to convert to an open procedure by stating that bile duct injuries (rather than “transections”) occur just as often in “open procedures” as in laparoscopic cholecystectomies. Defense couches negligence in terms of an “unpreventable injury” (Of course if a surgeon still cuts the wrong duct when he/she can “see and feel” what is being cut, the negligence is more egregious.)

How can the Plaintiff and his lawyer respond to this doublespeak?

The following scientifically-valid articles by leading experts are illustrative of the knowledge that should be possessed by all surgeons performing laparoscopic cholecystectomy after the year 1998.

After the large number of injuries during the early days of laparoscopic cholecystectomy in the United States, Dr. John G. Hunter published an article entitled “Avoidance of Bile Duct Injury During Laparoscopic Cholecystectomy”, Am. Journal of Surg. Vol. 162, pp. 71-76, July 1991. Dr. Hunter’s thorough teachings can be boiled down to 5 factors that should be followed in order to prevent common bile duct transections. They are:

1) Use of a 30 degree forward oblique viewing telescope over a 0 degree forward-viewing optic allows better visualization of the location of the common bile duct. The view of the common bile duct with a 30 degree optic is nearly the same as that obtained from a right subcostal incision (as done in “open technique”). In addition, the ability to change perspective by rotating the 30 degree optic allows better visualization of the critical anatomy than can be obtained with a 0 degree optic or through a subcostal incision.

2) Cephalic (“towards the head”) traction on the fundus of the gallbladder that is

necessary to open the porta hepatis and reduce redundancy in the gallbladder infundibulum. It can be difficult to expose the junction of the gallbladder and cystic duct if this step is not performed. It is during this step that the decision to convert to open cholecystectomy should be made. If the dissection is bloody, if a difficult teasing dissection results in gallbladder holes, or if the anatomy is unclear, the prudent surgeon will convert to open cholecystectomy. This decision is the most difficult to teach students of laparoscopic cholecystectomy.

3) Lateral retraction of the neck of the gallbladder which places the cystic duct at right angle to the common bile duct reducing the likelihood of misidentification.

4) No clip should be placed on and no incision should be made in any structure until the transition between the cystic duct and the gallbladder infundibulum is clearly visualized. It is not adequate to see the cystic duct "entering" the gallbladder as this may belie a tented common bile duct coursing behind the gallbladder, drawn up by chronic inflammation. That is, the cystic duct must be seen widening into the gallbladder before one can certify accurate anatomic identification. In case of the absent, or short, wide-mouthed cystic duct identified during this step or in step 5, the surgeon must consider conversion to open cholecystectomy or develop the skills to laparoscopically suture the cystic duct stump without impinging on the lumen of the common bile duct.

5) Operative cholangiography is as valuable for the anatomic information it provides as for the detection of stones within the common bile duct. Cholangiography involves injecting a dye contrast into the cystic duct which then travels up and down the common duct to identify stones and to illuminate the biliary tree providing the surgeon with a visual image of the biliary tree. If the biliary tree does not light up, then the surgeon should assume he or she has placed the catheter to inject a dye contrast into the common duct which should not be transected as the cystic duct is the only duct to be identified and transected.

Defendant surgeons and Defense experts advocate selective use of a laparoscopic cholangiography when an injury occurs and cholangiography was not performed. They cite the low incidence of clinically significant unsuspected bile duct stones as a reason not to do cholangiography. Dr. Hunter writes "...couched behind this argument may be the real reasons why a routine cholangiography is not being performed: many surgeons perceive it as difficult, time-consuming, and dangerous, and consider the initial films frequently inadequate. However, these perceived difficulties can be overcome with proper trocar placement and practice and fluoroscopic cholangiography only adds 5-10 minutes of additional procedure time."

Less professional surgeons fail to take the time to become proficient in laparoscopic cholangiography thus exposing the patient to risks by not using an important available safety measure. Further, if the surgeon is not sure of the anatomy, he or she should convert to an open

procedure to make sure that before the surgeon clips or cuts any duct that he or she has identified it to a certainty.

Dr. Nathaniel Soper has made numerous contributions to journals and his teaching is best illustrated by his chapter entitled "An Analysis of the Problem of Biliary Injury During Laparoscopic Cholecystectomy". The teachings to be gleaned by Dr. Soper's direction can be summarized as follows:

> "Because a cystic duct and artery are the structures to be divided, it is these structures and these structures only that must be conclusively identified in every laparoscopic cholecystectomy. Accordingly, the cystic duct and artery should not be clipped or cut until conclusively identified. To achieve conclusive identification, Calot's Triangle must be dissected free of fat, fibers, and areolar tissue and the lower end of the gallbladder dissected off the liver bed (the latter is an essential measure that precludes the possibility of injury to an aberrant duct). At the completed dissection, there should be only two structures seen to be entering the gallbladder, and the bottom of the liver bed should be visible. Note that it is not necessary to see the common duct. It is at this point that the surgeon has achieved the Critical View of safety and the cystic structures may be occluded because they have been conclusively identified. Failure to achieve the Critical View of Safety because of difficulty of dissection as a result of inflammation or any other cause is an absolute indication for cholangiography or conversion to open cholecystectomy to define ductal anatomy..."

Even Dr. Lawrence Way (frequently used as a Defense expert) of the University of California - San Francisco has written an editorial in a surgical journal entitled "Bile Duct Injury During Laparoscopic Cholecystectomy". Dr. Way's editorial was published shortly after Dr. Hunter's article published in 1991.

In 1992, Dr. Way in his Editorial cited the five steps proposed by Dr. Hunter aimed at preventing bile duct injuries during laparoscopic cholecystectomy. The five steps of Dr. Hunter are noted above. In addition, Dr. Way stated, "I would add the following items to Dr. Hunter's list:

6. Using a cautery device with suction/irrigation capabilities because it allows the surgoen to keep the operating field much cleaner;

7. Using caution when interpreting cholangiogram findings because it may be more difficult than anticipated to recognize when the cholangiogram catheter enters the common duct rather than the cystic duct;

8. Always assuming that the common duct is occluded when it does not opacify;

9. Never using the cautery, laser, or clips blindly to control bleeding."

Dr. Way continues, "In general, however, I believe that most duct injuries that occur during laparoscopic cholecystectomy can be avoided by more thorough proctoring of neophyte laparoscopic surgeons, more liberal 'routine' use of cholangiography, and a greater willingness to convert to open cholecystectomy when dissection becomes bloody or is otherwise difficult. Laparoscopic cholecystectomy has been performed widely in the United States for about 2 years (at the time in 1992). In a sense, it is fortunate that specific information on bile duct injuries has become available so soon, because it **provides clear directions for prevention** (Emphasis added)..."

Later, in 2002, Dr. Way changed his mind. Wonder why? Now, Dr. Way, in his article entitled "Causes and Prevention of Laparoscopic Bile Duct Injuries - Analysis of 252 Cases from the Human Factors and Cognitive Psychology Perspective" Volume 237, Number 4, pages 460-469, *Annals of Surgery*, April 2003, concludes that the primary cause of error in 97% of the cases reviewed in the study was a "visual perception illusion" and that fault in technical skill was present in only 3% of the cases. Dr. Way's reversal of his opinion that most all common bile duct injuries can be prevented by using proper technique is based upon his review of medical records of 252 cases where surgeons charted their technique. Based on the author's 18 years of medical negligence practice for both the Defendant and the Plaintiff, no surgeon is going to dictate that he used improper technique during any general surgery or laparoscopic surgery. Dr. Way concluded that a mis-perception (like an "optical illusion" maybe) and not errors of skill, knowledge or judgment was the cause of the bile duct injury and these mis-perceptions were so compelling that in most cases the surgeon did not and could not recognize a problem; hence no negligence, even though the same studies by Dr. Way continued to show there are only a few stages within laparoscopic cholecystectomy where the injury -causing errors occur (which suggests that focused training to heighten vigilance would be able to decrease the incidence of bile duct injury.)

Dr. Way wrote in 1992 that if the detailed steps were followed, bile duct transections would be prevented. Yet, in 2002, after testifying for many years for Defendants in laparoscopic cholecystectomy cases, he wrote that injuries were not caused by a lack of skill and technique but due to a "visual perception illusion".

It is interesting that none of the leading surgeons across the country at the top medical schools have experienced a common bile duct transection during laparoscopic cholecystectomies they performed. This fact directly contradicts the insurance industry's campaign to mislead the factfinder by stating that a common bile duct transection of the wrong duct is a "recognized complication." Recognized complications of surgery are infection and sometimes bleeding, but not misidentification and transection of the wrong anatomy. If the

surgeon can't see clearly sufficient to identify the cystic duct to a certainty laparoscopically, he must open the patient's abdomen, then see, then cut .

Judges have begun to recognize and censure such Defense industry tactics in other medical malpractice cases. On June 1, 2005, a five-judge Court in *Salvant v. State, 2004-0805* (La.App.4Cir.), the Court of Appeal REVERSED a finding of no negligence by the trial court at a review panel. The Court found that an American College of Obstetrics and Gynecology (ACOG) article authored and relied upon by the Defense expert was misleading. The article had concluded that 50% of all brachial plexus injuries to newborns occurred without shoulder dystocia. (Shoulder dystocia occurs when the shoulder gets stuck in the birth canal and the nerves of the neck are pulled apart as the obstetrician pulls the baby's head out of the uterus forcefully rather than performing a C-section.) In support of their contention that the cause of the child's injury was not due to the doctor's negligence, the Defendants sought to prove that brachial plexus injuries occur without a shoulder dystocia diagnosis by introducing a study by a defense expert concerning brachial plexus injuries. The article ("Brachial Plexus Palsy, an in Utero Injury") which appeared in the American College of Obstetrics and Gynecology (ACOG) bulletin basically stood by the conclusion that 50% of all brachial plexus injuries occur without shoulder dystocia. These results were compiled based upon a computerized review of all hospital discharge summaries between 1991 and 1995, and concluded that 34%-47% of all brachial plexus injuries occur routinely without a shoulder dystocia diagnosis by the medical staff.

However, as pointed out by the Plaintiff's expert during his testimony, the findings of the defense expert's study are misleading. If an infant is diagnosed as having a shoulder dystocia complication during the delivery procedure, and the diagnosis is not documented in the medical chart, but the child suffers a brachial plexus injury which is documented in the medical chart, then the conclusion may be incorrectly drawn that the shoulder dystocia had nothing to do with the brachial plexus injury.

The study was found to be unreliable and misleading and the Appellate Court reversed the decision in favor of the Defendant at the trial court. The Court found that the study had an inherent ascertainment bias in that physicians may not chart what actually occurred during the delivery process or there may be incomplete documentation by medical staff who prepare the medical notes.

In other examples of "Litigation Literature" In the area of birth-injury when brain injury occurs due to oxygen deprivation, the purpose is to try to convince judges and juries of two things: (1) Depriving babies of oxygen during the birth process almost never causes brain injury; and (2) nothing an OB does or does not do can cause or prevent a baby from suffering a brain injury. These articles are dangerous according to Joel Cunningham, Esq. not only because they can and do mislead judges and juries, but also because they can and do mislead healthcare providers. "The Litigation Literature", by Joel Cunningham, Esquire, Washington State Trial Lawyers Association, Volume 39-2, October 1, 2003.

ACOG "produced" a 2003 study entitled "Neonatal Encephalopathy in Cerebral Palsy: Defining the Pathogenesis and Pathophysiology." This ACOG article sets forth criteria that it said had to be met before an acute hypoxic intrapartum event (lack of oxygen during the birth process) could be said to cause cerebral palsy in a baby. The "essential criteria" were defined as:

1. Cord blood Ph of less than 7.0 and base excess of 12 mmol/L or more;

2. Early onset of severe or moderate neonatal encephalopathy in babies 34 or more weeks gestation;

3. Cerebral palsy of a quadriplegic or dyskenetic type; and,

4. Exclusion of other causes.

If each of these criteria have not been met, said ACOG, then the baby was not damaged from a lack of oxygen during the birth process (Please note that MRI studies of the brain, which can actually document with pictures of the brain, the cause and timing of the brain injury were relegated to only being "supportive" of an intrapartum event. MRI and CT's in the neonatal period can provide conclusive proof of intrapartum hypoxic injury. If the above criteria are not met, the MRI pictures of the brain are simply overruled. This is a huge hole in ACOG's attempt to define a way intrapartum hypoxic events cause Cerebral Palsy.)

In effect, the ACOG authors so narrowly defined birth asphyxia as a diagnosis of Cerebral Palsy that it virtually would never be diagnosed using such strict criteria. Criteria #4 went so far as to make birth asphyxia a diagnosis of exclusion. Thus, when epidemiologic studies were done using this narrow definition, birth asphyxia was found to be a minuscule cause of Cerebral Palsy.

The ACOG article claimed that its purpose was to accurately define and diagnose acute hypoxic and intrapartum events and to help clinicians in practice. However, the true purpose of the article was not something that helped doctors accurately "define" birth asphyxia but rather to rule it out for professional liability purposes. In fact, ACOG advertised the monograph purpose to its members when it stated:

> "This report contains a set of criteria that may be used to define (or rule out) an acute intrapartum hypoxic event sufficient to cause or suggest cerebral palsy. These criteria and the body of the evidence contained in the report may prove to be useful reference tools for addressing clinical care **and professional liability"** (Emphasis added).

Another "litigation literature example" - Technical Bulletin #163 (1992) by ACOG averred that fetal or neonatal brain injury cannot be said to be caused by birth events like lack of oxygen unless all four of the following criteria were met:

1. Ph of less than 7.0;

2. Apgars of 0-3 for five or more minutes;

3. Neonatal difficulties like seizures and coma; and,

4. Multi-organ dysfunction following birth.

(Please carefully note that criteria #2 and #4 are no longer "essential" under ACOG's latest criteria.)

Statistics from the medical literature were manipulated to create this false sense of "essential criteria." Obstetricians and hospitals quickly discovered they could defeat causation in court under Bulletin #163 simply by having the nurses assign an Apgar of 4 (on a scale of 10) at five minutes of age, thereby denying the Plaintiff one of the four criteria. Higher Apgar scores became more "liberally" assigned to very sick babies according to Attorney Cunningham. The ACOG theory that a huge majority (80%-90%) of babies born with neonatal encephalopathy suffer brain damage *before* labor begins (making the brain damage un-preventable by the OB of course) was put to test by physicians at the Imperial College, Hammersmith Hospital, England; the University Medical Center, Utrecht, Netherlands; and Catholic University, Rome, Italy. 351 infants with either neonatal encephalopathy (Group 1) or seizures without neonatal encephalopathy (Group 2) were studied. If the baby lived, MRI was used to determine the existence and timing of brain injury; if the baby died, an autopsy was performed.

When the results of the infants' MRI's were performed, 80% of the infants who had scans had evidence of hypoxic-ischemic brain damage that had occurred during labor and delivery. Of the 45 who had autopsies (some had scans and autopsies) all 100% had evidence of hypoxic-ischemic brain damage that occurred in labor and delivery.

With Group 2 infants, 69% of the babies showed brain injury occurring acutely during the labor and delivery process. In the remaining 28 babies, some had a specific non-hypoxic-ischemic diagnosis and several had a normal scan.

These results are almost exactly the opposite of what ACOG had predicted in the 2003 article. The study trashes 3 out of the 4 criteria that ACOG called "essential" in 2003. ACOG's article in 2003 had stated:

> "Our findings show that more than 90% of term infants with neonatal encephalopathy, seizures, or both, but without specific syndromes or major congenital defects, had evidence of perinatally acquired insults, there was a very low rate of established brain injury acquired before birth...
>
> Our data therefore, did not support findings suggesting that the main cause of Cerebral Palsy in term infants with intrapartum hypoxic events arise in the antenatal period (but rather occur due to lack of oxygen during the birth process). ACOG's findings were not

supported by the autopsy results and MRI pictures of the brain that cannot seriously be refuted. For those interested in looking at the world literature for honest medical literature, they would not be well-served by looking at the ACOG literature, at least on causation of brain injuries." Id., Cunningham.

Defense experts and insurance companies are not the only ones who can write misleading article to be used by Defense experts in litigation. If you will remember the $5.3 billion punitive damages award given in the *Exxon vs. Valdez* case, and the fact that the Appellate Court sent the case back for a reassessment of punitive damages. On December 3, 2003, the *Los Angeles Times* published an article entitled "Funding Studies to Suit Need." The article stated:

> "In 1994, it was the biggest punitive damages judgment in history: $5.3 billion that an Alaskan federal judge awarded to a fisherman...
>
> Three years later, as Exxon waged its appeal, a new line of research began to appear in several respected academic journals and Ivy League law reviews. Some articles challenged the competence of juries to fairly set punitive damages. Others suggested that such awards were ultimately bad for society.
>
> Exxon Corporation cited several of the articles in the Appeal. **What it did not say in court filings is that it had funded the research** (Emphasis added)." Cunningham, "Litigation Literature" (Part 2), Volume: 39-6, Feb. 1, 2004 WSTLA.

Bias is also found in published "studies" of laparoscopic cholecystectomies and bile duct injuries in which the Author experts fail to distinguish between transections of bile ducts that were misidentified versus small nicks, tears, injuries to accessory ducts, leaks from the ducts of Luschka, intentional but harmless small slits into the duct to perform a cholangiogram that are easily repaired when the wrong duct has been cannulated, and other similar events. Defense experts generally group all of these together claiming that larger numbers of injuries occur, (and thus are "well-recognized complications") if it fits their purpose under the individual circumstances of a particular case. "Peer-reviewed" defense-biased articles stating that transecting the wrong bile duct is "a well-known complication" are thus used to mislead jurors not only by their failure to cite known techniques that prevent misidentification of the common duct but also group nicks, intentional incisions used to perform cholangiograms, injury to accessory ducts (often causing no harm to the patient closing off on their own) with preventable common duct transections. That grouping is comparing apples to oranges but identifying all as apples.

Surgeons have studied and trained for many years. They are highly paid and should be held responsible for the damage they cause when they fail to take sufficient steps to certify that they are about to transect the correct duct (cystic duct). There is only one duct to be transected in a laparoscopic cholecystectomy. If a surgeon is not sure, he or she should stop and either perform a cholangiogram (dye study that highlights the biliary tree) or convert to an open

procedure where he or she can see, touch and feel and distinguish the anatomy. **How many bile duct transection lawsuits occurred before 1990 when the old-fashioned technique for gallbladder surgery was utilized? <u>The answer is none or close to none</u>**. The reason there were no lawsuits filed is because there were no bile duct transections because the surgeon was able to distinguish and identify the correct duct to transect to remove the gallbladder when the procedure is performed using the "open technique." Defendants also go to trial today knowing that the transection injury resulted from carelessness or improper technique. However, they hope to take advantage of the defense bias of jurors that the insurance industry has cultivated for the last decade. Many jurors are simply not going to award, in the current climate, significant money to a Plaintiff because insurers (and politicians) have convinced the public that medical negligence cases are too expensive to society. (In fact, all litigation costs, attorneys' fees and pay-outs amounted to less than 1% of the nation's total health costs at the height of the "Medical Malpractice Crisis". False and misleading articles, stories, speeches and advertisements similar to the false and misleading data mentioned in this paper led to this erroneous belief. .

People often don't know they are being misled because surgery, obstetrics, prescription medicine, and oil spills are outside their experience. Now that we and the Courts are somewhat better informed, at least the surgeon can do is pay (like any other profession does) for their preventable errors and mistakes.

At the very least, if the "non-preventable" error defense is to be used by the surgeon, he/she should have the patient sign the following "informed consent" form:

> I have been informed by Dr. Goodknife, that as careful as he may be, it is possible that he may still misidentify and cut across the wrong bile duct during my surgery , and even though this will cause serious and permanent future injury, pain and suffering, he simply "can't help it". With this knowledge, I consent to the surgical procedure, and all the severe risks that can't be avoided , as my doctor has advised. I choose not to undergo an open procedure where there is essentially no risk of misidentification and cutting across the wrong duct .

How many patients would sign up?

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