

statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

The rationale for the part of the rule stating that a treatise should not be made an exhibit is to prevent the jury from “roaming at large” through a treatise “forming conclusions not subjected to expert explanation and assistance.” See the attached section from Federal Practice & Procedure on the corresponding federal rule, discussing this very topic.¹

Under Texas law, a party can read an entire learned treatise into evidence, and/or show portions of the article or the whole article to the jury. See *Mauzey v. Sutliff*, 125 S.W.3d 71 (Tex. App. - Austin 2003, pet. denied) attached.² The Mauzey court recognized that when the rationale for the rule doesn't apply, there can be an exception made. Mauzey referenced the Advisory Committee statements about that, citing a federal decision where the court allowed charts from a treatise to be admitted as exhibits. The court observed that “[t]he Advisory Committee's Note shows that the purpose of the last sentence was to prevent a jury from rifling through a learned treatise and drawing improper inferences from technical language it might not be able properly to understand without expert guidance.” *Mauzey*, 125 S.W.3d at 84. In the *Mauzey* case, there was no danger that the jury would have misinterpreted the information or rifled through other parts of the learned treatises, because this was the only portion of the learned treatises the jury would have seen. *Id.*

¹ Exhibit A

² Exhibit B

APPLICATION TO THE CASE AT BAR

In the instant case, Plaintiffs' expert Dr. Good has recognized the Alan Spitzer text, Intensive Care of the Fetus and Neonate, as a reliable source. The Spitzer text is clearly a learned treatise under TRE 803(18). Moreover, Plaintiffs have questioned numerous expert witnesses, including Defendant Dr. Ponte, on Chapter 51 throughout the trial. Chapter 51, entitled *Retinopathy of Prematurity* was written by Defendants' expert witness, Graham E. Quinn.

Plaintiffs do not seek to admit the Spitzer text as an exhibit. Rather, Plaintiffs request that this Court allow Plaintiffs to admit only the 13 pages of Chapter 51 of the text.³ As in *Mauzey*, using only a portion of a learned text will minimize the concern of having a jury misinterpret the information or rifle through other parts of the learned treatise, because this would be the only portion of the treatise they would see.

FOR THESE REASONS, Plaintiffs request that the Court allow Plaintiffs to enter as an exhibit the relevant portion of the Spitzer text at trial.

Respectfully Submitted,

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³ Exhibit C

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing has been served upon all counsel of record on this 31st day of October, 2011, as follows:

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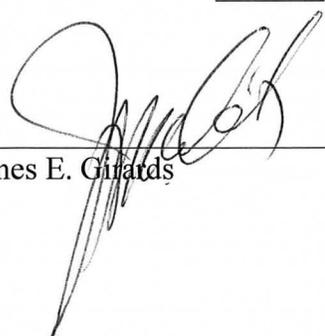
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30B Fed. Prac. & Proc. Evid. § 7059 (1st ed.)

Federal Practice & Procedure
 Federal Rules Of Evidence
 Current through the 2011 Update
 Michael H. Graham³⁸⁰
 Chapter 9. Hearsay
 B. Confrontation and Hearsay
 Rule 803(18) Learned Treatises

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§ 7059 Rule 803(18): Learned Treatises

To the extent called to the attention of an expert witness upon cross-examination or reasonably relied upon by an expert witness on direct examination, statements contained in published treatises, periodicals, or pamphlets¹ on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice, are admissible as an exception to the hearsay rule, Rule 803(18).² However the statement may only be read into evidence; the published authority may not be received as an exhibit.³

Views of recognized authorities, expressed in treatises, pamphlets or periodicals written for professional colleagues, may be employed on cross-examination of an expert witness to impeach⁴ provided the author's competency is established by an admission of the expert witness, by other expert testimony,⁵ by judicial notice,⁶ or possibly otherwise determined to be reliable by the court.⁷ Moreover, under Rule 803(18) such statements employed to impeach may also be received as substantive evidence.⁸ Statements in established reliable authorities may also be admitted for the truth of their content when relied upon by an expert witness upon direct examination.⁹

Whether a particular published authority has been sufficiently established as reliable is a decision for the court, Rule 104(a). Rule 803(18) provides that statements contained in a learned treatise, periodical, or pamphlet may be established as a reliable authority by the testimony of a witness expert in the profession, art, or trade of the author testifying that the learned treatise is a reliable authority or by judicial notice.¹⁰ Publications containing articles do not qualify wholesale; a foundation must be laid with respect to the particular article under consideration.¹¹ The burden of establishing that the authority is reliable is upon the party offering the item. The burden is easily satisfied.¹² Rule 803(18) is subject to Rule 403.^{12.5}

A safeguard against jury misuse of the published authority is found in the final sentence of Rule 803(18) which provides that statements may be read into evidence but shall not be taken to the jury room.¹³ This provision attempts to prevent jurors from overvaluing the written word and from roaming at large through the treatise thereby forming conclusions not subjected to expert explanation and assistance. In addition, statements in published authorities are admissible only under circumstances in which an expert is testifying. Whether relied upon in support of direct examination or raised on cross-examination, an expert witness will have an opportunity to evaluate and explain to the trier of fact how the statement contained in the learned treatise relates to the issues that they are to decide. *

Footnotes

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¹ Videotapes are also encompassed under Rule 803(18). *Costantino v. David M. Herzog, M.D., P.C.*, 203 F.3d 164, 171 (2d Cir.2000) ("In sum, we agree with the Texas Court of Appeals that '[v]ideotapes are nothing more than a contemporary variant of a published treatise, periodical or pamphlet.' *Loven v. State*, 831 S.W.2d 387, 397 (Tex.Ct.App. 1992). Accordingly, we hold that videotapes may be considered learned treatises under Rule 803(18).").

² With respect to the requirements of admissibility applicable generally to hearsay exceptions, see § 7041 supra. See generally *In re Welding Fume Products Liability Litigation*, 534 F.Supp.2d. 761, 764–65 (N.D. Ohio 2008) ("In a very real way, then, the authors of these articles and studies have a strong presence in the courtroom, providing 'virtual testimony' through repeated quotation and citation by the parties' attorneys and experts. That the quoted out-of-court statements in these articles and studies are not made under oath or subjected to cross-examination, of course, suggests a hearsay concern. But Federal Rule of Evidence 803(18) addresses precisely this point: ... The basis for this 'learned treatise exception' to the hearsay rule is that

learned treatises usually have ‘sufficient assurances of trustworthiness to justify equating them with the live testimony of an expert. *First, authors of treatises have no bias in any particular case.* Second, they are acutely aware that their material will be read and evaluated by others in their field, and accordingly feel a strong pressure to be accurate.’ 2 McCormick on Evidence § 321 (6th ed.2006) (emphasis added).”)

3 See *Johnson v. William C. Ellis & Sons Iron Works, Inc.*, 604 F.2d 950, 957 (5th Cir.1979) rehearing denied in part, opinion amended 609 F.2d 820 (5th Cir.1980) (“Rule 803(18) provides for the admission of information taken from treatises, periodicals or pamphlets that are ‘established as reliable authority.’ We have held that safety codes and standards are admissible when they are prepared by organizations formed for the chief purpose of promoting safety because they are inherently trustworthy and because of the expense and difficulty involved in assembling at trial those who have compiled such codes. *Frazier v. Continental Oil Co.*, 568 F.2d 378, 382 (5th Cir.1978); *Muncie Aviation Corp. v. Party Doll Fleet, Inc.*, 519 F.2d 1178, 1183 (5th Cir.1975); accord, *Davis v. Fox River Tractor Co.*, 518 F.2d 481 (10th Cir.1975); *Wallner v. Kitchens of Sara Lee, Inc.*, 419 F.2d 1028 (7th Cir.1969); *Boston and Maine Railroad v. Talbert*, 360 F.2d 286 (1st Cir.1966).”)

4 *Maggipinto v. Reichman*, 607 F.2d 621, 622–23 (3d Cir.1979), on remand 481 F.Supp. 547 (E.D.Pa.1979):
 Defendant was next confronted with two medical texts, *Oral Surgery* (3d ed.), edited by Kurt H. Thoma (Thoma); and *Oral and Maxillofacial Surgery* (5th ed.), edited by Archer (Archer). He acknowledged both to be authoritative. Plaintiffs’ counsel, who contends here that he was proceeding under Fed.R.Evid. 803(18), then proceeded in the fashion traditionally used to impeach an expert witness, referring the defendant to Thoma and asking

Do you agree with this statement: “Injury to the lingual nerve is not usually caused by the removal of a third molar, although it may occur if a tooth that erupts at the lingual surface of the jaw below the mylohyoid ridge must be removed. *In ordinary cases injury of the lingual nerve would occur only by gross negligence, the slipping of a hand chisel or a lever used with uncontrolled application of excessive force.*” (emphasis added).

Defendant’s counsel, apparently under the impression that plaintiffs’ counsel was simply trying to impeach the defendant, made only a limited objection to the question, namely, that no foundation had been laid for such impeachment. The district judge overruled the objection. No reference was made by anyone to Rule 803(18); the record at that point is barren of even a suggestion that the quoted portion of the text was intended to be, or would be, given substantive value. The defendant then answered: “I disagree with that statement wholeheartedly. I know it is written in Thoma’s text and it is totally erroneous.”

Thereafter plaintiffs’ counsel referred the defendant to Archer’s text:

Doctor, I show you a book which you have considered authoritative, “Archer on Oral and Maxillofacial Surgery,” and it says, “Complications,” and I refer you to “Complications during or after removal of impacted malopposed or rudimentary teeth,” and can you tell me in the nineteen things that it mentions, does it mention a permanent injury to the lingual nerve?

The defendant responded:

It does not. However, No. 18 ... “forcing an apex through the lingual plate of the mandibular sub-lingual space,” which is pertinent. They mention something else which is not pertinent.

It appears to me that if this were to happen, you would have an injury to the lingual nerve, but it doesn’t mention it specifically.

5 *United States v. Turner*, 104 F.3d 217, 221 (8th Cir.1997) (“In the present case, there was no expert testimony establishing the texts as authoritative. Federal Rule of Evidence 803(18) provides that the portions of the text may be read only to the extent that it is called to the attention of an expert witness or relied upon by the expert witness in direct examination. Thus, the district court correctly ruled that the medical texts could not be admitted pursuant to Federal Rule of Evidence 803(18).”); *Carroll v. Morgan*, 17 F.3d 787, 790 (5th Cir.1994) (“Although Dr. Bennett refused to recognize the materials as authoritative, another medical expert, Dr. Charles McIntosh, recognized the authorities as reliable. The plaintiff therefore was entitled to use the publications to cross-examine Dr. Bennett. See *Dawsey v. Olin Corp.*, 782 F.2d 1254 (5th Cir.1986).”)

6 Given the requirements for judicial notice, Rule 201, and the nature and importance of the item to be authenticated, the likelihood of judicial notice being taken that a particular published authority other than the most commonly used treatises is reliable is not great. See e.g., *Hemingway v. Ochsner Clinic*, 608 F.2d 1040 (5th Cir.1979).

7 Problems associated with requiring the trial court to make an independent determination on its own rather than have an expert, on either direct or cross-examination, establish the learned treatise as a reliable authority are illustrated by *Costantino v. David M. Herzog, M.D., P.C.*, 203 F.3d 164, 173 (2d Cir.2000):

In any event, other factors—quite apart from ACOG’s status as a reputable organization—established the authoritativeness of the video. In particular, Dr. Nathanson recalled seeing a version of the ACOG video at a staff conference, “inferentially conced[ing]” that it was exactly what the defense said it was: a training resource for the continuing medical education of obstetricians and gynecologists. *Dawson v. Chrysler Corp.*, 630 F.2d 950, 960–61 (3d Cir.1980). And the video’s use as a training resource—“written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy, with the reputation [of its producers and sponsors] at stake”—is clearly an important index of its authoritativeness under Rule 803(18). Fed. R. Evid. 803(18) Advisory Committee Note.

Moreover, Judge Gleeson himself took the additional precaution of reviewing the ACOG video in camera. Through the review, Judge Gleeson knew that the tape’s narrator, Dr. Young, was a physician at Dartmouth College’s Hitchcock Medical Center, and

that the video itself had won an ACOG award, credentials which compared favorably with those of any expert who testified at trial. And after the same review, Judge Gleeson found that the video was what the defense represented it to be: a training resource—with recommendations culled from the “available literature”—used to show doctors “how they should go about dealing with this problem [of shoulder dystocia].” Having viewed the videotape ourselves, and having observed its clinical format, as well as its calm and instructional tone, we cannot say this finding amounts to “manifest error.” *Starter Corp.*, 170 F.3d at 297 (internal quotation marks omitted); see *Loven*, 831 S.W.2d at 397 (affirming trial court’s finding of authoritative nature after viewing challenged video).

In sum, we conclude that Judge Gleeson’s determination that the ACOG video was sufficiently authoritative to deserve admission rested on an appropriate foundation. This was not a case in which there was “no basis” for finding the proffered treatise trustworthy. *Schneider*, 817 F.2d at 991. And while some of the indicia of the video’s reliability came to light through Judge Gleeson’s independent in camera review, rather than through testimony, the authoritative inquiry is a freewheeling one and may be conducted by “any means.” *Fed. R. Evid.* 803(18) Advisory Committee Note; see also Weinstein’s *Federal Evidence* § 803.23[4] (2d ed. 1997) (“trial judge[s] should be liberal in allowing other proof of ... authoritative nature, so long as it indicates that the [treatise] is recognized by the medical profession”) (citing *Ward v. United States*, 838 F.2d 182, 187 (6th Cir.1988)).

Judge Gleeson did not abuse his discretion in finding that the ACOG video was sufficiently authoritative to be presented to the jury.

Why a defense expert did not lay the appropriate foundation in *Costantino* is not disclosed in the opinion.

Rule 803(18) in fact does not on its face authorize independent judicial inquiry or any system other than the testimony or admission of an expert that the learned treatise is reliable. It is suggested that *Daubert/Kumho*, *Rule* 702, § 702.5 *supra*, should not be interpreted to alter the role of the trial court under *Rule* 803(18), i.e., the trial court’s gatekeeping should be limited to that expressly required by *Rule* 803(18) and nothing more. As stated in § 702.5 *supra*, gatekeeping is a search for sufficient assurances of trustworthiness to permit the jury to consider the evidence. Pursuant to the liberal thrust underlying *Rule* 803(18), the testimony of an expert is enough. Otherwise in every case in which one expert refuses to state that a particular learned treatise is a reliable authority, the trial court would be placed in a position of determining whether a particular learned treatise does in fact possess sufficient assurances of trustworthiness, a determination that would place the trial judge right in the middle of a dispute he or she is truly unequipped to easily resolve. While such gatekeeping makes sense as to the explanative theory controlling the outcome of the case, to impose such a gatekeeping determination on the trial court whenever any expert denies the reliability of a learned treatise would dramatically alter current practice under *Rule* 803(18), add significant uncertainty, as well as introduce substantial expenditure of time and money to resolve an often difficult to resolve collateral issue.

- 8 A question has arisen as to whether statements employed to impeach may be considered as substantive evidence absent a formal offer of the statements into evidence. *Maggipinto v. Reichman*, 607 F.2d 621, 623 n. 5 (3d Cir.1979), on remand 481 F.Supp. 547 (E.D.Pa.1979) (“The uncertain state of the record may result in part from the provision in *Rule* 803(18) that ‘[i]f admitted, the statements may be read into evidence but may not be received as exhibits.’ The district judge may have been under the impression that while being used for impeachment the ‘statements’ were not being ‘read into evidence’ under *Rule* 803(18), since plaintiffs’ counsel made no formal offer of the ‘statements’ under *Rule* 803(18), a requisite were the treatises themselves to have been ‘received’ in evidence. We leave unanswered, since not raised by the defendant on this appeal, whether *Rule* 803(18) requires such a formal offer.”).

It is suggested that no real question exists and that any statement in a published authority presented to the trier of fact as part of the impeachment of an expert witness, see note 3 *supra*, is by that process admitted as substantive evidence. Any other construction would reintroduce the unreality of admitting such evidence solely for the purpose of impeachment which *Rule* 803(18) specifically set out to avoid.

- 9 *Sullivan v. United States Department of Navy*, 365 F.3d 827, 833–34 (9th Cir.2004) (“Dr. Wallace’s opinion that an abnormally long back operation substantially increased the risk of complications including wound infection and skin necrosis appears to be relevant to this case. Its reliability appears to be supported by the four textbooks to which Dr. Wallace referred. Each textbook identifies the length of operation as a major factor in causing infection during surgery. Sabiston on Surgery (15th ed.1997) says an exogenous infection of a surgical wound ‘is uncommon and usually indicates a break in aseptic technique or an excessively lengthy procedure.’ Schwartz on Principles of Surgery (1999 ed.) lists under ‘Influencing Factors in Wound Infection’ the ‘duration of operation.’ The textbook states: ‘Duration of operation is an important variable; 3.6 percent of procedures that take 30 minutes or less become infected, while 18 percent of procedures over 6 hours in duration are followed by infection.’ Fry on Surgical Infections (1995) states: ‘Several authors pointed out that the development of a seroma after mastectomy is strongly associated with the development of wound infection.’ Fry cites four authorities for ‘the length of the procedure’ leading to ‘the development of complications.’ Hoepfick on Infectious Diseases (1994) states as to infection following surgery: ‘Technical factors, such as the skill and experience of the surgeon, affect the risk of SWI [surgical wound infection]. Increased tissue trauma and prolonged duration of surgery are contributing factors.’ ”); *United States v. Sene X Eleemosynary Corp., Inc.*, 479 F.Supp. 970, 975 (S.D.Fla.1979) (“Both Dr. Talbott and Dr. Boucek further testified that it is their expert opinion that there is no clinical proof, in the form of adequately controlled clinical studies, that GH-3, or any similar procaine product, is effective in the treatment of any disease. Both doctors based their opinion in this regard, *inter alia*, on an article by Adrian M. Ostfeld, et al., published in the January, 1977 issue of the Journal of the American Geriatrics Society, portions of which were read into the record, pursuant to *Rule* 803(18), *Federal Rules of Evidence*, by Doctors Talbott and Boucek.”); *United States v. An Article of Drug*, 661 F.2d 742, 745 (9th Cir.1981) (“The district court allowed expert witnesses to read excerpts from treatises into evidence during the course of their testimony, but refused to admit the treatise themselves as exhibits, thus following the ‘learned treatise’

exception to the hearsay rule, [Fed.R.Evid. 803\(18\)](#).”).

Whether an expert may summarize the literature for the general purpose of educating the jury when the expert had not conducted the tests and could not testify concerning the methods and procedures has been questioned. See [Mielke v. Condell Memorial Hospital](#), 124 Ill.App.3d 42, 79 Ill.Dec. 78, 463 N.E.2d 216 (1984).

With respect to employment of the learned treatise at trial, see generally [In re Welding Fume Products Liability Litigation](#), 534 F.Supp.2d 761, 764 (N.D. Ohio 2008) (“From the inception of this MDL, the parties have shined their brightest spotlights on the scientific, medical, and epidemiological evidence that addresses whether, and to what extent, exposure to welding fumes can cause neurological damage. For example, very early on, the Court held a multi-day *Daubert* hearing addressing, among other questions, whether ‘the sum of the epidemiological and other evidence proffered by the parties [is] sufficiently reliable to support the assertion that exposure to welding fumes can cause, contribute to, or accelerate a parkinsonian syndrome that some doctors will diagnose as [Parkinson’s Disease]?’ [In re Welding Fume Prods. Liab. Litig.](#), 2006 WL 4507859 at *36 (N.D. Ohio Aug. 8, 2006). In addressing this question, ‘[t]he parties and their affiants ... cited to literally hundreds of medical and scientific articles and treatises.’ *Id.* at *2 n. 2. Similarly, during the course of every bellwether trial over which this Court has presided, plaintiffs and defendants have both repeatedly: (1) asked their own and the other parties’ experts about their familiarity with these articles and studies, (2) quoted statements the articles and studies contain, and (3) asked whether the experts’ opinions are supported or undermined by the conclusions the articles and studies reach. If there is a publication touching even tangentially on the question of general or specific causation of neurological injury by welding fumes, the parties in this MDL have probably asked each other’s experts about it”).

- 10 [Schneider v. Revici](#), 817 F.2d 987, 991 (2d Cir.1987) (“The trial judge repeatedly instructed defense counsel on the appropriate method for laying a foundation for the introduction of Dr. Revici’s text as a learned treatise: ‘Get some expert to come in here and testify that it is a recognized treatise as the rule requires,’ Joint App. at 270; ‘the proper question to the witness is whether that book is recognized in the medical profession as an authoritative book on the treatment of cancer,’ Joint App. at 696. It is apparent, however, from a review of the record, that defense counsel never asked the appropriate foundation question of its expert witness, Gerhard Schrauzer. See Joint App. at 719–721. The district court was therefore correct in excluding the text. Moreover, even if the text qualified as a learned treatise under [Rule 803\(18\)](#), its admission would remain subject to a balancing of probative value against danger of prejudice under [Fed.R.Evid. 403](#), [Apicella v. McNeil Laboratories, Inc.](#), 66 F.R.D. 78, 86 (E.D.N.Y.1975); see *Annot.*, 64 A.L.R.Fed. 971, 976 (1983), a balancing that would favor exclusion because of the danger of prejudice inherent in recognizing a book authored by the defendant in a medical malpractice case as a learned treatise.”). See also 6 Wigmore, Evidence § 1694 at 12 (Chadbourn rev. 1976) (“The treatise writer must, like every other witness, be shown beforehand to be properly *qualified* to make statements upon the subject in hand. This will require, unless judicial notice is appropriate, another witness who will testify to these qualifications—which means here the summoning of anyone in the profession, art, or trade of the writer and ascertaining from him the writer’s standing as an authority. This removes the danger of an ignorant use of statements by writers of no standing; but it is merely the application of the general principle as to testimonial qualifications.”) (emphasis in original).
- 11 [Meschino v. North American Drager, Inc.](#), 841 F.2d 429, 434 (1st Cir.1988) (“We add that in any event we would not accept plaintiff’s argument that the contents of all issues of a periodical may be qualified wholesale under [Rule 803\(18\)](#) by testimony that the magazine was highly regarded. In these days of quantified research, and pressure to publish, an article does not reach the dignity of a ‘reliable authority’ merely because some editor, even a most reputable one, sees fit to circulate it. Physicians engaged in a research may write dozens of papers during a lifetime. Mere publication cannot make them automatically reliable authority. The price of escape from cross-examination is a higher standard than ‘qualified,’ set for live witnesses who do not. The words have a serious meaning, such as recognition of the authoritative stature of the writer, or affirmative acceptance of the article itself in the profession. For this reason we concur in the exclusion of the ‘Ventilation Alarms’ article against NAD.”). Compare [Costantino v. David M. Herzog, M.D., P.C.](#), 203 F.3d 164, 172 (2d Cir.2000) (“We, of course, agree with the Meschino court that the contents of a periodical cannot be automatically qualified ‘wholesale’ under [Rule 803\(18\)](#) merely by showing that the periodical itself is highly regarded. 841 F.2d at 434. We do not, however, read Meschino to say that the reputation of the periodical containing the proffered article is irrelevant to the authoritativeness inquiry. Publication practices vary widely, and an article’s publication by an esteemed periodical which subjects its contents to close scrutiny and peer review, obviously reflects well on the authority of the article itself. Indeed, because the authoritativeness inquiry is governed by a ‘liberal’ standard, good sense would seem to compel recognizing some periodicals—provided there is a basis for doing so—as sufficiently esteemed to justify a presumption in favor of admitting the articles accepted for publication therein. See generally Weinstein’s Federal Evidence § 803.23[4] (2d ed. 1997); [Allen v. Safeco Insurance Co.](#), 782 F.2d 1517, 1519–20 (11th Cir.), vacated on other grounds, 793 F.2d 1195 (11th Cir.1986); [McCarty v. Sisters of Mercy Health Corp.](#), 176 Mich.App. 593, 440 N.W.2d 417, 419–21 (1989).”).
- At this moment, the introduction of the gatekeeping requirement with respect to expert witness testimony, see § 702.5 *supra*, has not migrated in any form to [Rule 803\(18\)](#). It is suggested that the two areas are distinct and that imposition of a gatekeeping requirement is neither necessary nor helpful. [Rule 803\(18\)](#) “ain’t broke,” thus “don’t fix it.” See also note 7 *supra*.
- 12 The burden is satisfied even if the expert being examined denies that the learned treatise is a reliable authority if an expert called by the examining party will so testify. [Dawsey v. Olin Corp.](#), 782 F.2d 1254, 1264 (5th Cir.1986) (“Had the plaintiffs desired to cross-examine Dr. Comstock with statements contained in the original articles, they had merely to obtain copies of the original articles and have Dr. Comstock or one of their own numerous experts identify the articles as authoritative.”).

The court is *not* required to determine reliability of the authority before permitting impeachment.

A purported “learned treatise” prepared for purposes of litigation will not be found to have been established as a reliable authority. See *U.S. v. Martinez*, 558 F.3d 301, 313 (6th Cir. 2009):

At the outset, we note that we have not before considered whether a video constitutes a “learned treatise.” In *Costantino v. Herzog*, however, the Second Circuit reviewed the district court’s admission of a fifteen-minute training video from the audiovisual library of the *American College of Obstetricians and Gynecologists*. 203 F.3d 164, 168 (2d Cir.2000). Both parties recognized that the video was hearsay, but the district court found the video admissible under the “learned treatise” exception. *Id.* at 168-69. The Second Circuit affirmed, holding that the video was a “contemporary variant of a published treatise,” and “the video’s use as a training resource-‘written primarily and impartially for professionals, subject to scrutiny and exposure for accuracy, with the reputation [of its producers and sponsors] at stake’-is clearly an important index of its authoritativeness.” *Id.* at 171, 173 (quoting *Fed.R.Evid.* 803(18) advisory committee’s note) (alteration in original). The court also acknowledged that the video included recommendations culled from available literature and the video’s narrator had “credentials which compared favorably with those of any expert who testified at trial.” *Id.* at 173.

The *Boswell* video does not have the same indicia of reliability as the training video at issue in *Costantino*. “[L]earned treatises usually have ‘sufficient assurances of trustworthiness.... [A]uthors of treatises have no bias in any particular case... [and] are acutely aware that their material will be read and evaluated by others in their field, and accordingly feel a strong pressure to be accurate.’ ” *In re Welding Fume Prods. Liab. Litig.*, 534 F.Supp.2d 761, 765 (N.D. Ohio 2008) (quoting 2 *McCormick on Evidence* § 321 (6th ed. 2006)). In this case, the *Boswell* video was prepared for and given to the FBI for litigation purposes, it was not subjected to peer review or public scrutiny, and it was not “‘written primarily for professionals... with the reputation of the writer at stake.’ ” *Schneider v. Revici*, 817 F.2d 987, 991 (2d Cir.1987) (quoting the advisory committee’s note accompanying *Rule* 803(18) to reject the application of the “learned treatise” exception to video evidence). Because the *Boswell* video does not have the necessary qualities of reliability, we do not need to decide whether a video *could* satisfy the “learned treatise” exception—we simply conclude that the video in this case was impermissible hearsay.

12. With respect to the possibility of bias on the part of the author of the learned treatise by reason of financial interest associated
5 with preparation of the learned treatise in anticipation of litigation, see generally *In re Welding Fume Products Liability Litigation*, 534 F.Supp.2d. 761, 765–66 (N.D. Ohio 2008):

As the case law notes, however, the assumption underlying the learned treatise exception that the author has “no bias in a particular case” is not always true. For example, in *O’Brien v. Angley*, 63 Ohio St.2d 159, 407 N.E.2d 490 (1980), a medical malpractice action, the Ohio Supreme Court reversed a jury verdict for the defendant physicians because the trial court had allowed cross-examination of the plaintiff’s expert with an editorial contained in a learned treatise written by a possibly-biased author. The court wrote: “[w]here ... the author publishes an article with a view toward litigation ... a probability of bias exists which undermines the logic supporting the admission of this material in evidence as an exception to the rule against hearsay.” *Id.* at 494. Similarly, in *Schneider v. Revici*, 817 F.2d 987 (2d Cir.1987), the appellate court ruled it was not error for the trial court to exclude a book written by the defendant doctor in a malpractice action, because “even if the text qualified as a learned treatise under *Rule* 803(18), its admission would remain subject to a balancing of probative value against danger of prejudice under [*Rule*] 403.” *Id.* at 991. The very basis for the learned treatise exception, then—that the author has no bias in a particular case—is susceptible to challenge.

Indeed, there is little doubt that, as might any witness who testifies live in court, the author of a learned treatise whose statements are admissible in court under *Rule* 803(18) may also suffer prejudices or biases. The most obvious of these possible biases is receipt of money from one of the parties. Just as an expert who testifies live may reasonably be asked, for the purpose of revealing possible bias, whether and to what extent he has received remuneration from a party, it is reasonable for a litigant to want to reveal to the jury any financial incentives supplied by another party to the author of a learned treatise introduced at trial. And, as this MDL reveals, the magnitude of the financial incentives in question can be substantial. For example, one of defendants’ experts, Dr. Warren Olanow—who is a highly respected neurologist and researcher—received from defendants over \$1.6 million between October of 1999 and March of 2006. During this same time period, Dr. Olanow published at least a dozen articles upon which various experts testifying in *Jowers* have relied to form their opinions. It is fair to say that the assumption underlying the admissibility of all these articles—that is, that Dr. Olanow’s views regarding the medical issues central to this MDL are not subject to outside influence or bias—is susceptible to attack. And, as the *O’Brien* court concluded, since Dr. Olanow necessarily published his articles “with a view toward litigation,” this Court could conceivably exclude them altogether.

The Court has chosen not to take this dramatic step, however, for two reasons. First, the plaintiffs and defendants in this MDL have consulted with—and paid—a “who’s who” list of neurologists and epidemiologists. To exclude from evidence the articles and studies written by these experts would be to keep from the jury the great bulk of relevant medical information related to causation. Second, absent a showing of bias so extreme that exclusion is appropriate under *Daubert*, the Court believes that disclosure of possible financial bias coupled with cross-examination by the parties is a more appropriate and fine-tuned mechanism for arriving at the truth. See Leslie Boden & David Ozonoff, *Litigation-Generated Science: Why Should We Care?*, 116 *Environmental Health Perspectives* 117, 119 (Jan.2008) (hereinafter, “*Litigation-Generated Science*”) (“The antidote to [litigation-driven science] is not to use the litigation motive as a blunt instrument for exclusion but as a commonsense argument for expanded discovery and greater latitude for cross-examination by the parties.”). It is for this reason that the Court, with its Discovery Order, imposed on the parties its “funding discovery directive” in the first place.

- 13 *Johnson v. William C. Ellis & Sons Iron Works, Inc.*, 604 F.2d 950 (5th Cir.1979), rehearing denied in part, opinion amended 609

F.2d 820 (5th Cir.1980).

If the material is not capable of being read into evidence, such as a chart, and its significance had been fully explored with the expert, “good sense could seem to favor its admission into evidence.” *United States v. Mangan*, 575 F.2d 32, 48 (2d Cir.1978), certiorari denied 439 U.S. 931, 99 S.Ct. 320, 58 L.Ed.2d 324 (1978). However material not capable of being read into evidence should not be allowed to accompany the jury during its deliberations.

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125 S.W.3d 71
Court of Appeals of Texas,
Austin.

Mike MAUZEY and wife, Melissa Kay Mauzey,
Individually and as Next Friend of their Minor
Daughter, Mikayla Melissa Elaine Mauzey,
Appellants,

v.

Lourell E. SUTLIFF, M.D. and Shannon Clinic,
Appellees.

No. 03-02-00188-CV. April 17, 2003.

Parents brought medical malpractice action individually, and on behalf of minor child, against physician and medical clinic, after child suffered from a respiratory disorder shortly after her birth and required 17 days of hospitalization. The 119th Judicial District Court, Tom Green County, [Rae Leifeste, J.](#), entered judgment on a jury verdict against parents. Parents appealed. The Court of Appeals, [Lee Yeakel, J.](#), held that: (1) trial court's decision in allowing physician's expert to testify as to the standard of care physician observed in treating child was not unreasonable or arbitrary; (2) trial court's error, in allowing physician's expert to testify regarding his personal practice in documenting patients' psychological issues, and whether he had conducted both medical and elective inductions of labor at a gestational age of greater than 38 weeks, was harmless; and (3) trial court did not abuse its discretion in not allowing jury, by means of overhead display, to view two tables taken from **learned treatises** that displayed the incidence rate of respiratory distress syndrome (RDS) infants born at various gestational ages.

Affirmed.

West Headnotes (8)

1 Appeal and Error

Depositions, Affidavits, or Discovery

An appellate court reviews a trial court's decision relating to discovery sanctions for an abuse of discretion.

2 Appeal and Error

Rulings on Admissibility of Evidence in General

An appellate court uses an abuse of discretion standard to determine whether the trial court erred in an evidentiary ruling.

3 Appeal and Error

Abuse of Discretion

Under an abuse of discretion standard of review, an appellate court will reverse the trial court only when it finds that the court acted in an unreasonable or arbitrary manner, or without reference to any guiding rules or principles.

4 Pretrial Procedure

Failure to Comply; Sanctions

Decision of trial court to allow physician's expert to testify as to the standard of care physician observed in treating child shortly after child was born was not unreasonable or arbitrary, in medical malpractice action brought by parents of minor child against physician, even though parents claimed that letter of expert that was obtained during discovery was inadequate for not specifying what expert would be testifying to; parents failed to take expert's deposition which would have provided them with more details concerning expert's proposed testimony, and parents made no motion to compel or motion for continuance. [Vernon's Ann. Texas Rules Civ. Proc., Rule 192.3\(e\), 193.1, 193.6\(a\), 194.2\(f\)\(3\), \(f\)\(4\)\(A\).](#)

5 Appeal and Error

Opinion Evidence and Hypothetical Questions

Parents of minor child, who brought medical malpractice action brought against physician and medical clinic after child had been born with

respiratory disorder, failed to preserve for appellate review their claims that trial court erred in allowing physician's expert to testify to the use of medical bulletins, the risks associated with amniocentesis, causation, and whether the induction of mother's labor was elective or medically indicated, where parents did not object to expert's testimony concerning such issues at trial. *Rules of App.Proc., Rule 33.1.*

physician after child was born with a respiratory disorder, did not abuse its discretion in not allowing jury, by means of overhead display, to view two tables taken from **learned treatises** that displayed the incidence rate of respiratory distress syndrome (RDS) infants born at various gestational ages, where rule of evidence governing hearsay exception for information found in **learned treatises** provided that such treatises could not be received as **exhibits**. *Rules of Evid., Rule 803(18).*

6 Pretrial Procedure

Failure to Comply; Sanctions

Trial court's action of allowing physician's expert to testify regarding his personal practice in documenting patients' psychological issues and whether he had conducted both medical and elective inductions at a gestational age of greater than thirty-eight weeks, constituted error in medical malpractice action brought by parents of minor child against physician after child was born with a respiratory disorder, where such matters were outside scope of report submitted by expert concerning what he would testify to.

Attorneys and Law Firms

*72 **Drew Mouton, Charles Myers**, Mouton, Mouton & Myers, PC, Big Spring, for Appellants.
James H. Harp, Smith, Rose, Finley, Harp & Price, PC, San Angelo, for Appellees.

*73 Before Justices **KIDD, B.A. SMITH** and **YEAKE**L.

Opinion

OPINION

LEE YEAKEL, Justice.

This is a medical malpractice action arising from the birth of Mikayla Mauzey who, at birth or soon thereafter, suffered from a respiratory disorder requiring seventeen days' hospitalization. Her parents, appellants Mike and Melissa Mauzey (together the "Mauzeys") sued appellees Lourell E. Sutliff, M.D. and the Shannon Clinic (the "Clinic"), Dr. Sutliff's employer.¹ The district court rendered judgment on the jury's verdict that the Mauzeys take nothing; the Mauzeys appeal. We will affirm the district-court judgment.

7 Appeal and Error

Particular Cases

Trial court's error, in medical malpractice action brought by parents of minor child after child was born with a respiratory disorder, in allowing physician's expert to testify regarding his personal practice in documenting patients' psychological issues, and whether he had conducted both medical and elective inductions of labor at a gestational age of greater than 38 weeks, was harmless; evidence was cumulative of other testimony offered.

1 Cases that cite this headnote

BACKGROUND

8 Evidence

Scientific and Technical Works; Safety Standards

Trial court, in medical malpractice action brought by parents of minor child against

Mikayla Mauzey was born as a result of labor induced by Dr. Sutliff. Mikayla's gestational age upon delivery was thirty-eight weeks and four days; she was not considered premature. Although the parties dispute the facts surrounding the decision to induce labor, the record indicates that Dr. Sutliff was scheduled to leave town on the anticipated delivery date, and Melissa preferred that

Mikayla be born at Shannon Medical Center, a larger hospital in San Angelo, rather than a hospital in Big Spring, where the Mauzeys resided. Shortly after birth, Mikayla developed respiratory difficulties necessitating her transfer to Cook Children's Hospital in Fort Worth. There, Mikayla received treatment for seventeen days, requiring a ventilator to assist her breathing for part of the time. Once Mikayla achieved normal respiration, the hospital released her. The parties also dispute the specific medical infirmity affecting Mikayla. The Mauzeys' expert testified that Mikayla suffered from "respiratory distress syndrome ["RSD"], including hyaline membrane disease ["HMD"] and persistent pulmonary hypertension of a neonate";² Dr. Sutliff's expert diagnosed the problem as "pulmonary hypertension of an unknown cause"; Mikayla's neonatal physician identified her ailment as pulmonary hypertension, which may or may not be associated with HMD.

The Mauzeys filed suit, originally naming Shannon Medical Center and two of its nurses in addition to Dr. Sutliff and the Clinic. Shortly thereafter, the Mauzeys nonsuited all but Dr. Sutliff and the Clinic. *See Tex.R. Civ. P. 162*. The five-day trial centered on the testimony of four physicians, one of whom was Dr. Sutliff. Four expert witnesses were called by the Mauzeys: (1) Dr. Sutliff, called as an adverse witness; (2) Dr. David Turbeville, Mikayla's treating neonatologist at Cook Children's Hospital; (3) Dr. Russel Jelsema, the Mauzeys' retained expert; and (4) Dr. Micheal Stephens, Melissa's and Mikayla's treating family practitioner. Dr. Sutliff also retained a testifying expert, Dr. Richard Stanley. On the basis of the jury's finding of no liability, the district court rendered a take-nothing judgment against the Mauzeys, who now appeal.

DISCUSSION

By two issues, the Mauzeys assert that the district court erred in failing to exclude *74 Dr. Stanley's testimony because of an inadequate discovery disclosure and in refusing to allow the Mauzeys, by way of overhead projector, to display to the jury two tables published in **learned treatises**.

Standard of Review

¹ ² ³ We review a trial court's decision relating to discovery sanctions for an abuse of discretion. *See Bodnow Corp. v. City of Hondo*, 721 S.W.2d 839, 840 (Tex.1986); *Pape v. Guadalupe-Blanco River Auth.*, 48 S.W.3d 908, 912 (Tex.App.-Austin 2001, pet. denied). We apply the same standard to determine whether the trial

court erred in an evidentiary ruling. *City of Brownsville v. Alvarado*, 897 S.W.2d 750, 753 (Tex.1995); *Codner v. Arellano*, 40 S.W.3d 666, 674 (Tex.App.-Austin 2001, no pet.). Under such standard, we will reverse the trial court only when we find that the court acted in an unreasonable or arbitrary manner, or without reference to any guiding rules or principles. *Beaumont Bank, N.A. v. Buller*, 806 S.W.2d 223, 226 (Tex.1991); *Downer v. Aquamarine Operators, Inc.*, 701 S.W.2d 238, 241-42 (Tex.1985).

Dr. Stanley's Testimony

By their first issue, the Mauzeys attack the district court's decision to admit Dr. Stanley's testimony. The issue stems from the district court's March 2, 2001 scheduling order, which directed the Mauzeys to designate their expert witnesses by September 28 and Dr. Sutliff to designate his expert witnesses by October 31. The order instructed the parties to provide: "A list including each expert's name, address, and report of the witness' testimony...."³

On October 31, Dr. Sutliff responded, designating Dr. Stanley as an expert. He provided Dr. Stanley's address and telephone number and attached a brief letter, which Dr. Sutliff characterizes as a "report." The letter, addressed to Dr. Sutliff's attorneys and dated October 22, provides the basis for the conflict before us and reads as follows:

I have had the opportunity to review the following records, depositions, and documents. 1) medical records of Shannon West Texas Memorial Hospital and Shannon Clinic of Melissa Mauzey. 2) plaintiff's original petition. 3) deposition of Dr. Lourell Sutliff, M.D. 4) plaintiff's expert opinion of Dr. Russel D. Jelsema, M.D. of Michigan.

I am a Board Certified OB-Gyn and have been in private practice of Obstetrics and Gynecology in Abilene, Texas for the past 25 years. I have reviewed the above listed records and based upon my training and years of clinical experience, I find the care provided for Melissa Mauzey to be within the standard of care expected for physicians caring for pregnant women.

On the same day, Dr. Sutliff also filed "Second Supplemental Responses to [the Mauzeys]' Request for Disclosure," stating that

Dr. Stanley will testify to the applicable standard of care in the treatment of Melissa Mauzey, on whether Dr. Sutliff breached the applicable standard of care in his treatment of Melissa Mauzey and on whether any violation of the standard of care by Dr. Sutliff in his

treatment of Melissa Mauzey was the proximate cause of damages to Mikayla Mauzey and/or [Mike and Melissa Mauzey].

In response to the Mauzeys' request that he provide "the general substance of [Dr. Stanley]'s mental impressions and opinions and a brief summary of the basis for them," Dr. Sutliff responded, "See report," *75 referring to Dr. Stanley's October 22 letter. A brief resume of Dr. Stanley was attached.⁴

On November 19, the Mauzeys, by letter to Dr. Sutliff's attorneys, questioned the sufficiency of the "report":

I believe the report prepared by your expert, Richard D. Stanley, M.D., dated October 22, 2001, fails to meet the letter or the spirit of the Texas Rules of Civil Procedure or the Court's Scheduling Order. If you wish to submit a new report containing the general substance of his mental impressions and opinions and a brief summary of the basis for them, I need it by noon, Wednesday, November 28, 2001, so Dr. Jelsema can review it prior to his deposition testimony that Friday.

Dr. Sutliff responded the next day:

I disagree regarding Dr. Stanley's report. The Court's Scheduling Order only required a report be supplied. Further, as a Defendant, I have no obligation to supply an expert report except on order of the Court, which I have done. As we discussed, I have no 4590i requirements. More importantly, we have supplemented our disclosure responses and complied with the requirements of that rule. Once again, I will be happy to get dates for you to take Dr. Stanley's oral deposition should you wish to depose him as provided by [Rule 195, Tex.R. Civ. P.](#)

The scheduling order established a December 14 discovery deadline, but provided that it could be extended by agreement of the parties. The Mauzeys, however, did not seek to take Dr. Stanley's deposition. Although the district court held pretrial hearings on discovery disputes on December 9 and 17, the Mauzeys lodged no objection to the adequacy of Dr. Stanley's "report" under either the district court's scheduling order or the discovery rules germane to expert witnesses and their reports.

On January 9, 2002, nineteen days before trials and twenty-six days after the close of scheduled discovery, the Mauzeys filed a written motion to exclude Dr. Stanley's testimony, arguing that the October 22 letter "does not provide any summary of Dr. Stanley's mental impressions, opinions, or the basis for them." The motion further asserted that Dr. Sutliff has

wholly failed to provide Dr. Stanley's mental

impressions and opinions, much less the facts known to Dr. Stanley that relate to or form the basis of his mental impressions, despite the fact that the parties were ordered to provide a report by the Court. As communicated to [Dr. Sutliff] via [the Mauzeys' November 19] letter referred to herein above [sic], the report of Dr. Stanley fails to comply with either the letter or the spirit of the Texas Rules of Civil Procedure or the Court's Scheduling Order.

The Mauzeys argued that the "report" was "wholly inadequate," should be treated by the court "as a failure to provide a report all together [sic]," and the court "should disallow the testimony of Dr. Richard D. Stanley, M.D., in its entirety." The Mauzeys' final opposition to Dr. Stanley's testimony came during trial, when they objected both before and during his testimony that the matters to which he was testifying had not been included in the October 22 letter. The district court, after a hearing, denied the Mauzeys' motion to exclude Dr. *76 Stanley's testimony and overruled the Mauzeys' trial objections.

In this Court, the Mauzeys contend that because Dr. Stanley's October 22 letter is so lacking in substance as to be no report at all, the district court was required to automatically exclude Dr. Stanley's testimony and reversibly erred when he declined to do so. Dr. Sutliff responds to the contrary, arguing that the district court did not err in admitting Dr. Stanley's testimony, and that even if the letter fails as a report, Dr. Stanley's testimony was cumulative and its result harmless. The Mauzeys also assert that, if the letter is sufficient to constitute a "report," Dr. Stanley should not have been allowed to give opinions beyond those contained in the letter.

We will first determine whether the district court should have allowed Dr. Stanley to testify at all. The Texas Rules of Civil Procedure provide: "When responding to written discovery, a party must make a complete response, based on all information reasonably available to the responding party or its attorney at the time the response is made." [Tex.R. Civ. P. 193.1](#). As is relevant here, a party may discover the subject matter on which a testifying expert will testify, the relevant facts known to the expert, the expert's mental impressions and opinions made in connection with the case, and any methods used by the expert to derive his impressions and opinions. [Tex.R. Civ. P. 192.3\(e\)](#). Similar information is available to a party upon a proper request for disclosure: (1) "the general substance of the expert's mental impressions and opinions and a brief summary of the basis for them..." [Tex.R. Civ. P. 194.2\(f\)\(3\)](#); and (2) "all documents, tangible things, reports, models, or data compilations that have been provided to, reviewed by, or prepared by or for the expert in anticipation of the expert's testimony." [Tex.R. Civ. P. 194.2\(f\)\(4\)\(A\)](#). A party failing to make, amend, or supplement a discovery response in a timely manner may

not introduce “in evidence the testimony, material, or information that was not timely disclosed,” unless there is good cause for such failure or the failure to disclose will not unfairly surprise or prejudice the other party. *Tex.R. Civ. P. 193.6(a)*.

The Mauzeys direct this Court to several cases to support their contention that the district court was required to automatically exclude Dr. Stanley’s testimony. In *VingCard A.S. v. Merrimac Hospitality Systems, Inc.*, Merrimac, in response to a request for disclosure, identified the subject matter on which its expert might be called to testify but did not disclose “his mental impressions and opinions, nor a brief summary of the basis for those opinions.” 59 S.W.3d 847, 854 (Tex.App.-Fort Worth 2001, *pet. denied*). Moreover, Merrimac provided no documents, data, or reports reviewed or prepared by the expert. *Id.* at 855–56 (citing *Tex.R. Civ. P. 194.2(f)(4)*). The expert’s testimony was allowed over objection made for the first time at trial. *Id.* at 856–57. The court of appeals held that Merrimac’s responses were not simply inadequate, but that Merrimac “wholly failed to respond” in compliance with the rule, and that the trial court erred in admitting the expert’s testimony in light of rule 193.6. *Id.* The court observed that “Merrimac made no attempt to establish good cause, lack of surprise, or lack of prejudice.” *Id.* at 856. The court, however, found the error harmless, as the admitted testimony proved cumulative. *Id.* at 859.

4 *Reichhold Chemicals v. Puremco Mfg. Co.* concerned the failure to provide an expert’s report more than thirty days before trial. 854 S.W.2d 240 (Tex.App.-Waco 1993, *writ denied*). In discovery, Reichhold had requested information on *77 how Puremco had computed its damages. Thirty-three days before trial Puremco supplemented its previous discovery response and advised that the damage calculations were available in a report prepared by an expert, “which is available for review.” *Id.* at 245. When, at trial, Puremco attempted to offer the expert’s testimony, Reichhold objected. *Id.* Reichhold argued, and Puremco agreed, that Reichhold’s attorney in charge was not provided a copy of the report outside of thirty days before trial. *Id.* at 245–46. Thus, testimony should be excluded under previous rule 215.5.6 *Id.* The trial court allowed the testimony, but the court of appeals reversed, holding that Puremco did not offer good cause for its failure to timely provide the report, *id.* at 246, and that Reichhold demonstrated harm, because Puremco relied heavily on the testimony and the testimony’s admission probably resulted in an improper judgment, *id.* at 249. We do not find *Reichhold Chemicals* controlling. Here, when the district court denied the Mauzeys’ motion to exclude Dr. Stanley’s testimony, Dr. Sutliff was entitled to rely on that ruling insofar as testimony regarding the disclosures made in the October 22 letter and had no duty to supplement his earlier discovery response.

The Mauzeys also seek support from *Dennis v. Haden*, arguing that a party is entitled to rely on the fact that if no report is furnished, the expert will not be allowed to testify. 867 S.W.2d 48, 51–52 (Tex.App.-Texarkana 1993, *writ denied*). This case is distinguishable as well. In *Dennis*, the trial court permitted an expert witness to testify when the proffering party had not provided its opponent with a written report, as ordered by the court. *Id.* at 50–51. The court of appeals disagreed and reversed and remanded the case for a new trial. *Id.* at 52. The court opined that a party had the right to rely on the fact that if its opponent desired to call an expert, the opponent would submit a written report to the other side. *Id.* at 51. The issue before this Court is not the complete lack of a report, but the adequacy of what was submitted.

In *Taylor Foundry Co. v. Wichita Falls Grain Co.*, Taylor Foundry argued that the trial court erred in admitting an expert’s testimony after the grain company allegedly did not disclose the substance of the expert’s mental impressions and opinion in accordance with rule 194.2(f)(3). 51 S.W.3d 766, 772–73 (Tex.App.-Fort Worth 2001, *no pet.*). The parties argued a number of issues, including whether the rule applied at the time the witness was designated. *Id.* However, the court of appeals found the trial court acted within its discretion because the court, as gatekeeper of evidence, conducted a full evidentiary hearing on the proposed testimony and the court’s ruling was supported by “ample” evidence. *Id.* Here, the district court likewise conducted a pretrial hearing on the Mauzeys’ motion to exclude. In response to the Mauzeys’ argument against the adequacy of Dr. Stanley’s opinion that there was no deviation from the standard of care, the court opined:

[W]hen you’re stating a negative, I don’t think that you should have to state the basis upon which you found the negative. *78 In other words, a negative is a negative. I don’t find any deviation in the standard of care; and I don’t think when you state the negative you’re expected to say: And the reason I don’t is that—Here is all the care I saw, each and every step, and I find them all to be okay. To me, that sounds like it’s included in the statement that says: I don’t find any deviation of care.

Moreover, the court stated, “I really believe that the rules contemplate that the deposition would have provided that opportunity to ask the doctor each of those detailed questions.” After hearing from both sides, the court responded that he would “take the matter under advisement ... but I’m inclined to deny that motion.” The court later denied the Mauzeys’ motion to exclude.

Dr. Sutliff counters that although he did not supplement, as informally requested by the Mauzeys, he did make Dr. Stanley available for deposition. Similarly, he contends that the Mauzeys should have filed a motion to compel or

motion for continuance. He correctly points out that the Mauzeys could have done more to protect themselves. It would not have been difficult for the Mauzeys to depose Dr. Stanley, considering that Dr. Stanley's office was in Abilene and the Mauzeys' attorneys practiced in nearby Big Spring. Furthermore, the Mauzeys released their expert to leave the state after testifying, when they might have retained him longer or sought a continuance to effectively rebut Dr. Stanley's testimony.

At the hearing on the Mauzeys' motion to exclude, Dr. Sutliff's counsel advised the court that Dr. Stanley

is going to take the stand. He's going to talk about his qualifications. He's going to talk about what I asked him to review, what he did review, which is identified in his report and in our Disclosure Responses; and he's going to tell this jury whether or not Lourell Sutliff deviated from the standard of care that caused Mikayla Mauzey's damage. I have more than complied with the rules.

....

They know who this expert was [sic].... I think the report is adequate. I think I designated appropriately. I think my Disclosure Response is accurate. You want his deposition; you give me some dates and I'll give them to him.

....

... We believe that the disclosure, the supplements to it, the report and the expert designation comply exactly with what the rules require, and that Doctor Stanley ought to be allowed to talk about the materials identified that he relies upon in rendering his opinion.

He's not done any tests. He's not done any photographs. He's not made any calculations. He doesn't have any factual observations, any different from what is reflected in the medical records....

... They know about him. They know what he's going to talk about. They know every piece of paper that he's seen, every piece of paper that he's going to rely upon, as well as his experience. They have his C.V. They are fully prepared to be able to cross examine this doctor. And did they feel they were not, all they had to do was give me a date for his deposition.

In *Birnbaum v. Alliance of American Insurers*, this Court found answers to interrogatories unresponsive when they failed to disclose the expert's factual observations and opinions. 994 S.W.2d 766, 781 (Tex.App.-Austin 1999, *pet. denied*). We noted that the rule "mandates the exclusion of expert testimony when a party has failed to respond to or supplement responses *79 to discovery." *Id.*

However, we also recognized the good-cause exception and that the "trial court observes in its discretion whether a party has established good cause" for the admission of otherwise inadmissible expert testimony. *Id.* After conducting a hearing, the trial court, over Birnbaum's objection, allowed the expert, Dr. Finis Welch, to testify. After reviewing a record not dissimilar to the one now before us, we stated:

The trial court may reasonably have concluded from the record that Birnbaum had adequate opportunity to learn the opinions of Dr. Welch. Although the interrogatory answers were certainly not responsive in any meaningful way, they did provide Birnbaum notice of the topics of the expert's testimony. As appellees' counsel noted, cross-examination would provide Birnbaum an opportunity to examine and test the substance to the expert's report. Under these circumstances, we cannot conclude that the trial court's admission of Dr. Welch's testimony was an abuse of discretion.

Id. at 781–82.

By any standard, Dr. Stanley's October 22 letter is a pitiful example of an expert's "report." The district court, however, had the opportunity to consider the court's scheduling order, the applicable rules of civil procedure, and the arguments of the parties and, in his discretion, held Dr. Sutliff's responses adequate. As in *Birnbaum*, we cannot conclude that the district court's decision to allow Dr. Stanley to testify *as to the standard of care* Dr. Sutliff observed in treating Melissa was unreasonable or arbitrary.

5 6 Our conclusion, however, does not end our inquiry because the Mauzeys also assert error by the district court in allowing Dr. Stanley to testify as to matters other than the applicable standard of care. They specifically argue that the court erred in allowing Dr. Stanley to testify concerning: (1) whether the induction of Melissa's labor was elective or medically indicated; (2) his opinion of Mikayla's gestational age; (3) his personal practice as a physician; (4) the use of medical bulletins; (5) the risks associated with amniocentesis; and (6) causation. At trial the Mauzeys only objected to Dr. Stanley's testimony regarding his personal practice in documenting patients' psychological issues and whether he had conducted both medical and elective inductions at a gestational age of greater than thirty-eight weeks. We examine error only as to these objections because the Mauzeys failed to object to the testimony regarding the other issues. See *Tex.R.App. P. 33.1* (to preserve error for appellate review, party must have presented to trial court a timely request, objection, or motion stating its specific complaint). Because the objected-to subject matter was outside the scope of the report, when viewed in its most

favorable light, we conclude that it was error for the district court to allow this testimony over the Mauzeys' objections.

7 We must now determine whether the error constituted reversible error. See *VingCard*, 59 S.W.3d at 859; *Reichhold Chemicals*, 854 S.W.2d at 249. To constitute reversible error, we must conclude that the trial court's error "probably caused the rendition of an improper judgment." *Tex.R.App. P. 44.1(a)(1)*; *Gee v. Liberty Mut. Fire Ins. Co.*, 765 S.W.2d 394, 396 (Tex.1989). Dr. Sutliff argues that Dr. Stanley's testimony was cumulative to that of the other experts, and therefore the testimony's admission was harmless. The Mauzeys counter that there were only "two real issues, and Dr. Stanley testified as to both." These two issues were: (1) "the applicable standard of care and whether appellee breached it by electively inducing appellant's labor prior *80 to 39 weeks gestation without documented pulmonary maturity by amniocentesis," and (2) "causation, i.e., whether such breach of the standard of care proximately caused the baby to [be] born with [HMD]." We conclude that the cumulative nature of the testimony renders the error harmless.

Dr. Sutliff testified that he had a medical reason to induce labor: Melissa's anxiety and fear of a problematic birth. He testified that Melissa expressed fear that the baby might breech and, in his words "that something was going to happen to that baby." Dr. Sutliff testified that fetal maturity in 1998 was established at thirty-eight weeks gestation, and that he believed "the incidence of pulmonary immaturity at that stage is less than one in a thousand ... so we had a ninety-nine point nine percent assurance that this baby's lungs were mature." Dr. Sutliff also testified as to the reasons he did not perform an amniocentesis prior to induction, and the fact that the procedure could detect HMD but not pulmonary hypertension. Finally, Dr. Sutliff testified that he did not violate the standard of care in delivering Mikayla. Dr. Sutliff, however, did admit that he chose not to annotate Melissa's fear and anxiety in her medical record because her feelings were not uncommon and such annotations were unwarranted.

Dr. Stanley testified that Dr. Sutliff did not deviate from the standard of care when he induced Melissa's labor. Dr. Stanley also testified that Dr. Sutliff's decision not to perform an amniocentesis, in an effort to detect the potential for underdeveloped lungs at thirty-eight weeks and four days gestation, did not deviate from the standard of care. His opinion would be the same whether Dr. Sutliff's decision to induce Melissa was medically necessitated or elective. On cross-examination, Dr. Stanley did admit that his information was based only on Dr. Sutliff's deposition and office medical records.

Dr. Stephens testified that he currently treats Melissa and Mikayla as their family practitioner. On cross-examination, Dr. Stephens testified that he had annotated in Melissa's medical records Melissa's self-described history of depression, dating back five years to about 1995, which would include the period before Mikayla was born. He testified that he had recently treated Melissa for depression and agoraphobia⁷ with antidepressants. Melissa's medical records also revealed that another doctor at the same clinic where Dr. Stephens was employed had earlier recommended that Melissa seek treatment from a psychologist.

Dr. Turbeville, Mikayla's treating neonatal physician, testified as the Mauzeys' witness to the possible causes of Mikayla's respiratory distress and the type of care she received in Fort Worth. It was his opinion that the cause of Mikayla's respiratory problems was uncertain. Although his initial diagnosis was HMD, he testified on cross-examination that HMD was unlikely because Mikayla's Apgar test, scored at birth, indicated that her breathing was normal shortly after delivery.⁸ He stated that Mikayla's respiratory distress, occurring a few hours after birth, was indicative of problems not associated with underdeveloped *81 lungs. He opined that Mikayla most likely suffered from pulmonary hypertension of an unknown origin, but he did not rule out the possibility of HMD. He admitted that confirming HMD was only possible by way of biopsy, which was not performed. Dr. Turbeville further testified that in most cases where infants are admitted with respiratory disorders, the procedure is to treat them as if HMD were the cause even though it may not be the problem. This, he said, was the reason for his initial diagnosis of HMD.

Dr. Jelsema contradicted Dr. Sutliff's, Dr. Stanley's, and Dr. Turbeville's testimony. He testified that, in his opinion, there was no medical reason for Dr. Sutliff to induce labor, and that such induction, performed without the benefit of amniocentesis, resulted in the birth of Mikayla before her lungs had fully developed. Dr. Jelsema testified that the standard of care applicable in this case required Dr. Sutliff to document pulmonary maturity by amniocentesis for an elective induction of labor before thirty-nine weeks gestation. He testified that he believed Mikayla suffered from HMD but admitted that confirming HMD was only possible by way of biopsy, which was not done. He also admitted that his area of practice did not involve care of infants after birth. When asked about the incidence of RDS in infants induced at thirty-eight weeks gestation, Dr. Jelsema testified that in one study "there were forty-five babies ... and one of those babies had respiratory distress problems." On cross-examination he conceded that induction at thirty-eight weeks and beyond was medically acceptable, and that a baby born at thirty-eight weeks was not considered premature. He also testified that an

amniocentesis does not guarantee detecting HMD, and the test would not have detected pulmonary hypertension of an unknown origin.

The Mauzeys offer *Boothe v. Hausler* to support their argument that Dr. Stanley's testimony was not merely cumulative. 766 S.W.2d 788 (Tex.1989). In *Boothe*, the trial court permitted Hausler's wife to testify on his behalf, despite the fact that he failed to supplement his answers to interrogatories to advise Boothe of his wife's whereabouts. Boothe was thus unable to serve the wife with a subpoena, depriving him of the opportunity to take her pretrial deposition. Applying the harmless-error standard, the supreme court held that her testimony was not cumulative and may have been crucial to the jury's determination, because the wife was the only nonparty witness called by Hausler to dispute Boothe's allegations that Hausler had assaulted him. *Id.* at 789. Thus, it was error to admit the testimony without a showing of good cause. *Id.*

Boothe, however, is distinguishable. In the instant case, Dr. Stanley's testimony regarding his personal practice in documenting patients' psychological issues and whether he had conducted both medical and elective inductions at a gestational age of greater than thirty-eight weeks were not "material issue[s] dispositive of the case." *Id.* The cumulative nature of the evidence is apparent. Dr. Stephens's testimony corroborated Dr. Sutliff's testimony concerning Melissa's depression and anxiety existing before Mikayla's birth. Additionally, Dr. Turbeville testified that Mikayla's respiratory distress was probably caused by pulmonary hypertension of an unknown origin, which may or may not be associated with HMD, an opinion supporting Dr. Sutliff's actions because amniocentesis would not have detected pulmonary hypertension of an unknown origin. Dr. Stanley testified that Dr. Sutliff did not deviate from the standard of care, while Dr. Jelsema testified as to the requisite standard of care in light of Dr. Sutliff's actions. Therefore, absent Dr. Stanley's *82 testimony that was admitted in error, the jury was left to consider the testimony offered by the five physicians: (1) Dr. Sutliff's opinion that Melissa suffered from anxiety concerning Mikayla's birth and that induction absent amniocentesis was proper; (2) Dr. Stanley's opinion that Dr. Sutliff did not deviate from the standard of care; (3) Dr. Stephens's testimony that Melissa had suffered from depression and anxiety before Mikayla's birth; (4) Dr. Turbeville's opinion that Mikayla suffered from a medical infirmity unrelated to a premature induction of labor; and (5) Dr. Jelsema's belief that induction was improper, as was Dr. Sutliff's failure to document Melissa's psychological concerns. In reviewing the disputed evidence, we bear in mind that the jury is the sole judge of the credibility of the witnesses and is entitled to accept or reject any testimony it wishes, as well as to decide what weight to give the testimony. *Simons v. City of Austin*, 921 S.W.2d 524, 531 (Tex.App.-Austin

1996, writ denied). The jury apparently found the other physicians' testimony more persuasive than Dr. Jelsema's or gave their testimony more weight. We overrule the Mauzeys' first issue.

Visual Presentation of **Learned Treatises**

By their second issue, the Mauzeys argue that the district court erred in refusing to allow the jury, by means of an overhead display, to view two tables taken from **learned treatises**. The tables at issue displayed the incidence rate of RDS in infants born at various gestational ages. One table, titled "Incidence and mortality rate of RDS," contained three columns: (1) "Gestational Age (weeks)," (2) "No. of Live Born Infants," and (3) "Incidence of RDS (%)." The rows under each column represented the results of the study for different gestational ages, with the first row being greater than forty weeks and the bottom row twenty-nine to thirty weeks. By choosing the gestational age under the first column, a reader could determine the number of infants studied in each group and the group's RDS incidence rate. The row applicable to this case concerned infants with a gestational age of between thirty-seven and thirty-eight weeks. The number of live infants born was 1392, and the incidence of RDS was 0.80%. Dr. Sutliff, however, disputed these numbers on cross-examination, arguing that Mikayla fell between the 37-38 week row and the 39-40 week row, because her gestational age at birth was thirty-eight weeks and four days. The second table was similarly formatted, and it represented that one in forty-five infants born through induced labor at thirty-seven to thirty-eight weeks suffered from RDS. During Dr. Sutliff's direct testimony, he stated that the rate of pulmonary immaturity in infants born at thirty-eight weeks was less than one in one thousand. Seeking to impeach Dr. Sutliff with contrary incidence rates, the Mauzeys requested that the two tables be displayed to the jury while Dr. Sutliff was questioned. Dr. Sutliff objected, arguing that a **learned treatise** may be read into evidence but may not be received as an **exhibit**. See *Tex.R. Evid. 803(18)* (statements from **learned treatise** may be read into evidence but may not be received as **exhibit**). The district court agreed, and the applicable portions of the tables were only read into evidence by the Mauzeys' counsel.

The Mauzeys contend that during the testimony, the applicable standard of care was misrepresented to the jury by Dr. Sutliff. The Mauzeys argue that this misrepresentation and the inability to visually display the tables while attempting to impeach Dr. Sutliff confused the jury and probably resulted in the rendition of an improper verdict. The Mauzeys urge that the purpose of *rule 803(18)* is to prevent *83 the jury from drawing improper inferences, without guidance, from technical information contained in the **learned treatise**, which the tables do not display. Dr. Sutliff responds that the district

court did not abuse his discretion. Additionally, he argues that the ruling was correctly based on the language of the rule and, even if erroneous, the error was harmless.

8 Rule 803(18) does not prohibit the *display* of such tables. It is a general hearsay exception for the information found in **learned treatises**:

Learned Treatises. To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. *If admitted, the statements may be read into evidence but may not be received as exhibits.*

Tex.R. Evid. 803(18) (emphasis added). The issue is whether the district court reversibly erred in strictly adhering to the “read into evidence” language of the rule. In support of their position, the Mauzeys direct this Court to Texas criminal cases and cases from other jurisdictions.

United States v. Mangan is the most instructive and is also cited in the criminal cases. 575 F.2d 32, 48 (2d Cir.1978). In *Mangan*, the defendant desired to cross-examine the government’s handwriting expert concerning his testimony that the defendant’s handwriting **exhibited** certain characteristics. *Id.* The defendant attempted to introduce several charts extracted from a **learned treatise**. The trial court rejected the introduction of the charts into evidence, citing the last sentence of the **Federal Rule of Evidence 803(18)**.⁹ *Id.* The court permitted the jury to view the charts during defendant’s cross-examination of the expert but prevented the jury access to the charts during their deliberations. *Id.* Upholding the decision on appeal, the court of appeals opined that it would be difficult for a chart to be read into evidence, “and good sense would seem to favor its admission into evidence, at least in a case where, as here, its significance had been fully explored with the expert.” *Id.* The *Mangan* court noted that it could not fault the trial judge for “reading the black letter as closely as he could.” *Id.* The court observed that “[t]he Advisory Committee’s Note shows that the purpose of the last sentence was to prevent a jury from rifling through a **learned treatise** and drawing improper inferences from technical language it might not be able properly to understand without expert guidance.” *Id.* at n. 19. In the Mauzeys’ case, there was no danger that the jury would have misinterpreted the information or rifled through other parts of the **learned treatises**, because this was the only portion of the **learned**

treatises the jury would have seen.

Additionally, the Mauzeys cite *Loven v. State*, 831 S.W.2d 387 (Tex.App.-Amarillo 1992, no pet.). In *Loven*, the trial court allowed the jury to view an instructional video, which was admitted into evidence and taken to the jury room. *Id.* at 397. On appeal, the court held that a video could be admitted as a **learned treatise** and therefore shown to the jury when offered in conjunction with an expert’s testimony. *Id.* The court also ruled that admitting the video into evidence was error and in violation *84 of the last sentence of **rule 803(18)**; however, because the jury had no way to watch the video, the error was harmless. *Id.*

Here, it is undisputed that the information contained in the tables was read into the record during Dr. Sutliff’s testimony. The Mauzeys’ impeachment may have been more effective had the jury actually viewed the tables. However, as in *Mangan*, we cannot fault the district court for following the language of 803(18). The decision to display tables from **learned treatises** was properly within the district court’s discretion. Therefore, we cannot say that the district court’s evidentiary ruling was an abuse of that discretion. The Mauzeys’ second issue is overruled.

CONCLUSION

Although we hold that Dr. Stanley’s October 22 letter barely suffices as an expert’s report, thereby allowing Dr. Stanley to testify as to the matters disclosed within its four corners, it falls short of satisfying the spirit of full evidentiary disclosure. Here, once the district court ruled in advance of trial that he would allow Dr. Stanley to testify, the Mauzeys could have done more to determine the extent of Dr. Stanley’s proposed testimony. Under these circumstances, the district court did not abuse his discretion in allowing the testimony at trial. However, we urge trial courts to carefully consider such matters and ensure that a pretrial expert report fully discloses the breadth and substance of the expert’s mental impressions and their basis. We also urge trial courts to exercise their discretion in a manner that allows a case to be fully developed before the jury. Although we cannot say that the district court abused his discretion in denying the Mauzeys’ request to **exhibit** the **learned-treatise** tables by overhead projector when cross-examining Dr. Sutliff, such **exhibition** would not have violated evidentiary **rule 803(18)**.

We affirm the district court’s judgment.

Footnotes

¹ In this proceeding, the interests of Dr. Sutliff and the Clinic do not diverge. For convenience we will refer to them jointly as “Dr.

Sutliff,” unless individual distinction is required.

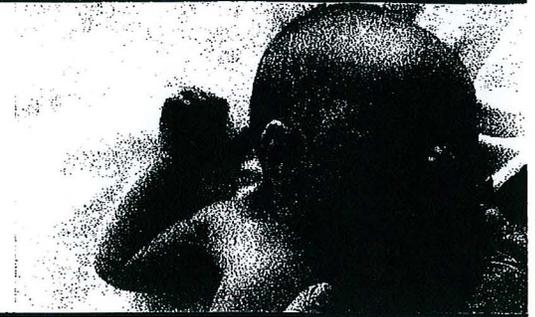
- 2 HMD results from immature lungs, which cannot produce surfactant. Surfactant is a liquid substance in the lungs that prevents the lungs from collapsing upon exhalation. RDS is a clinical syndrome that may result from a variety of cardiopulmonary disorders as well as HMD. Pulmonary hypertension is a respiratory problem that also can have many causes, and it can be associated with HMD.
- 3 The scheduling order was signed by Judge Ben Woodward.
- 4 The record presented to this Court contains neither a request for disclosure by the Mauzeys nor any earlier response by Dr. Sutliff.
- 5 The scheduling order established that trial would commence on either January 21 or 28, 2002. The trial actually began January 28.
- 6 Former rule 215.5 is the predecessor to and is substantially the same as the present [rule 193.6](#). Compare [Tex.R. Civ. P. 193.6](#), with 215.5 (1984, amended and renumbered 1999). The *Reichhold Chemicals* court refers to the former rule as “Rule 215(5),” *Reichhold Chems. v. Puremco Mfg. Co.*, 854 S.W.2d 240, 245 (Tex.App.-Waco 1993, writ denied), while this Court has referred to the rule as “Rule 215.5,” *Birnbaum v. Alliance of Am. Insurers*, 994 S.W.2d 766, 781 (Tex.App.-Austin 1999, pet. denied). We will refer to the rule as in *Birnbaum*.
- 7 Agoraphobia is an “abnormal fear of crossing or of being in the midst of open spaces.” *Webster’s Third New International Dictionary* 43 (Philip B. Gove ed., 1961).
- 8 The Apgar test generates a score of the infant’s immediate post-birth condition based on various observations. In scoring the infant, the physician observes such characteristics as crying, respiration, color, and muscle tone. The test is conducted at one and five minutes after birth. The maximum score is ten. Mikayla scored eight at one minute and nine at five minutes, indicating normal respiration.
- 9 Texas adopted the state rule *verbatim* from the [Federal Rule of Evidence 803\(18\)](#). See Hulen D. Wendorf, et al., *Texas Rules of Evidence Manual* § VIII at 129 (6th ed.2002).

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Retinopathy of Prematurity

Graham E. Quinn



Retinopathy of prematurity (ROP) is an oxidant disease that occurs in incompletely vascularized retinas of premature infants, particularly small, sick infants in the neonatal intensive care unit. It is characterized by the onset of visible vascular abnormalities in the second or third month after premature birth. In approximately 3% of children with birth weights of less than 1251 g, the retinopathy progresses to serious scarring in the posterior pole of the eye or to retinal detachment. This occurs despite the most aggressive surgical treatment currently available, such as cryotherapy or laser photocoagulation for sight-threatening disease.¹

ROP typically appears after the child has lived through life-threatening crises such as intraventricular hemorrhage and respiratory distress syndrome that are common in early life for very premature infants. Therefore, serious forms of ROP put a heavy emotional and psychologic burden on the child's family, physicians, and nurses. After all the hurdles the family and child have overcome, they must now face the fact that the child has another serious, potentially lifelong problem.

Retinopathy has been recognized since the early 1940s as a blinding disease of the premature infant,² and the incidence of blinding forms of the disease has varied greatly over the intervening decades.³⁻⁵ The development of the neonatal intensive care unit in the late 1960s and the subsequent explosion in technology for physical support of these children and in the understanding of their nutritional demands led not only to an increased number of survivors with very low birth weight but also to an increased number of children at risk for developing ROP. Increased survival and the development of treatment options have led to a resurgence in clinical and basic science research in the area.

The findings of the multicenter Cryotherapy for Retinopathy of Prematurity (CRYO-ROP) trial⁶ proved the efficacy of cryotherapy for severe ROP and increased the awareness of the disorder for neonatologists caring for the infant and the ophthalmologist performing ROP screening examinations and treatment. Before this trial,

there was no widely accepted "proven" treatment, and ROP surveillance in the nursery could be determined locally within broad guidelines published by the American Academy of Pediatrics, which suggested an examination by 8 weeks after birth or at discharge. Treatment protocols in place in the individual institution also determined when and which children to examine.

With the 1988 publication of the results of the CRYO-ROP trial,⁶ a new standard of care for infants with birth weights of less than 1251 g was required of infant intensive care nurseries. This included identifying children at risk for serious forms of ROP, which the study had defined as (1) ROP severe enough to qualify for entry into the randomized treatment trial or "threshold" ROP (zone 1 or 2, stage 3+ ROP with 5 contiguous or 8 discontinuous clock hours of involvement [see later discussion of classification]), and (2) ROP that necessitated more frequent examinations than the routine or "prethreshold" ROP, which consisted of (1) zone 1 or 2, stage 2 ROP with "plus disease" (to be described); (2) zone 1 or 2, stage 3 ROP without plus disease; or (3) zone 1 or 2, stage 3 ROP with plus but lacking the requisite hours of stage 3 to qualify for threshold. The hospitals and physicians caring for premature infants in intensive care units needed to develop systems to undertake serial eye examinations designed to detect serious ROP and needed to obtain the services of ophthalmologists familiar with cryotherapy and laser therapy for ROP in the premature infant.

Thus, the responsibility of physicians and nurses who give ophthalmic care for premature infants has changed radically since the mid-1980s and is likely to change even more. The purpose of this chapter is to present current knowledge about ROP natural history and its treatment, along with a historical perspective of the disorder.

CLASSIFICATION

Before the early 1980s, most ophthalmologists recorded observations about the natural course of ROP, using one of several different classification systems.^{3,7-10} Although

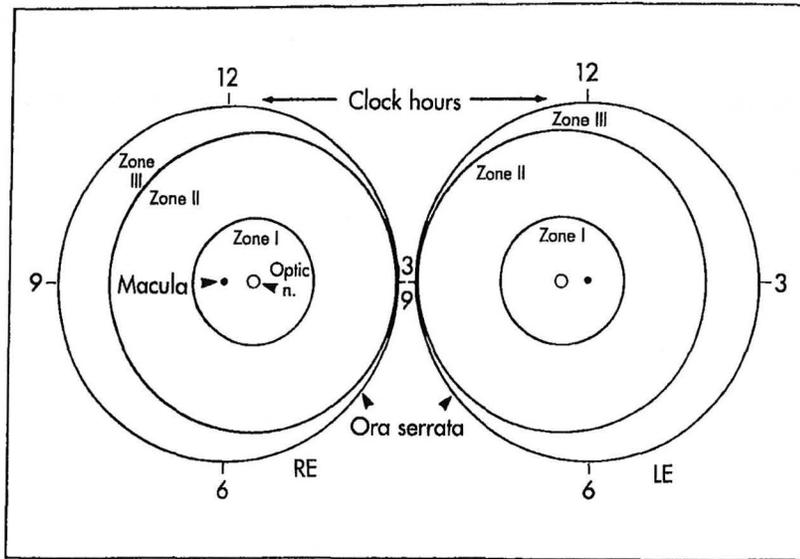


Figure 51-1. Drawings of right eye (RE) and left eye (LE) showing edges of zones and clock hours used to document location of retinopathy of prematurity. (From Committee for the Classification of Retinopathy of Prematurity: An international classification of retinopathy of prematurity. Arch Ophthalmol 102:1130, 1984.)

these systems were similar in the extreme degrees of ROP, the moderately severe grades of retinopathy had varying emphases, making discussion of ocular findings and comparison of treatment effects difficult. This situation was radically altered with the introduction of the International Classification of ROP in 1984.¹¹ This classification was a group effort of 23 ophthalmologists and ophthalmic pathologists from 11 countries that began meeting initially at a 1981 ROP conference sponsored by Ross Laboratories in Washington, D.C. The group subsequently met in Calgary, Alberta, Canada, and Bethesda, Maryland, over the next several years, while using the newly devised classification in their home nurseries. The group suggested four major components for an international classification including: (1) location, or **zone**, of the retinopathy between the optic disk and ora serrata; (2) severity, or **stage**, of disease at the junction between the vascularized and nonvascularized retina; (3) **extent** of involvement of disease (given in clock hours 0 through 12) at the junction, and (4) presence or absence of **plus disease**, defined as abnormal dilatation and tortuosity of the vessels of the posterior pole of the eye. The major theme of the classification was that more posterior, more severe, and more extensive retinopathy was likely to have more serious long-term morbidity for the child.

The ability to state the retinal location or zone of the retinopathy was a crucial advance in communicating about the disease. The decision that made this possible was changing the center of the zones from the fovea, where vision is sharpest, to the center of the optic disk, where the retinal vasculature emerges at about 16 weeks of gestation. As shown in Figure 51-1, the retina is divided into three zones. Zone 1, the most posterior, is the area bound by a circle in which the disk is at the center and whose radius is twice the distance from the disk to the foveal region. Zone 2 is doughnut-shaped and extends from the edge of zone 1 to the edge of a circle in which the disk is at the center and whose radius defined as the distance from the disk to the nasal ora serrata.

Zone 3 is the crescent of peripheral retina from the edge of zone 2 outward to the ora serrata. Thus, ROP that extends for 12 clock hours (360 degrees) must occur in zone 1 or zone 2.

Severity of retinopathy was defined initially in four stages of increasing severity. The earliest retinal finding that the International Committee believed was easily and uniformly recognizable was a demarcation line, or a thin white strip, at the junction between the vascularized and nonvascularized retina. This retinal change was designated stage 1 ROP. Stage 2 has a volume structure with height above the surrounding retina and bulk in the anterior-posterior location of the retinopathy. Stage 3 is characterized by extension of fibrovascular proliferation into the vitreous cavity (Fig. 51-2). Stage 4 included all retinal detachments that resulted from ROP. This stage was later expanded to stages 4 and 5 when several members of the original International Classification Committee met with other interested retinal specialists from 1985 to 1987.¹²



Figure 51-2. Fundus appearance of fibrovascular proliferation in stage 3 retinopathy of prematurity. (From Committee for the Classification of Retinopathy of Prematurity: An international classification of retinopathy of prematurity. Arch Ophthalmol 102:1130, 1984.)



Figure 51-3. Artist's sketch of stage 4B retinopathy of prematurity with subtotal retinal detachment involving macular area. (From *The International Committee for the Classification of the Late Stages of Retinopathy of Prematurity: An international classification of retinopathy of prematurity. II. The classification of retinal detachment. Arch Ophthalmol* 105:906, 1987.)

Stage 4A is now a partial retinal detachment not involving the macular region, stage 4B is partial retinal detachment involving the macula (Fig. 51-3), and stage 5 is total retinal detachment. In addition, stage 5 is divided according to the configuration of the retinal detachment: that is, with open or closed funnels anteriorly and posteriorly.

The presence of "plus disease" is an ominous prognostic sign in ROP. It is characterized by progressive vascular incompetence with increasing dilation and tortuosity of veins and arteries of the posterior pole (Fig. 51-4), in the presence of the peripheral retinal findings of ROP. Also seen frequently in moderate to severe plus disease are vascular engorgement in the iris, pupillary rigidity, vitreous haze, and increasing dilation and tortuosity of the



Figure 51-4. Photograph of posterior pole of the fundus, showing the venous and arteriolar dilation and tortuosity characteristic of "plus disease." (From *Committee for the Classification of Retinopathy of Prematurity: An international classification of retinopathy of prematurity. Arch Ophthalmol* 102:1130, 1984.)

peripheral retinal vessels. Quantification of plus disease is arbitrary and, in essence, a clinical judgment made from standard photographs and clinical impression. However, Freedman and associates noted that increased blood vessel tortuosity and dilation could be assessed reliably by observers, which is suggestive of this facilitated standardization of the diagnosis of plus disease.¹³

REGRESSION

Most acute-phase ROP does not progress to sight-threatening forms of the disease, such as retinal detachment or retinal fold involving the macular region. Rather, most ROP regresses to mild scarring or to no visible residua of the acute phases of the retinopathy. For example, in the CRYO-ROP study that involved infants with birth weights of less than 1251 g, ROP of some stage occurred in about 65% of the 4099 infants who were monitored during the period when ROP is likely to develop.¹ Progression to serious retinal scarring occurred in fewer than 5% of these children, and most cases regressed with a wide array of ocular findings.

Recognizing the range of clinical findings of regressed ROP but still without sufficient data to develop a severity hierarchy, the group of ophthalmologists and ophthalmic pathologists that developed International Classification of ROP in 1985-1987¹² chose to leave the categorization of increasing severity of regressed ROP findings to a later date. They suggested a simple cataloging of ocular findings that was based on whether the ocular residua of ROP were in the peripheral or posterior retina and whether they were of vascular or pigmentary origin primarily. Therefore, such findings as macular heterotopia and retinal fold would be listed as posterior retinal findings, whereas straightening of the temporal retinal arterioles would be considered posterior vascular residual findings. Peripheral pigmentary findings include pigmentary changes in the region of a regressed ridge, and peripheral vascular residua include areas of avascularity peripheral to regressed acute-phase retinopathy. Thus, a hierarchy for increasing severity of regressed ROP awaits further study and understanding of the visual consequences of regressed ROP. These data are gradually being accumulated with efforts of Birch and Spencer,¹⁴ Katsumi and colleagues,¹⁵ Hittner and associates,¹⁶ and the CRYO-ROP cooperative group,^{17,18} among others.

INCIDENCE

The best prevalence data on acute-phase ROP is from the natural history portion of the CRYO-ROP study for infants born between January 1, 1986, and November 30, 1987, and weighing less than 1251 g at birth.¹ The 4099 infants from 23 centers represented approximately 15% of the prematurely born population in the United States during that period. ROP was observed in 47% of infants with birth weights of 1001 to 1250 g, 78% of infants with birth weights of 751 to 999 g, and 90% of those with birth weights of less than 750 g. In addition, more severe ROP tends to occur in the smaller infants, as shown in Table 51-1. It is clear from the table that the smaller the

Table 51-1. Prevalence of ROP by Birth Weight in the CRYO-ROP Study

	<751 g	751-999 g	1000-1250 g
Stage 1 ROP	19.5%	28.6%	24.3%
Stage 2 ROP	32.8%	27.2%	13.2%
Stage 3 ROP	37.4%	21.9%	8.5%
Plus disease	24.6%	12.8%	4.7%
Prethreshold ROP	39.4%	21.4%	7.3%
Threshold ROP	15.5%	6.8%	2.0%

Adapted from Palmer EA, Flynn JT, Hardy RJ, et al: Incidence and early course of retinopathy of prematurity. *Ophthalmology* 98:1628, 1991.

CRYO-ROP, Cryotherapy for retinopathy of prematurity; ROP, retinopathy of prematurity.

infant is, the more likely the child is to develop severe ROP; for example, the infant with a birth weight of less than 750 g is almost eight times more likely to develop threshold ROP than is the infant with a birth weight of 1000 to 1250 g. A similar gradient is also seen for infants born earlier in gestation in comparison with those born later in gestation. For example, 10.4% of children born at gestational ages of younger than 28 weeks developed threshold ROP in the CRYO-ROP study, in comparison with 1.1% of infants born at gestational ages of 32 weeks or older.¹

Reports of ROP prevalence data from nurseries in the United States have been relatively infrequent since the extensive CRYO-ROP study. Hussain and coworkers⁵ reviewed the ROP data from the intensive care nursery at University of Connecticut from 1989 to 1997. They found a significant decrease in both incidence and severity of acute retinopathy when comparing their results with those from the CRYO-ROP study. Overall, for infants with birth weights of less than 1251 g, the incidence of acute-phase retinopathy was 34% (187 of 545) and, for infants with birth weights of less than 1000 g, it was 46% (160 of 347), considerably less than the 82% reported in the CRYO-ROP study.¹ This trend toward a lower prevalence of acute-phase ROP in nurseries in the United States is promising, but it must be confirmed in a number of other centers and in larger numbers of patients.

SIGHT-THREATENING RETINOPATHY OF PREMATURITY

Most ROP is mild in degree and regresses without serious ocular sequelae. It has also become more apparent that serious residua from ROP are rare among infants with higher birth weights. Therefore, a great deal of effort has gone into defining what constitutes serious forms of ROP and identifying the children likely to develop sight-threatening ROP. A major step forward was made by the selection of zone 1 or 2, stage 3+ ROP with 5 contiguous or 8 discontinuous clock hours of involvement as the minimal criteria, or "threshold," for participation in the randomized portion of the multicenter trial of cryotherapy for ROP.⁶ ROP of this severity was predicted to have a 50% likelihood of causing severe visual handicap or

blindness, according to preliminary data from the experience of the nurseries of the University of Pennsylvania, including Pennsylvania Hospital, Hospital of the University of Pennsylvania, and The Children's Hospital of Philadelphia.¹⁹ This hypothesis was supported by the results of the CRYO-ROP trial, in which eyes with "threshold" ROP that were randomly assigned to receive no treatment had a 51.4% likelihood of having a very poor structural outcome.²⁰ A further helpful division of ROP severity was also developed by the CRYO-ROP study: prethreshold ROP consisting of (1) zone 1 or 2, stage 2 ROP with plus disease; (2) zone 1 or 2, stage 3 ROP without plus disease; or (3) zone 1 or 2, stage 3 ROP with plus disease but lacking the requisite hours of stage 3 to qualify for threshold. Retinopathy observed to occur initially in zone 3 is not eligible for categorization as threshold ROP or prethreshold ROP.

RETINAL VASCULARIZATION WITHOUT RETINOPATHY OF PREMATURITY

Peripheral retinal vascularization proceeds in an orderly manner from the optic disk to the ora serrata in the developing fetus.³ In eyes that do not go on to develop ROP even though the child was born prematurely, the retinal vascular development continues in an orderly manner, although its progress may be momentarily interrupted by premature birth. In the CRYO-ROP study, 1400 infants with birth weights of less than 1251 g were monitored during the neonatal period and did not develop ROP. In Figure 51-5, the percentages of eyes with vascularization extending into zone 3 are shown for various postconception ages from 30 to 49 weeks.¹ It is apparent from the figure that retinal vascularization proceeds peripherally as the infant matures; most infants develop vessels into zone 3 by full-term due date, regardless of birth weight. It is also interesting to note that approximately one third of the eyes were judged to have vessels into zone 3 by 34 to 35 weeks of postconception age and are thus at low risk for developing serious ROP.

TIME OF ONSET

The appearance of ROP seems to be determined both by the immaturity of the child at birth and by perinatal events that are associated with an increased incidence of ROP. These events are essentially indices of how sick the child is after birth, such as the occurrence of intraventricular hemorrhage and sepsis and the need for prolonged ventilatory support and multiple transfusions. These events probably occur early after birth, when the child is most unstable medically.²¹⁻²³

In a series of 639 infants examined in the early 1980s, Flynn documented that most acute-phase ROP was observed "between 32 and 44 weeks postconceptional age."²¹ He suggested that the time to development of ROP should be considered in terms of postconception age to "relate all infants to the same time axis." About 5 years later, in a series of 572 infants with birth weights of less than 1701 g who were examined from the age of 3 weeks, Fielder and associates²⁴ reported an ROP incidence of

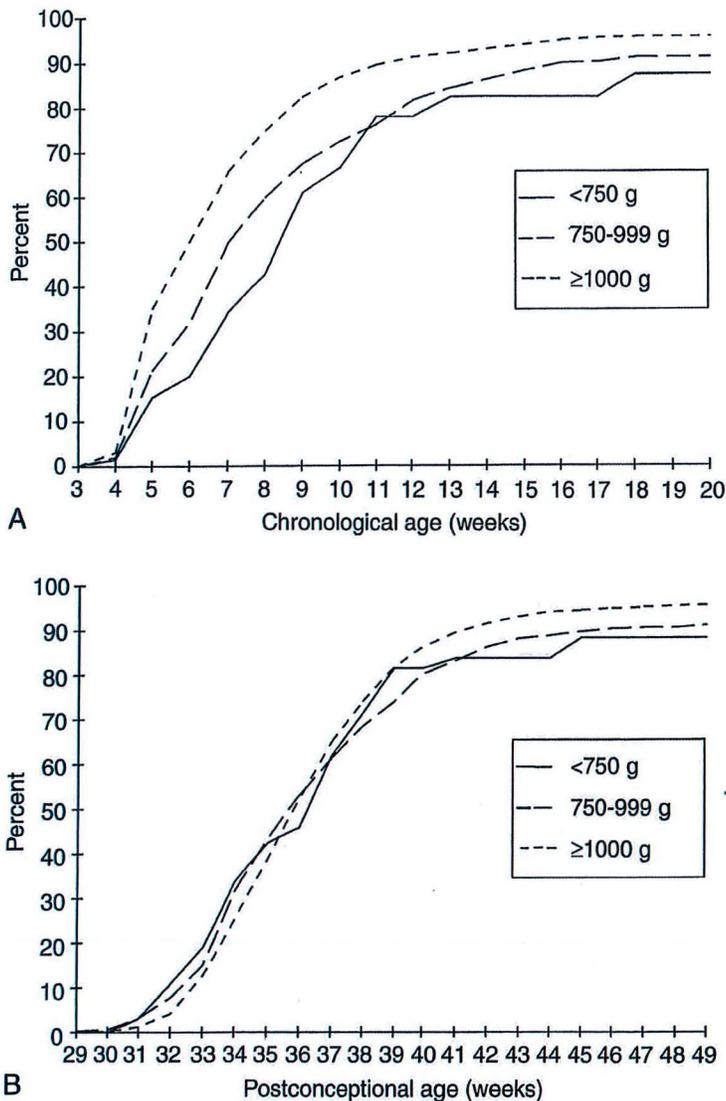


Figure 51-5. Proportion of infants with no retinopathy of prematurity with retinal vessels into zone 3 by age from birth (A) and postconceptional age (B). (From Palmer EA, Flynn JT, Hardy RJ, et al: *Incidence and early course of retinopathy of prematurity*. *Ophthalmology* 98:1628, 1991.)

50.9% (291 of 572) and that the onset of 65% of the ROP cases occurred between 30 and 35 weeks of postconception age. The 23 infants who developed ROP after 40 weeks of postconception age were born at gestational ages of 31 to 38 weeks, except for the case of an infant born at 27 weeks of gestation who had missed several examinations. The time after birth to onset of retinopathy was inversely related to birth weight and gestational age.

Our ROP study group in Philadelphia also reported the onset of ROP in a group of 755 infants²⁵ as part of a National Eye Institute-sponsored study conducted from 1979 to 1981 to assess the possible effect of vitamin E on ROP.^{26,27} Weekly examinations were undertaken as soon after birth as possible, and complete acute-phase ROP data were collected for 755 infants with birth weights of less than 2000 g or born at less than 37 weeks of gestational age but weighing more than 2000 g who required more than 23 hours of oxygen. Infants born earlier in gestation were found to develop ROP later postnatally than

infants born later in gestation. In addition, infants born at earlier gestational ages developed ROP at an earlier postconceptional age than did infants born at later gestational ages. For example, an infant born at 27 weeks of gestation developed ROP at approximately 34 to 35 weeks of postconceptional age, whereas an infant born at 32 weeks of gestational age was likely to develop ROP at approximately 35 to 37 weeks of postconceptional age.

Palmer and colleagues, on behalf of the CRYO-ROP Cooperative Group,¹ also reported the relationship between gestational age and onset of ROP in the cohort of 4099 infants with birth weights of less than 1251 g who participated in the natural history portion of the study. Because examinations started at 4 to 7 weeks after birth and 21.5% of the infants had ROP at the first examination, the data concerning onset of ROP had to be inferred from median values and 5th and 95th percentiles (Table 51-2). The median for onset of stage 1 ROP was 34.3 weeks of postconceptional age; 95% of all stage 1 events were

Table 51-2. Onset of Acute-Phase Retinopathy of Prematurity (ROP) by Postconceptional Age (Weeks)

	Median	5th Percentile	95th Percentile
Stage 1 ROP	34.3	—	39.1
Stage 2 ROP	35.4	32.0	40.7
Stage 3 ROP	36.6	32.6	42.9
Prethreshold ROP	36.1	32.4	41.5
Threshold ROP	36.9	33.6	42.0

Adapted from Palmer EA, Flynn JT, Hardy RJ, et al: Incidence and early course of retinopathy of prematurity. *Ophthalmology* 98:1628, 1991.

observed by 39.1 weeks. This report also documented that the appearance of stages 1, 2, and 3 is closely linked to gestational age and the sequence happened at approximately weekly intervals.

VISUAL MORBIDITY OF PREMATURE BIRTH

In comparison with full-term infants, premature infants who do not develop ROP are at increased risk for ocular problems later in life. The development of ROP during the neonatal period further increases the risk of later visual abnormalities, and the risk increases with increasing severity of ROP. Myopia, strabismus, nystagmus, and amblyopia are more common in preterm children who developed ROP during the neonatal period.²⁸⁻³² In addition, neurosensory impairments are much more likely to occur in infants with extremely low birth weights (28%) than in full-term controls (1%), as is the risk for requiring special educational assistance during their school years (58% versus 13%; odds ratio = 9.0).³³

Myopia (nearsightedness), in particular, occurs with greater frequency and greater severity as severity of ROP increases (Fig. 51-6).^{29,30} Myopia, especially high degrees, is associated with an increased risk of developing retinal tears and detachment, glaucoma, and retinal degeneration. In addition, retinal detachments are more common in older children who had ROP as infants. Thus, the premature infant, particularly the infant who develops serious ROP during the neonatal period, is at increased risk for serious ocular abnormalities later in life and should be monitored into adulthood.

CURRENT UNDERSTANDING OF THE PATHOGENESIS OF RETINOPATHY OF PREMATURE

ROP appears to consist of at least two phases, and the development of retinopathy is consistently tied to the state of development of the retina. In the initial phase, superficial retinal vessel growth ceases because of a number of insults that transpire as a result of premature birth. These include exposure to relatively high levels of oxygen in the extrauterine environment²¹ and complications such as intraventricular hemorrhage, sepsis, necrotizing

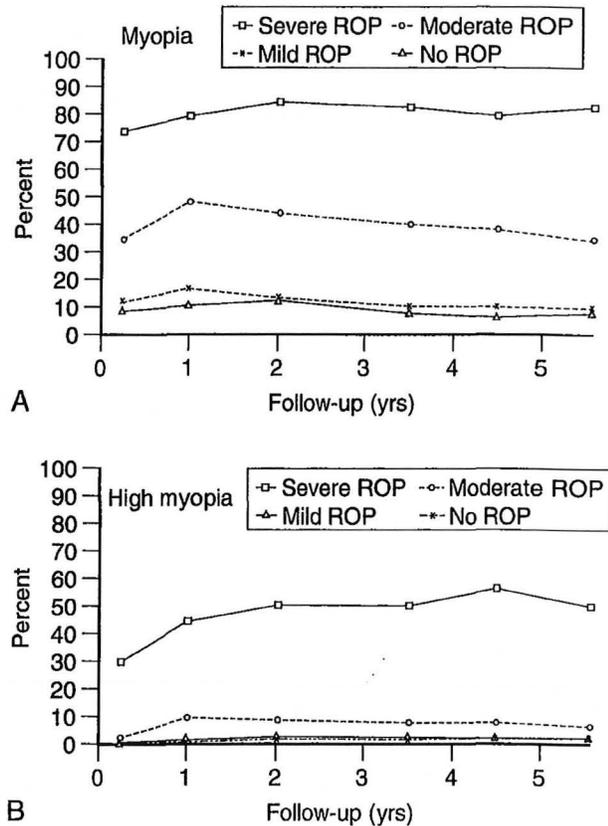


Figure 51-6. Prevalence of myopia (A) and high myopia (B) from ages 3 months to 5½ years compared to severity of acute-phase retinopathy of prematurity (ROP). High myopia is defined as 5 D or more. (From Quinn GE, Dobson V, Kivlin J, et al: Prevalence of myopia between three months and 5½ years in preterm infants with and without retinopathy of prematurity. *Ophthalmology* 105:1292, 1998.)

enterocolitis, and shock.^{23,27} A second phase of abnormal retinal vascularization ensues as retinal development proceeds, with associated increasing metabolic demands. The abnormal vasculogenesis is probably the result of the production of angiogenic factors in an avascular retina, resulting in exuberant new vessel formation, and is similar to the pathogenesis of neovascularization in diabetic retinopathy.³⁴

Among the cytokines and growth factors that have angiogenic activity, vascular endothelial growth factor (VEGF) has been shown to play a possible role in the development of vascular abnormalities in ROP.³⁵ Using a mouse model, Pierce and coworkers demonstrated that hyperoxia down-regulates expression of VEGF with resulting obliteration of immature retina vessels, and hypoxia up-regulates VEGF expression.³⁶ They also demonstrated that when VEGF is down-regulated by hyperoxia, exogenous VEGF would “rescue” the immature retinal vessels. Furthermore, Young and associates confirmed the mouse model VEGF findings in eyes at autopsy of an infant with ROP.³⁷

In a report by Hellstrom and colleagues,³⁸ insulin-like growth factor 1 (IGF-1) was found to be associated with

development of ROP in infants with low birth weights. The investigators found that low levels of IGF-1 in a knockout mouse model prevented the normal development of retinal vessels, even in the presence of adequate levels of VEGF. In addition, they studied the ocular findings in 31 infants born at gestational ages of 26 to 30 weeks. In some infants in the intensive care unit, they found near-normal levels of IGF-1 and did not detect the development of ROP in those infants. Infants who showed persistently low levels of IGF-1 and were slower to develop levels in the normal range were more likely to develop ROP. For the 19 infants who did not develop ROP, the mean time from birth to an IGF-1 level of 30 ng/mL was 19 days (range, 1 to 79), in comparison with 58 days (range, 29 to 120) for the 10 infants who developed ROP ($P \leq .0001$). In addition, during the critical period of 31 to 35 weeks, the mean levels of IGF-1 were consistently higher in the infants who did not develop ROP than in the infants who developed ROP. The authors suggest that reaching "normal" serum levels of IGF-1 late allows vasoproliferative factors to accumulate and, as the IGF-1 levels rise, the vasoproliferative factors, such as VEGF, incite exuberant overgrowth of retinal vessels. These findings in animal models, with support from studies of the eye findings in human infants, represent an exciting new area for increasing the understanding of the pathophysiologic mechanisms in ROP and potential treatment modalities.

TREATMENT

Therapy for ROP consists of both surgical and medical treatments and has undergone radical change since 1980. Surgical treatment is the most widely discussed form of therapy at present because of the results of the CRYO-ROP study. However, there is continued and active interest in the use of medical and other surgical means to prevent or to treat this disorder. In addition, the prevention of extremely premature birth would decrease the number of children at risk for the disorder.

Cryotherapy for Threshold Retinopathy of Prematurity

Cryotherapy to the avascular peripheral retina of eyes with severe forms of active ROP had been used in Japan since the early 1970s^{39,40} and gradually gained advocates in several countries.^{41,42} Many ophthalmologists were reluctant to employ this treatment modality because of untoward or unexpected results.^{43,44} However, in 1985, Tasman and colleagues⁴⁵ reported a beneficial effect of cryotherapy in a small, randomized trial of cryotherapy for severe ROP.

The large, randomized, multicenter trial of cryotherapy for ROP was designed to evaluate the effect of cryotherapy on stage 3+ ROP with 5 continuous or 8 cumulative clock hours of fibrovascular proliferation. Infants with birth weights of less than 1251 g born between January 1, 1986, and November 30, 1987, who were admitted to the nursery at one of the 23 participating centers were eligible to participate in a natural history study of ROP. If threshold ROP developed in one or both eyes, permission was sought for enrollment into

the randomized portion of the trial, in which one eye received cryotherapy and the other eye was observed as a control. Infants with threshold ROP could also be referred to a participating center to participate in the trial. In all, 4099 children were in the natural history cohort and 291 children were in the randomized cohort; the latter group included 218 from the natural history group and 73 referred from other hospitals with the diagnosis of threshold ROP. An unfavorable structural outcome was defined as a posterior retinal detachment or retinal fold involving the macular or retrolental tissue obscuring the retina.⁶

Preliminary results from CRYO-ROP were published in April 1988⁶ and showed that the incidence of unfavorable structural outcomes, as judged by masked grading of fundus photographs, was only 21.8% among eyes that received cryotherapy, in comparison with 43% among untreated eyes ($P < .00001$). A higher frequency of unfavorable structural outcomes was noted in infants with lower birth weights and in zone 1 retinopathy, regardless of treatment status. Thus far, these results have been substantiated at the 3-month,²⁰ 1-year,²⁸ 3½-year,⁴⁶ 5½-year,⁴⁷ and 10-year study examinations⁴⁸; the latest report, at 10 years, showed a 27.2% incidence of unfavorable structural outcomes among treated eyes, in comparison with a 47.9% rate among untreated eyes, as determined by examining ophthalmologists ($P < .001$).

Visual function as a quantitative outcome measure was added to the study at the 1-year study examination, when monocular grating acuity was measured by the Teller Acuity Card Procedure⁴⁹ by testers unaware of the treatment status of each eye. The results showed an unfavorable functional outcome in 35% of the treated eyes, in comparison with 56.3% of the control eyes ($P < .0001$), indicating both a functional and a structural benefit from cryotherapy in eyes with threshold ROP.²⁸

Because the children have matured and many have been able to provide more complex data, visual function measures such as recognition acuity, color vision, visual field extent, and contrast sensitivity have also been assessed. The structural benefits from cryotherapy have persisted from the 3-month study examination to age 10 years; however, the favorable effect of cryotherapy on visual function of eyes with threshold ROP has apparently been somewhat reduced, although it has remained statistically significant over the same time period. At age 10 years (the most recently reported examination), the children who had participated in the randomized trial during the neonatal period were tested with Snellen letters by testers unaware of each child's eye status. With a follow-up rate of 97% of eligible infants (36 of the original 291 had died before the examination), the results showed 20/200 or worse visual acuity in fewer treated eyes (44.4%) than control eyes (62.1%; $P < .001$). In addition, there was concern at the 5½-year examination that visual acuity was in the 20/40 range or better in slightly more eyes in the control group than in the treated group. This finding was not substantiated at the 10-year examination, inasmuch as there were almost equal numbers of treated eyes and control eyes in this excellent acuity range (25.2% of treated eyes versus 23.7% of control eyes; $P = .63$).⁴⁸

In addition to visual acuity, visual field,^{50,51} color vision,⁵² and contrast sensitivity⁵³ have been assessed in children from the randomized portion of the trial, as well as a subset of children from the natural history study who did not develop ROP during the neonatal period. Using double-arc perimetry at the 5½-year examination⁵⁰ and standard Goldmann perimetry at the 10-year examination,⁵¹ the CRYO-ROP investigators were able to document substantial overall favorable treatment effect of cryotherapy for threshold ROP; however, there was also a deficit in visual field extent of approximately 10% in treated eyes in which sight was preserved by the treatment. There did not appear to be an effect of cryotherapy on color vision⁵² or contrast sensitivity⁵³ in eyes that had undergone the treatment for threshold ROP. However, regardless of treatment status, eyes that had severe ROP during the neonatal period showed significantly poorer contrast sensitivity than did eyes of preterm children who did not develop ROP.

Follow-up for the children in the randomized portion of the CRYO-ROP study continued through age 15 years and was completed in 2003. This examination included an eye examination by a study ophthalmologist, as well as the assessment of Snellen visual acuity. The primary purpose of this examination was to detect untoward side effects of the treatment, including an increase in retinal detachments or visual acuity abnormalities.

Cryotherapy for severe stages of ROP has proved critical in preventing blindness in premature infants, but it should be viewed as a surgical procedure even though it can be performed in the nursery with local anesthesia. The CRYO-ROP Cooperative Group reported a rate of 5.3% for conjunctival laceration and of 22.3% for retinal, preretinal, or vitreous hemorrhage in eyes that underwent cryotherapy.²⁰ Systemic complications included a 9.4% incidence of bradycardia. Brown and associates⁵⁴ reported 3 cases of respiratory arrest and 1 of cardiorespiratory arrest among 80 infants treated with cryotherapy, only 5 of whom had general anesthesia for the procedure.

Laser Photocoagulation

The first surgical treatment investigated for acute phases of ROP was laser photocoagulation.⁵⁵ However, the treatment was technically quite difficult, and cryotherapy of the peripheral avascular area gradually replaced laser treatment. Cryotherapy was used in the large multicenter CRYO-ROP study that established the benefit of surgical treatment for threshold ROP. The binocular laser indirect ophthalmoscope was developed in the late 1980s and early 1990s, again making possible use of this potentially less destructive means of treatment of threshold ROP. Unfortunately, because of the large sample size necessary to prove equality of treatment modalities, no large-scale randomized trial comparing the outcomes and risks of laser photocoagulation and cryotherapy for severe ROP is likely to be undertaken. Laser, however, is an accepted alternative treatment modality for threshold ROP and may involve less stress for the infant. The largest data set that addressed the issue of equality of the two treatments consisted of a meta-analysis of three small randomized

studies with a total of 71 patients.⁵⁶ Laser therapy outcomes were determined to be "as good as cryotherapy." In addition, the authors noted the lessened stress for the child during treatment with laser, less postoperative pain, and less confluence of retinal scarring.

Whichever means of treatment is chosen, surgical intervention in threshold should be undertaken within 72 hours of the diagnosis of threshold ROP if the infant is stable enough to tolerate the procedure. Cryotherapy or laser photocoagulation may be used to ablate the entire avascular retina. Either technique may be performed with local or general anesthesia, and both are effective in preventing progression of disease in most cases. Laser photocoagulation may be a more reasonable choice in very posterior disease, inasmuch as conjunctival incisions and difficult probe placement are routine in cryotherapy for posterior disease but are not required for laser photocoagulation.

Scleral Buckle and Vitrectomy Procedures

Despite the success of cryotherapy in preventing blindness in many infants with severe ROP, the condition in a number of infants deteriorates to partial or total retinal detachment. The detachments are treated with scleral buckling and vitrectomy techniques.⁵⁷⁻⁶⁵ It is often difficult to determine clinically whether a detachment is partial or total and the timing of intervention is determined on an individual basis. This may help explain the variation in reported success rates, from 10% to 70%. Assessment of visual function in eyes that have undergone vitrectomy/scleral buckling procedures is usually difficult because many affected children have other handicaps⁶⁶⁻⁶⁸ and assessment of very low levels of vision is not standardized.

Greven and Tasman reported visual acuities of 20/400 or better in four eyes with stage 4B or stage 5 retinal detachments that had undergone scleral buckling procedures.⁶² Katsumi and colleagues suggested that in children with severe ROP residua and very low vision, moving targets may provide better acuity results than stationary ones.⁶⁹ The largest case series of visual outcomes after vitrectomy for stage 5 ROP was reported by Quinn and colleagues, on behalf of the CRYO-ROP Cooperative Group.⁷⁰ Of the 98 eyes with threshold ROP in the CRYO-ROP study that had undergone vitrectomy procedures for total retinal detachment, only 2 eyes of one patient had evidence of any pattern vision (although the level was the lowest measurable in the acuity card procedure) at the 1-year study examination. With further follow-up reported on the same cohort at 5½ years of age,⁷¹ these two eyes had become blind, and a single eye (one that had undergone a vitrectomy procedure before age 1 year) had minimal pattern vision.

Medical Treatment

The medical treatment of ROP has been less strikingly effective than cryotherapy, but, as Tasman suggested,⁷² the approximately 25% incidence rate of unfavorable structural outcomes after cryotherapy is "unacceptably high" and other strategies must be devised. A number of

medical treatments, both prophylactic and therapeutic for established retinopathy, have been used in an attempt to decrease the incidence or severity of ROP or decrease progression of established disease.

Through a prospective randomized study in infants with birth weights of less than 1251 g and gestational ages of less than 31 weeks, the Effects of Light Reduction on Retinopathy of Prematurity (Light-ROP) study⁷³ was designed as a prophylactic trial and an attempt to determine the effect on incidence of ROP by limiting light exposure early in life. The rationale for the study was that decreasing oxidant radical exposure in the developing retina of the premature infant would decrease the incidence of ROP. Shortly after birth, goggles were placed over the eyes of randomly selected infants. The goggles remained in place until 31 weeks postconception age or 4 weeks after birth, whichever was longer. When incidence of ROP in these infants was compared with that in infants who had no goggles, the investigators found no significant difference between the two groups (54% in the infants with goggles versus 58% in the control group; $P = .50$; relative risk = 0.9; 95% confidence interval [CI] = 0.8 to 1.1). Thus, it does not appear that reducing light exposure early in life decreases the likelihood of developing the ROP.

The Supplemental Therapeutic Oxygen for Prethreshold Retinopathy of Prematurity (STOP-ROP) study was designed as a therapeutic study of already established retinopathy. The randomized trial examined the efficacy and risk of using supplemental oxygen treatment at the diagnosis of prethreshold ROP in preventing progression to threshold ROP.⁷⁴ The rationale for the study was based on the hypothesis that increasing the oxygen available to overgrowing retinal vessels would decrease progression of disease. Infants with prethreshold ROP in one or both eyes were assigned to receive conventional oxygen treatment (pulse oximetry target was 89% to 94% saturation) or supplemental oxygen treatment (pulse oximetry target was 94% to 99%). Six hundred forty-nine infants from 30 centers were recruited over 5 years; the rate of progression to threshold ROP was 48% among infants receiving conventional treatment and 41% of those receiving supplemental treatment (adjusted odds ratio = 0.72; 95% CI = 0.5 to 1.01). In addition, supplemental oxygen increased the risk of adverse pulmonary events, including pneumonia and chronic lung disease. Thus, this treatment of established disease is not a standard of care.

The naturally occurring antioxidant vitamin E (α -tocopherol) has promise for decreasing incidence of retinopathy, and trials were conducted in several centers.⁷⁵ The rationales for its use were that (1) vitamin E is a naturally occurring, potent free radical scavenger that decreases lipid peroxidation and helps maintain membrane integrity and (2) the serum and tissue levels of vitamin E, a lipid-soluble substance, are known to be deficient in newborns, particularly premature infants.⁷⁶⁻⁷⁸ Its use in ROP prophylaxis, and the encouraging preliminary findings, were reported by Owens and Owens in 1949.⁷⁹ However, this observation was followed closely by reports that oxygen treatment of premature infants had a close

link with ROP,⁸⁰⁻⁸² and investigation into the effect of vitamin E on ROP was abandoned until the 1970s.

In 1974, during a period when the prevalence of ROP was again surging among premature infants, Johnson and associates reported a randomized clinical trial with oral and parenteral α -tocopherol acetate supplements (as an investigational new drug) to achieve physiologic serum levels (1 to 3 mg/dL) in premature infants, most of whom were vitamin E deficient in the nurseries of that time.⁸³ This and subsequent work through 1979⁸⁴ showed a beneficial effect on incidence and severity of ROP associated with vitamin E prophylaxis that targeted physiologic serum levels of the antioxidant. A National Eye Institute-sponsored randomized, controlled clinical trial was undertaken from 1979 to 1981 in an attempt to determine the likelihood of eliminating ROP or its serious sequelae by using pharmacologic serum levels with a target level of 4 to 5 mg/dL.²⁶ The results of this clinical trial showed a decrease in the incidence of ROP by multivariate logistic analysis that controlled for birth weight, gestational age, days on oxygen and ventilator therapy, and days in the hospital. This study also, however, documented an increased incidence of sepsis and late-onset necrotizing enterocolitis in infants with birth weights of less than 1501 g who had received vitamin E prophylaxis at pharmacologic serum levels since birth.²⁷

Also in the late 1970s and early 1980s, several other clinical trials were undertaken to determine the effectiveness of vitamin E in preventing ROP. In a clinical trial from 1979 to 1980, Hittner and associates supplemented infants with birth weights of less than 1501 g for the first 8 weeks after birth and raised serum levels from 0.3 mg/dL on admission to a mean of 1.2 mg/dL.⁸⁵ No threshold ROP was observed in the eyes of vitamin E-treated infants, in comparison with five cases in eyes of control subjects. Milner and coworkers reported a placebo-controlled trial with 114 placebo- and 111 vitamin E-treated infants with birth weights of less than 1501 g and observed that five placebo- and three vitamin E-treated infants developed severe ROP.⁸⁶ Finer and colleagues, in a phase 2 trial of 174 infants with birth weights of less than 1501 g, found a vitamin E treatment effect in multiple linear regression.⁸⁷ Puklin and associates, in a study of respiratory distress syndrome in larger infants, found no effect of vitamin E on ROP,⁸⁸ and Phelps and colleagues found no difference in stage 3+ ROP in a study of 196 infants with birth weights of less than 1501 g.⁸⁹ In a meta-analysis of these trials, Raju and coworkers found no difference in the incidence of retinopathy among treated infants versus placebo recipients, but they did find that the pooled odds ratio for developing stage 3+ ROP with vitamin E prophylaxis was 0.44 (95% CI = 0.21 to 0.81; $P < .02$).⁷⁵ Thus, the authors suggested that the role of vitamin E in reducing severe ROP should be reevaluated.

Inasmuch as most cases of ROP are mild and regress, pharmacologic prophylaxis with vitamin E is not recommended, because any serious side effects such as necrotizing enterocolitis and sepsis,²⁷ as well as a possible increased incidence of retinal hemorrhage⁹⁰ and an increase in intraventricular hemorrhage,⁸⁹ are unacceptable. However, prophylaxis with commercially available

preparations of vitamin E with serum target levels in the physiologic range of 1 to 3 mg/dL is recommended by Johnson and associates⁹¹ and others.^{92,93} Because threshold ROP is usually seen after 8 weeks of age,¹ the likelihood of vitamin E-associated side effects was thought to be minimal and the risk/benefit ratio likely to be favorable.

Thus, there are no established medical treatments currently available for prevention of ROP or for treatment of established retinopathy.

RECENT TREATMENT TRIALS

The Early Treatment of ROP (ET-ROP) study was a surgical treatment trial that began enrolling infants with birth weights of less than 1251 g who develop moderately severe ROP.⁹⁴ This National Eye Institute-funded multicenter collaborative trial was designed to test the hypothesis that eyes with moderately severe ROP (judged to have a 15% or greater risk of progression to severe cicatricial outcomes at 3 months after term, according to data from the CRYO-ROP study) will have better outcomes if treated earlier in the course of disease. For children in whom both eyes meet study criteria for randomization, one eye was randomly assigned to receive treatment before the accepted threshold level, and the other eye was observed and treated at threshold ROP, if the retinopathy had progressed to that point. When the condition of only one eye of a child was severe enough to meet study criteria for randomization, that eye was randomly assigned to receive early treatment or routine treatment if the retinopathy progresses. Results of structural outcomes at 6 and 9 months corrected age, and grating visual acuity at 9 months, were recently reported for 401 infants who had high-risk prethreshold ROP. Grating acuity results showed improvements in visual outcomes with earlier treatment, as did structural outcomes. Follow-up is planned through age 6 years. The investigators developed an algorithm based on international classification of ROP to define which eyes should be treated earlier.

IMPLICATIONS FOR MEDICAL PRACTICE

The obligation of the neonatologists and ophthalmologists in caring for the premature infant have changed since the 1980s from a passive role of observing the infant and keeping parents informed to an active role in which examinations must be carefully timed and undertaken to provide the child with the best chance of having the presence of threshold ROP detected at the earliest possible time. ROP screening must begin between 4 and 7 weeks after birth and continue on an every-other-week basis until the chance of developing threshold ROP is remote. This is the point at which the retinal vessels have nearly reached the ora serrata or previously observed mild or moderate ROP has regressed. Once threshold ROP has been diagnosed, cryotherapy, perhaps in conjunction with or even replaced by laser photocoagulation, needs to be undertaken within a brief period to minimize the chance of progression to retinal detachment.

The timing of the follow-up examinations is crucial for early detection of threshold ROP. Guidelines for ROP

screening have been suggested jointly by the American Academy of Pediatrics, the American Academy of Ophthalmology, and the American Association of Pediatric Ophthalmology and Strabismus⁹⁵ and have been revised. At present, when no or mild ROP is evident, examinations every other week are sufficient, but if moderate ROP or plus disease is noted, more frequent examinations are needed—sometimes every 2 to 4 days. Schaffer and associates, on behalf of the CRYO-ROP cooperative Group,⁹⁶ found that the rate of change from no or mild ROP to moderate ROP was also a strong indicator of whether serious ROP was likely to develop.

If threshold ROP is not reached and any ROP that developed has regressed, infants should have at least one follow-up ophthalmologic examination during their first 6 months; annual follow-up is recommended for those who have had significant active retinopathy.⁹⁵ The purpose of these visits is to detect strabismus, refractive errors, and other ocular abnormalities that are more common in premature infants.⁹⁷⁻⁹⁹

In the nursery at The Children's Hospital of Philadelphia, which serves an outborn population, my colleagues and I examine all infants with birth weights of less than 1500 g, as well as all infants receiving significant supplemental oxygen if birth weight was between 1501 and 1800 g or if the child was born at less than 32 weeks of gestation. Other infants are examined upon request by the neonatologist. All infants are examined initially at 4 to 6 weeks of age, if stable enough to tolerate the examination.

The benefit of timely detection and treatment of ROP was pointed out by Javitt and coworkers in an examination of CRYO-ROP data.¹⁰⁰ They calculated that, because of timely implementation of cryotherapy, a lifelong disability (i.e., blindness) is prevented in more than 300 infants per year and that the net savings of funds that would have been necessary to provide services for these children over their lifetime is between \$38.3 million and \$64.9 million per year of premature births.

FUTURE WORK

Although much progress has been made in ROP, much remains to be done, because the best treatment regimen to date, peripheral retinal ablation, still has an unacceptably high failure rate (as much as 1 per 4). Researchers must determine why ROP progresses to blindness in some children, despite timely intervention, whereas the retinopathy regresses in others who undergo the same treatment. Looking at the eye with an indirect ophthalmoscope does not appear adequate to detect which eyes might benefit from alternative therapeutic interventions or prophylaxis. Other useful parameters that could be examined include screening for genetic susceptibility mutations (e.g., Norrie disease gene),¹⁰¹ measuring blood and urine levels of vascular growth factors such as VEGF³⁶ and IGF-1,³⁸ and assessment of blood flow abnormalities in the retina to help quantify the definition of plus disease.¹⁰²

Many of these research initiatives, once fully developed, may challenge the current diagnostic and treatment strategies for ROP.

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