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Case Number 26,2018
TE OF DELAWARE

IN THE SUPREME COURT OF THE STATE OF DELAWARE

AMANDA M. NORMAN,

Plaintiff Below,

Appellant,

NO. 26, 2018

VS.

ALL ABOUT WOMEN, P.A., a

Delaware Corporation and

CHRISTINE W. MAYNARD, M.D.,

Individually,

Court Below:

Superior Court of the State of Delaware

C.A. No. K14C-12-003 WLW

Defendants Below,

Appellees.

APPELLANT'S OPENING BRIEF

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NATURE OF PROCEEDINGS

Amanda Norman ("Plaintiff") filed a Complaint against All About Women, P.A., a Delaware Corporation, and Christine W. Maynard, M.D. individually ("Defendants") in the Superior Court on December 3, 2014. The Complaint alleged that Ms. Norman was seriously injured when Defendant, Christine W. Maynard, M.D., negligently and in breach of the applicable standard of care, perforated Ms. Norman's bladder and then failed to recognize and treat this injury during a diagnostic laparoscopy. Defendants filed a Motion for Summary Judgment on January 16, 2017. Plaintiff responded to the Motion on January 30, 2017. Defendants filed five Motions in Limine on February 7, 2017. Plaintiff responded to Defendants' five Motions on March 7, 2017. On March 10, 2017, the trial court granted Defendants' requests to respond to Plaintiff's response in opposition. The trial court deferred Defendants' Motion for Summary Judgment. For appeal purposes, the trial court, on November 16, 2017, granted Defendants' Motion to exclude the expert testimony of Dr. Jeffrey L. Soffer, Plaintiff's standard of care expert. The trial court granted Defendants' Motion for Summary Judgment on December 19, 2017. Ms. Norman filed a timely appeal of these decisions with this Court on January 12, 2018. This is Ms. Norman's Opening Brief in support of her appeal which seeks the reversal of the Superior Court's dismissal of her claim on a Motion for Summary Judgment and a reversal of the Superior Court's Order

precluding the testimony of Dr. Soffer at trial of Plaintiff's claims against Defendants.

SUMMARY OF ARGUMENT

Under D.R.E. 402, D.R.E. 702, and relevant case law, a witness may 1. be qualified as an expert by knowledge, skill, experience, and/or training. Jeffrey L. Soffer, M.D. is qualified to provide expert testimony as to the applicable standard of care to be utilized by a physician performing a laparoscopy on the Plaintiff. Dr. Soffer has been board certified in obstetrics and gynecology for more Dr. Soffer has performed several hundred laparoscopic than twenty years. surgeries. Thus, Dr. Maynard's actions fall within Dr. Soffer's area of expertise and Dr. Soffer is 'familiar with the degree of skill ordinarily employed in the field of medicine on which he will testify' pursuant to 18 Del. C. § 6854. During his performance of several hundred diagnostic laparoscopy procedures in his practice, Dr. Soffer never caused an injury to the bladder. Defendants' expert witness, Jeffrey G. Obron, M.D., has performed approximately one thousand laparoscopic procedures in his thirty-six years of practice, and never caused damage to the bladder during any of these procedures.

In complying with the standard of care, Dr. Soffer testified about the importance of the operating physician knowing the exact anatomic position of adjacent structures in order to avoid injury. He also testified that injury to an adjacent structure should not occur when the physician has direct visualization during the placement of the secondary trocar (one of the surgical instruments used

in Ms. Norman's procedure). Dr. Soffer testified that Plaintiff's bladder injury occurred during Defendant Maynard's placement of a secondary trocar under direct visualization. Since Defendant Maynard testified she believed the bladder was nowhere near the operative field, Defendant Maynard failed to appreciate the anatomic position of Plaintiff's bladder and failed to appreciate her perforating it with a secondary trocar though she had visualization of this. Dr. Soffer's testimony regarding Dr. Maynard's failures to adhere to the applicable standard of care are warranted and constitute admissible evidence. To the extent another doctor disagrees, such a disagreement as to the applicable standard of care can only be resolved by the trier of fact. This is not a *Daubert* analysis because this matter deals with basic surgical technique.

2. Dr. Soffer raised a second issue of Dr. Maynard's deviation from the standard of care when she injured Ms. Norman's bladder and failed to appreciate and address the injury during the procedure. Before concluding a surgery, a physician is supposed to meticulously look at all adjacent structures and organs to ensure there is no injury. Dr. Maynard failed to appreciate the anatomic position of Plaintiff's bladder, and she also failed to appreciate perforating Ms. Norman's bladder. Dr. Soffer testified that because Dr. Maynard was able to visualize the surgical field, she should have appreciated the perforation of Ms. Norman's bladder and treated it during the procedure. Dr. Soffer's testimony regarding Dr.

Maynard's failures to adhere to the applicable standard of care are warranted. Dr. Maynard failed to appreciate the actual location of the bladder being in the operative field, and her causing injury to it. Thereafter, Defendant Maynard failed to meticulously examine the bladder and discover the harm she caused and treat it. This failure also places her surgical technique in the medically negligence realm for the jury's consideration. Another medical expert offered by Defendants, Dr. Kevin J.E. Stepp, M.D., testified he has performed approximately 750 laparoscopic procedures and he has injured a patient's bladder in at least one of these surgeries. Dr. Stepp further testified that in each procedure that he injured the bladder, he discovered the injury during the operation.

STATEMENT OF FACTS

Plaintiff, Amanda Norman, underwent a diagnostic laparoscopy performed by Defendant, Christine Maynard M.D. on October 22, 2013, at Christiana Hospital. (A-20-22). Immediately after surgery, Plaintiff, Ms. Norman experienced sharp, intense pain in her lower abdomen. (A-24). Ms. Norman immediately communicated her pains to a nurse. (A-24). Ms. Norman sought to see Dr. Maynard about this. (A-25). Ms. Norman recalls Dr. Maynard informing her that the results of her biopsy were negative, and stating that pain from surgery is expected. (A-26).

On October 23, 2013, the day after Ms. Norman's surgery, the pain worsened. (A-26). Ms. Norman was dizzy, she felt weak, and her muscles were not working. (A-26). On October 24, Ms. Norman's boyfriend called Defendant, All About Women, to relay Ms. Norman's symptoms. Defendant told him that she needed to go to OB Triage. (A-26-A-27). Ms. Norman went to OB Triage, at Christiana Hospital where a doctor who saw her told her the problem was not OB, and sent her to the emergency room. (A-27). At the emergency room, Ms. Norman underwent a CT scan to ensure she was not having a stroke. (A-27). Doctors did not know what was wrong with Ms. Norman, and they sent her home that day with instructions to drink water because she was dehydrated. (A-27).

The next day, October 25, 2013, Ms. Norman's boyfriend was not able to wake Ms. Norman up so he called 911. (A-28). Ms. Norman had no muscle control, she could not hold herself in a sitting position, she struggled to talk, and the pain in her stomach was greater than ever. (A-28). Ms. Norman remembers the ambulance taking her into Union Hospital in Elkton, Maryland on a stretcher, and hospital staff panicking because something was clearly wrong. (A-28).

Surgeons at Union Hospital discovered that Ms. Norman's bladder had been ruptured. (A-28). Ms. Norman's bladder was not able to excrete urine. (S-34). Ms. Norman was going into shock and her stomach was filled with fluids that leaked through her bladder. (A-29). High creatinine and BUN levels prompted the doctors to make the diagnosis of uremia and an emergent exploratory laparotomy was performed, which discovered her injured bladder condition. (A20-A22; A-34). The doctors at Union Hospital, Dr. Lowe and Dr. Woo, told Ms. Norman that the only way her bladder could have ruptured in that fashion was from the laparoscopic surgery. (A-28). Ms. Norman was hospitalized for a week from this corrective surgery. (A-29).

Ms. Norman gradually experienced less pain after this corrective surgery. (A-29). Dr. Maynard called Ms. Norman some time after the corrective surgery, she stated that she had no idea how the injury could have happened (A-30). The scarring from the corrective surgery is substantial and unsightly. (A-31).

Moreover, Ms. Norman was not able to do household chores for six months after the surgery because of the pain. (A-31).

Dr. Maynard cannot explain what went wrong during the procedure. (A-55). Dr. Maynard believed that she was nowhere near the ureter and the bladder. (A-55 59).

Dr. Soffer testified that the secondary trocars are not blind entries, they are to occur under direct visualization. (A-39). If a surgeon cannot see clearly, the trocar should not be inserted. (A-39). Dr. Soffer testified that it is the surgeon's job to watch every centimeter of the entry of the secondary trocar into the abdomen with care so that the trocar can be directed so as to avoid the bowel and the bladder. (A-39). Dr. Soffer opined that every professional who performs gynecologic surgery knows where the bladder is and they look for it specifically. (A-38). Dr. Soffer testified that he believes the secondary trocar caused Ms. Norman's bladder injury. (S 14). Dr. Soffer stated that if a surgeon pushes the trocar in too far and is too forceful with entry, the trocar will go directly into the dome of the bladder. (A-35).

Dr. Soffer has performed several hundred diagnostic laparoscopy procedures. (A-40). Dr. Soffer never caused an injury to the bladder in any of his diagnostic laparoscopy procedures. (A-40). Defendants' expert witness, Dr. Jeffrey G. Obron, M.D., testified that he has performed approximately one

thousand laparoscopic procedures in his thirty-six years of practice. (A-43). Dr. Obron further testified that he has never caused damage to the bladder during any of these procedures during the course of his extensive practice. (A-43). Defendants' other expert witness, Kevin J.E. Stepp, MD, testified that he has performed approximately 750 laparoscopic procedures and that he has injured a patient's bladder in at least one of these surgeries. (A-46). Dr. Stepp further testified that in each procedure that he injured the bladder, he discovered the injury during the operation. (A-46).

ARGUMENT

I. THE LOWER COURT ERRED IN PRECLUDING DR. JEFFREY L. SOFFER'S TESTIMONY REGARDING THE STANDARD OF CARE UNDER A DAUBERT ANALYSIS OF TWO SPECIFIC AREAS OF MEDICAL NEGLIGENCE. DR. SOFFER'S TESTIMONY FALLS WITHIN HIS AREA OF EXPERTISE, COMPLIES WITH DELAWARE'S STANDARD OF CARE, AND CONSTITUTES ADMISSIBLE TRIAL TESTIMONY. THUS, DEFENDANTS WERE NOT ENTITLED TO SUMMARY JUDGMENT OF DISMISSAL.

(1.) QUESTION PRESENTED:

Did the Superior Court err in granting summary judgment when it found that Dr. Soffer's opinion and testimony was unreliable because it did not rely upon medical literature or peer reviewed publications, when Dr. Soffer opined about two areas of medical negligence occurring during a basic diagnostic laparoscopy, given his expertise as a doctor specializing in gynecology with more than twenty years of experience, having performed several hundred laparoscopic surgeries and the reasons provided for his opinions? (See, Exhibits A & B; A-99-118; A-119-126; A127-144.)

(2.) SCOPE OF REVIEW:

On appeal from a grant of summary judgment, this Court reviews the matter de novo.¹ Summary judgment will only be granted upon a showing that there is no genuine issue of material fact and that the moving party is entitled to judgment as a

¹ ConAgra Foods, Inc., v. Lexington Ins. Co., 21 A.3d 62, 68 (Del. 2011).

matter of law.² The record must be read in a light most favorable to the party against whom summary judgment is sought.³ If there is any evidence supporting a favorable conclusion to the nonmoving party, stating facts in the light most favorable to him, summary judgment must be denied.⁴ Secondarily, this Court normally applies an abuse of discretion standard when it reviews a trial court's decision to admit or exclude expert testimony.⁵ "In reviewing the motion judge's decision, we review the motion judge's findings of fact 'to determine if they are supported by the record and are the product of a logical and orderly reasoning process."

(3.) MERITS OF ARGUMENT:

A. DR. SOFFER IS QUALIFIED TO GIVE EXPERT TESTIMONY AS TO THE APPLICABLE STANDARD OF CARE AND DEFENDANT MAYNARD'S DEVIATION THEREFROM BY UTILIZING IMPROPER SURGICAL TECHNIQUE WHEN SHE PERFORATED MS. NORMAN'S BLADDER. AS SUCH, DEFENDANTS WERE NOT ENTITLED TO SUMMARY JUDGMENT OF DISMISSAL OF PLAINTIFF'S MEDICAL NEGLIGENCE CLAIMS.

The trial court erred in its ruling which precluded the expert testimony of Dr. Soffer. There is no medical evidence of record to uphold the ruling that Dr.

² Super. Ct. Civ. R. 56 (c).

³ Matas v. Green, 171 A.2d 916 (Del. 1961).

⁴ Plant v. Catalytic Constr. Co. 287 A.2d 682 (Del. Super. Ct. aff'd. 297 A.2d 37 (Del. 1971)).

⁵ M.G. Bancorporation v. Le Beau, 737 A.2d 513, 522 (Del. 1999).

⁶ GMC v. Grenier, 981 A.2d 524, 527-28 (Del. 2009).

Soffer's opinions are not reliable. The trial court misused and confused the *Daubert* standard with the medical negligence standard of care that is relevant in this matter. This matter does not involve a bona-fide *Daubert* issue since it deals with basic surgical technique used during a standard, common procedure. *Daubert* analysis' is typically used to exclude novel and unaccepted medical theories or practices which some label "junk science." Dr. Soffer's testimony regarding Defendant Maynard's surgical techniques fall within his area of expertise.

Under D.R.E. 702, the judiciary is charged with assessing whether the reasoning or methodology of an expert is scientifically or technically valid. This assessment is a liberal one that supports admission of all expert testimony that will assist the trier of fact to understand the evidence or to determine a fact in issue. This liberal application is supported by D.R.E. 402, which states that all relevant evidence is admissible. Under the D.R.E. and pertinent case law, a witness may be qualified as an expert by knowledge, skill, experience and/or training. 10

To be qualified to provide expert testimony as to applicable standards of care, an expert witness must be "familiar with the degree of skill ordinarily employed in the field of medicine on which he or she will testify." The Supreme

⁷ See *Minner v. Am. Mortg. & Guar. Co.*, 791 A.2d 826 (Del. Super. Ct. 2000).

⁸ See A-40.

⁹ D.R.E. 702; Ward v. Shoney's, Inc., 817 A.2d 799, 803 (Del. 2003).

¹⁰ Bell Sports, Inc. v. Yarusso, 759 A.2d 582, 588 (Del. 2000).

¹¹ 18 Del. C. § 6854.

Court in *Dishmon*, while discussing the Affidavit of Merit requirements of 18 *Del*.

C. § 6853, reinforces the standard that § 6854 only requires a practitioner "establish his or her familiarity with the degree of skill ordinarily employed by a practitioner of the type about which he or she will be offering an opinion." ¹²

"As a threshold matter, Daubert neither requires nor empowers Trial Courts to determine which of several competing scientific theories has the best performance." Daubert hearings were created for Courts to determine the soundness of an expert's opinions." A Daubert hearing is meant to be a manageable evidentiary hearing where the Trial Judge can outline and evaluate the qualifications of an expert prior to trial. Expert opinion evidence under Delaware law is governed by Delaware Rule of Evidence 702, which provides:

"If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." ¹⁶

¹² Dishmon v. Fucci, 32 A.3d 338, 343 (Del. 2011).

¹³ Minner v. Am. Mortg. & Guar. Co., 791 A.2d 826, 848 (Del. Super. Ct. 2000).

¹⁴ *Id.* at 844.

¹⁵ *Id*.

¹⁶ *Tumlinson v. Advanced Micro Devices, Inc.*, No. : 08C-07-106 FSS, 2013 Del. Super. LEXIS 601, at *3-4 (Super. Ct. Oct. 15, 2013).

Testimony based on experience rather than literature is properly allowed under the United States Supreme Court *Daubert* standard.¹⁷ "*Daubert* requires the trial judge to act as a 'gatekeeper,' determining whether the proffered evidence is both 'relevant' and 'reliable.'"¹⁸ "Under *Daubert*, 'relevant' means the evidence relates to an issue and it will aid the fact finder."¹⁹ "'Reliable' means testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known."²⁰ Dr. Soffer's opinion was based on good grounds, and what is known. Dr. Maynard had visualization of the surgical field, should have appreciated the bladder's location, and should not have perforated it with a secondary trocar. Under these circumstances, Defendant Maynard's surgical techniques deviated from the standard of care.

The reliability of the expert's opinion depends, in part, upon his competency within his field of expertise, i.e., the expert must be qualified to render the opinions he intends to offer at trial.²¹ "...[T]he key to the 'reliability' inquiry is to ensure that an expert, whether basing testimony upon professional studies <u>or personal</u> experience, employs in the courtroom the same level of intellectual rigor that

¹⁷ See Seifert v. Balink, 2017 WI 2, 372 Wis. 2d 525, 888 N.W.2d 816.

¹⁸ *Id.* at *4.

¹⁹ *Id.*

 $^{^{20}}$ *Id.* at 5.

²¹ Jones v. Astrazeneca LP, No. 07C-01-420-SER, 2010 Del. Super. LEXIS 128, at *23 (Super. Ct. Mar. 31, 2010).

characterizes the practice of an expert in the relevant field."²² Thus, under a Daubert analysis, Dr. Soffer meets all applicable qualifications to give opinion testimony on Dr. Maynard's breach of the standard of care in light of his twenty years of experience in the relevant field of medicine and the performance of several hundred laparoscopic procedures without bladder injury.

Dr. Soffer opined as to negligent technique employed in a fairly standard surgical procedure. At best, this case involves a difference in opinion between medical doctors. This contradiction is for the jury to decide, not for the trial court to exclude testimony of one expert. Defendants misguide their focus, stating that Dr. Soffer's testimony is not reliable because he stated that because there was an injury, there was negligence. This is inaccurate. Rather, Dr. Soffer testified that Dr. Maynard was able to visualize the surgical field during Ms. Norman's diagnostic laparoscopy, it was not a blind procedure. Dr. Soffer is qualified to testify as to methods and techniques employed in surgery as they relate to ensuring that the operating physician know the exact position of where they are operating and the position of a patient's organs in order to avoid injury and that a patient does not suffer injuries as a result of the surgery. Dr. Maynard testified that she did not think she was anywhere near the bladder. (A-54). Dr. Maynard also testified that Ms. Norman was normal, anatomically speaking. Dr. Soffer's

²² *Id.* at 24.

testimony was that there was negligence because Dr. Maynard was able to visualize the location of the organs, and because she could see the operative field and see where she was placing her instruments, a secondary trocar's injury to the bladder was the result of poor surgical technique. (A-65 – A-66). This testimony does not require a *Daubert* analysis.

This matter deals with the standard of care employed when performing a diagnostic laparoscopy. This particular procedure does not involve the bladder.

Ms. Norman's bladder was perforated when Dr. Maynard exercised improper technique, falling below the applicable standard of care. Dr. Soffer's opinions are reliable based on his own experience in the same/similar field of practice. Dr. Soffer has performed two hundred diagnostic laparoscopy procedures over the course of his practice. (A-40). Dr. Soffer never caused an injury to the bladder in any of his diagnostic laparoscopic procedures. (A-40). Defendants' expert witness, Dr. Jeffrey G. Obron, testified that he has performed approximately one thousand laparoscopic procedures (like the one in this matter) in his thirty-six years of practice. (A-43). Dr. Obron further testified that he has never caused damage to the bladder during any of these procedures in his practice. (A-43).

Dr. Soffer testified that he has read many articles and journal publications in his years of training and practice. Dr. Soffer explained that because Dr. Maynard could see the operative field, she should not have injured the bladder. Dr. Soffer

stated that with visualization, this injury should not occur. Because Dr. Maynard had visualization, and because Ms. Norman did not have any anatomical abnormalities, Dr. Maynard should not have injured the bladder. Her negligence is further amplified by her testimony that she did not think she was anywhere near the bladder, which was incorrect. This combination of facts is what Dr. Soffer explained to be Dr. Maynard's breach of the standard of care in her treatment of Ms. Norman.

Dr. Maynard cannot explain what went wrong during the procedure. (A-54). Dr. Maynard believed that she was not near the ureter and the bladder. (A-59). Dr. Soffer testified that he believes the secondary trocar caused Ms. Norman's injuries. (A-35; A-65 – A-66). Dr. Soffer stated that if a surgeon pushes the trocar in too far and is too forceful with entry, the trocar will go directly into the dome of the bladder. (A-35). Dr. Soffer's medical expert opinions are based upon substantial experience and are well grounded. His determination that a breach of the standard of care occurred during Defendant Maynard's surgical treatment is admissible to support Plaintiff's claim of medical negligence and is not defective under an appropriate *Daubert* analysis.

B. DR. SOFFER IS QUALIFIED TO GIVE EXPERT TESTIMONY AS TO THE APPLICABLE STANDARD OF CARE AND DEFENDANT MAYNARD'S DEVIATION THEREFROM WHEN SHE FAILED TO APPRECIATE AND TREAT THE PERFORATION OF MS. NORMAN'S BLADDER CAUSED BY HER. AS SUCH, DEFENDANTS WERE NOT ENTITLED TO SUMMARY JUDGMENT OF DISMISSAL OF PLAINTIFF'S MEDICAL NEGLIGENCE CLAIMS.

Dr. Soffer's opinion is based on 'reasonable grounds, and what is known.' During a diagnostic laparoscopy, like the one in this matter, the bladder is under direct visualization. (A-38). Introduction of the secondary trocars are not blind entries. (A-39). In fact, if a surgeon cannot see clearly, the trocar should not be inserted. (A-39). Dr. Soffer testified that it is the physician's job to watch every centimeter of the entry of the secondary trocar into the abdomen with care so that the trocar can be directed so as to avoid the bowel and the bladder. (A-39). Dr. Soffer opined that every professional who performs gynecologic surgery, knows where the bladder is and they look for it specifically. (A-38).

Defendants' medical expert, Dr. Kevin J.E. Stepp, testified that he has done approximately 750 laparoscopic procedures similar to the one in this matter. (A-46). Dr. Stepp stated that he has injured a patient's bladder in at least one of these surgeries. (A-46). Dr. Stepp went on to testify that in each procedure that he injured the bladder, he discovered the injury during the operation. (A-46).

Dr. Soffer testified that with Plaintiff's type of perforation, a surgeon will see a hole, and sometimes bleeding or a leakage of urine. (A-36). He stated that

the key is to look carefully to ensure nothing is out of order once the procedure is finished. (A-36). There is usually bleeding or oozing around the area of the perforation when it occurs. (A-37). Dr. Soffer opined that there was a full perforation caused by a trocar during Dr. Maynard's laparoscopic procedure on October 22, 2013. (A-37). After every surgery, a surgeon is supposed to meticulously look at all adjacent structures and organs to ensure there is no injury. (S 33; A -65 - A-66). The injury was missed and should have been discovered. (A-38).

Dr. Soffer's second opinion concerning a breach of the standard of care is both relevant and reliable. Dr. Soffer testified that because the surgical field is visible, Dr. Maynard should have appreciated the perforation and treated it. After Dr. Maynard failed to appreciate the actual location of the bladder being in the operative field and injuring it, she then failed to appreciate the injured bladder and treat it. This failure again places her surgical technique in the medically negligence realm for the jury's consideration. The record establishes that in more than a thousand procedures, none of the three medical experts injured the bladder and failed to appreciate and treat the injury during their procedure. Only Defendant Maynard deviated from this standard of care. Only she left an injured bladder untreated during her procedure, resulting in the emergent hospitalization and surgical treatment of her patient. Of note, Defendant Maynard's operative

report makes no mention of inspecting the bladder before ending the procedure though other structures are identified.²³ Thus, this record cannot permit one to conclude that a logical and orderly evaluation would determine there is no reliable basis to support the medical opinion of Dr. Jeffrey Soffer. This record supports a finding that Dr. Soffer's opinions are admissible and a view of the entire record in the light most favorable to the Plaintiff does not support Defendants' Motion for Summary Judgment.

²³ See A-20-A22.

CONCLUSION

For the aforesaid reasons, the Superior Court's Order precluding the testimony of Dr. Soffer at trial should be reversed and the Superior Court's Order granting summary judgment to Defendants should be reversed.

Respectfully submitted,

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