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Cailyn Reilly

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WHERE IS CONCUSSION LITIGATION HEADED?
THE IMPACT OF *RIDDELL, INC. V. SCHUTT SPORTS,
INC.* ON BRAIN INJURY LAW

CAILYN M. REILLY*

I. INTRODUCTION

Concussions are no joke; they are deadly.¹ They lead to cognitive problems, physiological brain damage, and physical and emotional disorders.² But concussions are the reality of contact sports.³ And contact sports, such as football, are not going anywhere.⁴

* Managing Editor of Student Works, *Jeffrey S. Moorad Sports Law Journal*, Vol. XX; J.D. Candidate, Villanova University School of Law, May 2013; B.A., 2007, Colgate University.

1. See Reeves Wiedeman, *The Sporting Scene: Football in Hell*, THE NEW YORKER, Nov. 21, 2011, <http://www.newyorker.com/online/blogs/sportingscene/2011/11/football-in-hell.html> (describing physical magnitude of “what football’s really like”); Michelle D. McGrit, *Do Universities Have a Special Duty of Care to Protect Student-Athletes from Injury?*, 6 VILL. SPORTS & ENT. L.J. 219, 219 (1999) (describing omnipresent risk of injury or death when participating in sports); see also Alan Schwarz, *Helmet Design Absorbs Shock in a New Way*, N.Y. TIMES (Oct. 27, 2007), http://www.nytimes.com/2007/10/27/sports/football/27helmets.html?page_wanted=all [hereinafter Schwarz 10/27/07] (reporting concussion effects “can range from persistent memory problems and depression to coma and death”).

2. See Malcolm Gladwell, *Offensive Play; How different are dogfighting and football?*, THE NEW YORKER, Oct. 19, 2009, at 50, available at http://www.newyorker.com/reporting/2009/10/19/091019fa_fact_gladwell (explaining Doctors Bennett Omalu, Ann McKee, and Robert Cantu’s findings of physiological effect on brain, called chronic traumatic encephalopathy (CTE), that results from multiple head impacts).

3. See McGrit, *supra* note 1 at 219-20 (describing risk of participation in sports as something that “anyone who has watched or participated in sports knows”); see also Gerard T. Noce & Frans J. von Kaenel, *Individual and Institutional Liability for Injuries Arising From Sports and Athletics: Participants, Coaches, Clubs and Schools May Incur Liability for Sports-Related Injuries, But Different Standards Apply*, 63 DEF. COUNS. J. 517 (1996) (“Participation in sports is inherently dangerous Physical contact is a fundamental and sanctioned component of many sports.”); see also Richard Obert, *Suffering the Sideline Injuries Are More Than Dealing With Pain*, THE ARIZ. REPUBLIC, Nov. 14, 1997, at C11 (“Physical injuries, such as concussions and broken bones, are an unavoidable risk in any sport.”).

4. See Mike Wise, *Super Bowl 2012: Football coaches and players need to get health issues through their heads*, WASH. POST. (Feb. 1, 2012), http://www.washingtonpost.com/sports/redskins/super-bowl-2012-football-coaches-and-players-need-to-get-health-issues-through-their-heads/2012/01/31/gIQAbnPziQ_story.html (proposing culture change in football).

Thus, the question remains: what can be done?⁵ The answer is unclear.⁶ Although steps have been taken to educate players, parents, and coaching staff about the dangers of concussions—and certain rule changes and state legislation have decreased the opportunity for concussions to occur during play—concussions, nevertheless, continue to occur.⁷ The answer is not to eliminate contact sports.⁸ This is America; what a travesty an autumn weekend would be without the anticipation of a football game.⁹

Various measures have been proposed to make the game of football safer.¹⁰ In addition to rule changes, these include more disciplined forms of contact, education, and better screening and post-play testing.¹¹ Some of these measures are already in place in

5. See Jorge Castillo, *College Athlete Died of Head Trauma, Father Says*, N.Y. TIMES (Aug. 30, 2011), <http://www.nytimes.com/2011/08/31/sports/ncaaf/college-football-player-died-from-head-trauma-father-says.html> (asking that “something . . . be made better, through education or equipment or whatever . . .” to protect others following death of son from concussive hit).

6. See Brittany Sauser, *The Search For a Safer Helmet*, TECHNOLOGY REVIEW (Jan. 26, 2011), <http://www.technologyreview.com/computing/27126/?a=f> (referring to attempts to protect against concussions through better equipment and concluding, “frankly, I don’t think people know which way to go at this point”; quoting Chris Nowinski, president of Sports Legacy Institute). For a further discussion of Nowinski’s involvement in concussion research, see *infra* notes 94-96 and accompanying text.

7. See, e.g., H.R. 1347, 111th Cong. (2nd Sess. 2010) (seeking to create and implement new guidelines for the prevention and treatment of concussions in school-aged children); see also Jorge Castillo, *An Ordinary Football Game, Then A Player Dies*, N.Y. TIMES (Oct. 19, 2011), <http://www.nytimes.com/2011/10/20/sports/seemingly-ordinary-football-game-then-a-player-dies.html> (“As those who play football learn new ways to improve safety—through training, medical response, and equipment—sometimes they are left to contemplate this: brains remain vulnerable, and even the most ordinary collisions on the field can kill.”); see also Alan Schwarz, *Senator Calls for Helmet Safety Investigation*, N.Y. TIMES, Jan. 4, 2011, at A5, available at <http://www.nytimes.com/2011/01/04/sports/football/04-helmets.html> [hereinafter Schwarz 1/4/11] (“The estimated 500,000 concussions sustained annually by [athletes under 18 who play organized football] have become a pressing health concern in football across the United States, leading to rule changes and state legislation . . .”).

8. See, e.g., KJ Dell’Antonia, *Motherlode, Adventures in Parenting: Football and the Fear of Concussions*, N.Y. TIMES (Jan. 12, 2012, 1:24 PM) <http://parenting.blogs.nytimes.com/tag/concussions/> (“NFL touch football will not revolutionize the game. If you’re going to play football . . . you have to accept that it’s always going to be a rough sport.”).

9. See *id.* (“[F]ootball is special, both because of the hits and because of the history – in this country, it’s easy to find generations of football players watching We love our football, urban and rural”).

10. See Sauser, *supra* note 6 (condoning NFL’s attempts to protect against concussions through better awareness, equipment, and rules).

11. See *id.* (describing “significant rule changes” enacted in 2010-2011 season in response to “greater awareness of head injuries,” including more serious penalties and fines for helmet-to-helmet and defenseless player hits).

many youth, collegiate, and professional leagues, but concussions, ostensibly, have only increased.¹² Many proposals focus on equipment changes.¹³

In football, the three leading helmet makers, Riddell, Inc. (“Riddell”), Schutt Sports, Inc. (“Schutt”), and Adams U.S.A., have competed with each other in a way that has benefited the ever-growing body of concerned football helmet purchasers.¹⁴ These companies have competed to produce football helmets that purportedly lower the risk of concussions.¹⁵ Riddell was the first to advertise and market one such helmet, which it called the Revolution.¹⁶ The Revolution model, introduced in 2002, was the first football helmet designed for “concussion resistance.”¹⁷ In 2003, Schutt introduced

12. See, e.g., WASH. REV. CODE ANN. § 28A.600.190 (West 2009) (providing Washington State concussion and head injury guidelines); see also XENITH ACAD., BUILDING THE ENLIGHTENED WARRIOR, at 5 (2009), available at http://www.xenith.com/mission_control/assets/Uploads/BuildingtheEnlightenedWarrior.pdf (explaining that increased awareness generally leads to “significant short term increase in diagnoses”). But see Micky Collins et al., *Examining Concussion Rates and Return to Play in High School Football Players Wearing Newer Helmet Technology: A Three-Year Prospective Cohort Study*, 58 NEUROSURGERY 275, 286 (Feb. 2006) (“Despite modifications in equipment and rules in football, concussive injury remains a serious consideration with regard to the well-being of athletes.”).

13. See, e.g., Alan Schwarz, *As Injuries Rise, Scant Oversight of Helmet Safety*, N.Y. TIMES, Oct. 21, 2010, at A1, available at <http://www.nytimes.com/2010/10/21/sports/football/21helmets.html?pagewanted=all&r=0> [hereinafter Schwarz 10/21/10] (expressing exasperation at fact that football helmet research and development have yet to determine effective means for preventing concussions in contact sports: “this has become a serious impediment to making a safer football helmet”).

14. See Schwarz 10/27/07, *supra* note 1 (“Contemporary helmet manufacturers have made a point of improving protection against concussions.”); Schwarz 10/21/10, *supra* note 13 (“Recent engineering advances made by Riddell, Schutt, Adams and other manufacturers have undoubtedly improved the performance of the football helmet . . .”).

15. See Shelly Anderson, *New Helmet Designs Have Concussions in Mind*, PITTSBURGH POST-GAZETTE (July 28, 2002), <http://old.post-gazette.com/steelers/20020728helmets0728p4.asp> (describing “movement to try to reduce [concussions] in football through better helmets” from which Riddell and Adams produced Riddell Revolution and Adams Pro Elite). Competition among these suppliers of football equipment has a long history, and is not limited merely to concussion-reduction technology. See *Schutt Manufacturing Co. v. Riddell, Inc.*, 673 F.2d 202, 203-04 (7th Cir. 1982) (memorializing storied history of competition between companies).

16. See Anderson, *supra* note 15 (introducing Riddell’s helmet, designed to reduce incidence of concussion). Despite its name, critics were skeptical of how revolutionary the helmet truly was. See *id.* (demonstrating response to Riddell’s Revolution anti-concussion claims, stating “the jump to the conclusion that the Riddell helmet is indeed a revolutionary design is premature”).

17. Gregg Easterbrook, *Virginia Tech helmet research crucial*, ESPN (July 19, 2011), http://sports.espn.go.com/espn/page2/story?page=easterbrook-110719_virginia_tech_helmet_study&sportCat=nfl. For a further discussion of Riddell manufacturing, see *infra* notes 39-42 and accompanying text.

its own line of high-end protective products, including the DNA football helmet, which also purported to protect players through concussion-reduction cushioning technology.¹⁸

In December 2008 Riddell filed a lawsuit against Schutt in the Western District of Wisconsin.¹⁹ In *Riddell, Inc. v. Schutt Sports, Inc.*,²⁰ the manufacturer claimed infringement of its jaw flap patents, false advertising under section 43(a) of the federal Lanham Act, 15 U.S.C. § 1125(a), trade libel, and product disparagement.²¹ In response, Schutt brought counterclaims for false advertising under the Lanham Act, and deceptive trade practices under the Wisconsin Deceptive Trade Practices Act.²² The District Court addressed the patent infringement claim in a separate opinion.²³ This Note focuses on the Court's decision as to the claims of false advertising and deceptive trade practices, for which the District Court ultimately ruled in favor of Riddell, finding that there was "no evidence that Schutt suffered any injury from those advertisements."²⁴

This Note explores the *Riddell* decision and briefly hypothesizes on how future courts will treat claims of false advertisement regarding concussions.²⁵ Section II describes the factual and legal

18. See *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 977 (W.D. Wis. 2010) (identifying Schutt's high-end products); see also *Schutt Sports Historical Timeline*, SCHUTT, <http://www.schuttsports.com/asp/general/historytimeline.aspx> (describing timeline of Schutt Sports). For a further discussion of Schutt manufacturing, see *infra* notes 43-46 and accompanying text.

19. See *Riddell*, 724 F. Supp. 2d. at 966 (introducing cause of action). For a further discussion of the lawsuit, see *infra* notes 47-84 and accompanying text.

20. 724 F. Supp. 2d 963 (W.D. Wis. 2010). For a further discussion of Riddell's claims, see *infra* notes 59-77 and accompanying text.

21. See *id.* at 966 (describing plaintiff's claims). For a further discussion of the elements of false advertising under the Lanham Act, see *infra* notes 127-167 and accompanying text.

22. See *id.* (providing Schutt's counterclaims). Schutt also brought counterclaims for declaratory judgment of non-infringement, invalidity and inequitable conduct. See *id.* (listing other counterclaims). For a further discussion of Schutt's counterclaims, see *infra* notes 35-54 and accompanying text.

23. See *id.* (distinguishing defendant Schutt's counterclaims for false advertising and deceptive trade practices and plaintiff Riddell's patent infringement claims and noting "[t]hose motions will be addressed in a separate opinion"). For a further discussion of the procedural posture of the case, see *infra* notes 35-54 and accompanying text.

24. See *id.* at 966, 975, 979 (granting Riddell's motion for partial summary judgment on Schutt's counterclaims for false advertising and deceptive trade practices and finding that Schutt did not provide any evidence to support "a conclusion that the results or methods of [Riddell's] concussion study are unreliable" or that Schutt suffered any harm from Riddell's advertisements). For a further discussion of the District Court's decision, see *infra* notes 78-84 and accompanying text.

25. For a further discussion of the court's decision in *Riddell*, see *infra* notes 192-293 and accompanying text. For a further discussion of the application of this

dispositions that fueled the case.²⁶ Section III explores the broader factual and legal background that led to the case.²⁷ It discusses the body of scientific findings on concussions, Riddell's helmet study, false advertising under section 43(a) of the Lanham Act, state legislation on concussions and false statements, and concussion-related lawsuits.²⁸ Section IV explains the specific counter-claims brought by the defendant and the holding of the court.²⁹ Specifically, it discusses the issues of false advertising, the reliability of Riddell's study, and injury to the defendant.³⁰

Section V analyzes the reasoning of the court and its application to concussion regulation and prevention.³¹ This section also analyzes the public policy, and the truthful dissemination of the risk of concussions from participation in contact sports, regardless of what studies may show.³² Section VI concludes by explaining the impact of the case on future concussion-related false advertising lawsuits.³³ There has been much attention given to the issue recently, which has focused on protecting and educating the consumer, and more is undoubtedly to come.³⁴

II. FACTS

The parties to the *Riddell* case were Riddell and Schutt. Riddell, the plaintiff, is a brand of Easton-Bell Sports, Inc., which manufactures and supplies protective sports equipment, including

case to future concussion-related lawsuits and false advertising, see *infra* notes 362-370 and accompanying text.

26. For a further discussion of the factual and legal background that generated the claims, see *infra* notes 85-191 and accompanying text.

27. For a further discussion of the broader factual and legal background that led to the case, see *infra* notes 85-191 and accompanying text.

28. For a further discussion of the broader factual and legal background that led to the case, see *infra* notes 85-191 and accompanying text.

29. For a further discussion of the counterclaims raised by the defendant and the court's analysis, see *infra* notes 192-293 and accompanying text.

30. For a further discussion of the District Court's rationale, see *infra* notes 192-293 and accompanying text.

31. For a further discussion of the application of this case to the issue of concussion regulation and prevention, see *infra* notes 294-359 and accompanying text.

32. For a further discussion of the application of this case to the issue of concussion regulation and prevention, see *infra* 294-359 and accompanying text.

33. For a further discussion of the application of this case to future concussion-related lawsuits and false advertising, see *infra* notes 362-370 and accompanying text.

34. For a further discussion of the application of this case to future concussion-related lawsuits and false advertising, see *infra* notes 362-370 and accompanying text.

football gear.³⁵ Riddell is also the official helmet manufacturer of the NFL.³⁶ Schutt, the defendant, is a competing manufacturer and supplier of sports equipment and football gear.³⁷ Riddell and Schutt have historically competed for ninety percent of the marketplace for football helmets.³⁸

In 2002 Riddell introduced the Revolution, a redesigned helmet, intended to prevent the incidence of concussions in football.³⁹ The Revolution was described as “slightly larger but lighter” than previous helmets, with “large ventilation holes along the top.”⁴⁰ It also featured a more rounded facemask, intended to “deflect some hits rather than absorb them,” a feature in previous helmets thought to contribute to the incidence of concussions.⁴¹ The distinctive feature of the Revolution was its shape, which “swe[pt] back toward the ear, then jutt[ed] out along the jaw line,” intended to accommodate for side-impacts, also thought to contribute to concussions.⁴²

35. See *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 966 (W.D. Wis. 2010) (introducing plaintiff and defendant as manufacturers and sellers of sports equipment, including football gear); see also Joel Curran, *Riddell Wins Patent Infringement Suit Against Schutt*, PR NEWSWIRE (Aug. 10, 2010), <http://www.prnewswire.com/news-releases/riddell-wins-helmet-patent-infringement-suit-against-schutt-100335199.html> (detailing Riddell, Inc. and parent company Easton-Bell Sports, Inc.); Schwarz 10/21/10, *supra* note 13 (providing background on five football helmet makers, including Riddell, Schutt, Adams U.S.A, Rawlings, and Xenith).

36. See Rodd Zolkos, *NFL Sued Over Players' Brain Injuries: Helmet Company Also Named in Suit Alleging Negligence*, BUSINESS INSURANCE (July 24, 2011, 6:00 AM), <http://www.businessinsurance.com/article/20110724/NEWS04/307249980> (noting Riddell is official helmet manufacturer of NFL).

37. See Schwarz 10/21/10, *supra* note 13 (describing Riddell and Schutt). Riddell is the official helmet supplier of the NFL and occupies the largest share of the overall football helmet market; Schutt occupies a slightly smaller, but highly competitive, share of the market. See *id.* (attributing Riddell's position in market to its “2002 introduction of its Revolution model, which the company markets aggressively as having features . . . that reduce concussion risk . . .”).

38. See *Riddell*, 724 F. Supp. 2d at 967 (situating parties in football economic market).

39. See Anderson, *supra* note 15 (announcing introduction of Riddell's Revolution and Adams' Pro Elite helmets).

40. See *id.* (detailing Revolution design changes).

41. See *id.* The facemask was available, for the first time, in a lighter, titanium option, as well as the traditional steel. See *id.* (revealing that titanium option is more expensive but “much lighter than the standard steel”).

42. See *id.* (noting helmet shape was “designed in response to the first scientific study of concussions in football, which found that many concussions are caused by blows to the jaw and side of the head”). Differences in the design of the jaw strap, facemasks, lining, and shell were thought to affect a helmet's ability to prevent, or reduce, the risk of concussion. See *Riddell*, 724 F. Supp. 2d at 970 (stating differences in design of features in high-stress areas may affect helmet's ability to prevent or reduce concussion). Although Adams' Pro Elite helmet came to

In 2003 Schutt introduced the DNA football helmet, which was also designed to reduce the incidence of concussions in football.⁴³ The DNA helmet was the first helmet to implement Schutt's Thermoplastic Urethane (TPU) Cushioning system.⁴⁴ Schutt continued to expand its line of high end concussion-reduction helmets and in 2008 it unveiled the ION, "the heir apparent to the DNA Pro."⁴⁵ The ION also featured TPU Cushioning and a shock absorbing faceguard.⁴⁶

The *Riddell* action arose from Riddell's allegations of patent infringement, false advertising, trade libel, and product disparagement against its competitor, Schutt.⁴⁷ In December 2008, Riddell filed its complaint in the United States District Court for the Western District of Wisconsin.⁴⁸ The complaint alleged infringement of Riddell's jaw flap patents, false advertising under section 43(a) of the federal Lanham Act, 15 U.S.C. § 1125(a), trade libel, and product disparagement.⁴⁹ Riddell sought monetary, declaratory, and injunctive relief.⁵⁰

In February 2009 Schutt filed an answer and counterclaims.⁵¹ In its defense, Schutt asserted invalidity of Riddell's patent, non-

market before the results of the concussion study were revealed, it had a similar shape, and lighter optional titanium facemask. See Anderson, *supra* note 15 (describing Pro Elite: "[i]t mimics the shape of the head, with a curved indentation in back"). The rationale for the design change was simple: "it was lighter and reduced fatigue late in the game. You want athletes to keep their heads up. When they get tired and start dropping their heads, that's when they become more vulnerable to head and spine injuries." *Id.*

43. See *Schutt Sports Historical Timeline*, *supra* note 18 (providing historical timeline of Schutt Sports).

44. See *Riddell*, 724 F. Supp. 2d 963, 977 (W.D. Wis. 2010) (identifying Schutt's high-end products); see also *ION 4D*, SCHUTT, <http://www.schuttsports.com/asp/Sport/ProductCatalog.aspx?id=787> (last visited Apr. 21, 2013) (describing Thermoplastic Urethane (TPU) Cushioning system, introduced in 2003).

45. See *Schutt Sports Historical Timeline*, *supra* note 18 (noting introduction of ION4D to market in 2008).

46. See *id.* (chronicling announcement of ION4D and its special features).

47. See *Riddell*, 724 F. Supp. 2d at 966 (stating cause of action). The substance of Riddell's patent claim is beyond the scope of this Note, and is discussed in a separate opinion: *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 981 (W.D. Wis. 2010). This Note focuses on the court's opinion and order regarding Riddell's motion for summary judgment on Schutt's counterclaims for false advertising and deceptive trade practices, as discussed in *Riddell*, 724 F. Supp. 2d 693 (W.D. Wis. 2010).

48. See Complaint at 1 *Riddell*, 724 F. Supp. 2d 963 (W.D. Wis. Dec. 19, 2008) (No. 3:08-cv-00711-BBC), 9632008 WL 5596624 (providing complaint).

49. See *Riddell*, 724 F. Supp. 2d at 966 (reiterating plaintiff's claims).

50. *Id.* (stating plaintiff's requested relief).

51. See Answer at 1 *Riddell*, 724 F. Supp. 2d 963 (W.D. Wis. Feb. 16, 2009) (No. 08CV00711), 2009 WL 7985652 (answering complaint and filing counterclaims).

infringing use of the patent, and inequitable conduct.⁵² Moreover, Schutt brought counterclaims for false advertising under the Lanham Act and deceptive trade practices under the Wisconsin Deceptive Trade Practices Act.⁵³ Schutt sought a declaratory judgment to enjoin Riddell from causing further alleged harm.⁵⁴

In July 2010 the District Court issued an opinion granting Riddell's motion for partial summary judgment as to Schutt's counterclaims for false advertising and deceptive trade practices.⁵⁵ The court addressed Riddell's patent infringement claims in a separate opinion.⁵⁶ This Note focuses on the Court's decision as to the false advertising and deceptive trade practice issues; accordingly, the patent issue is not discussed here.⁵⁷ That decision focused exclusively on Riddell's motion for summary judgment on Schutt's counterclaims.⁵⁸ As such, this Note considers only Schutt's counterclaims as the claims at issue, and does not discuss Riddell's claims.

A. Schutt's Lanham Act Counterclaims

The crux of Schutt's Lanham Act claim concerned the allegedly false, "misleading safety claims and deceptive practices" that

52. *See id.* (describing Schutt's defense).

53. *See id.* (detailing Schutt's counterclaims); Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B) (stating "[a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act").

54. *See Answer at 1 Riddell*, 724 F. Supp. 2d 963 (W.D. Wis. 2009) (No. 08CV00711), 2009 WL 7985652 (praying for declaratory judgment relief from alleged harm caused by Riddell).

55. *See Riddell*, 724 F. Supp. 2d at 975, 979 (distinguishing defendant Schutt's counterclaims for false advertising and deceptive trade practices and plaintiff Riddell's patent infringement claims and noting "[t]hose motions will be addressed in a separate opinion").

56. *See id.* at 966 (noting motions related to patent claims "will be addressed in a separate opinion").

57. *See id.* at 966, 975, 979 (granting Riddell's motion for partial summary judgment on Schutt's counterclaims for false advertising and deceptive trade practices and finding that Schutt did not provide any evidence to support "a conclusion that the results or methods of [Riddell's] concussion study are unreliable" or that Schutt suffered any harm from Riddell's advertisements). For a further discussion of the District Court's decision, see *infra* notes 78-84 and accompanying text.

58. *See id.* at 966 (issuing opinion on "plaintiff's motion for partial summary judgment on defendant's counterclaims for false advertising and deceptive trade practices").

Riddell used in advertising its Revolution helmet.⁵⁹ The objectionable claims took two forms: (1) non-comparative false establishment claims, which did not compare Riddell's helmets to Schutt's, and mentioned only the Riddell Study (as defined below); and (2) comparative advertisement claims, which explicitly compared Schutt's helmets to Riddell's products.⁶⁰

The majority of Riddell's advertisements did not mention Schutt by name. Of these non-comparative advertisements, Schutt objected to four types of statements, which the District Court described as: (a) "statements to the effect that 'research shows a 31-41 percent reduction in concussions in players wearing Riddell Revolu-

59. Section 43(a) provides:

(1) the defendant made a false statement of fact about its product or another's product in a commercial advertisement, (2) the statement has a tendency to deceive or actually deceived a substantial segment of its audience, (3) the deception is material, that is, it is likely to influence purchasing decisions, (4) the defendant caused its false statement to enter interstate commerce, and (5) the plaintiff has been or is likely to be injured as a result, either by direct diversion of sales from itself to defendant or by a loss of good will that is associated with its products.

Hot Wax, Inc., v. Turtle Wax, Inc., 191 F.3d 813, 819 (7th Cir. 1999) (quoting Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B)) (providing five elements for proving false advertising under statute); see also Frederic Frommer, *AP NewsBreak: FTC Looking Into Helmet Claims*, WASH. POST, (Jan. 14, 2011), <http://www.washingtontimes.com/news/2011/jan/14/ap-newsbreak-ftc-looking-helmet-claims/> (describing Federal Trade Commission investigation into Riddell and Schutt Sports' "misleading safety claims used in online video advertisements for helmets"). The particularly disconcerting marketing claim, the FTC explained, was a statement on Riddell's website, which provided: "research shows a 31 percent reduction in the risk of concussion in players wearing a Riddell Revolution football helmet when compared to traditional helmets." *Id.* However, according to the FTC, "there is actually very little scientific evidence to support the claim," and the percentage by which the risk is decreased "has been criticized by experts for years." *Id.* (quoting N.M. Senator Tom Udall, who requested FTC investigation into helmet manufacturers' claims); Schwarz 1/4/11, *supra* note 7 (recalling experts' criticisms of Riddell's claims); see also Jonah Lehrer, *The Fragile Teenage Brain: An In-Depth Look at Concussions in High School Football*, GRANTLAND (Jan. 10, 2012), http://www.grantland.com/story/_/id/7443714/jonah-lehrer-concussions-adolescents-future-football (Jan. 10, 2011) (quoting Jeffrey Kutcher, who "told a committee of United States senators that all of the current concussion-prevention products being sold were largely useless"). In October 2011, two months after *Riddell* was decided, Kutcher, the chairman of American Academy of Neurology's sports section, testified before a congressional committee on helmet safety, stating: "The simple truth is that no current helmet, mouth guard, headband, or other piece of equipment can significantly prevent concussions from occurring It is extremely unlikely that helmets can prevent concussions the way they can prevent skull fractures." *Id.* Kutcher went on to "criticize numerous claims by helmet manufacturers suggesting otherwise." *Id.* ("[N]oting that even Riddell's specialized anti-concussion helmet has only been shown to *reduce* the rate of concussions by 2.6 percent.") (emphasis added).

60. For a further discussion of Schutt's specific Lanham Act claims, see *infra* notes 70-84 and accompanying text.

tion helmets’”; (b) “statements that the ‘technology’ used in Riddell’s Revolution line of helmets has been shown to reduce the incidence of concussion”; (c) “one statement that the ‘research shows’ that wearers of ‘Riddell Revolution *Youth* helmets’ were 31 percent less likely to suffer a concussion than traditional helmet wearers”; and (d) “statements that appear only in PowerPoint presentations to [Riddell’s] sales force.”⁶¹ In addition, Riddell issued a press release in March 2009 stating “the Riddell Revolution helmet is the standard against which all football helmets are measured”⁶² The claims appeared in general advertisements, in a March 2009 press release, and in one rush mailer.⁶³

The Riddell advertisements relied heavily on a 2002-2004 self-commissioned scientific study (the “Riddell Study”).⁶⁴ Starting in 2002, the University of Pittsburg Medical Center, funded by a grant from Riddell, conducted a study to compare the concussion rates and recovery times for athletes wearing the Riddell Revolution helmet compared to those wearing traditional helmets.⁶⁵ The study was criticized by experts because of its inherent subjectivity, including the facts that it was commissioned by Riddell, funded by Riddell, executed by at least one author who was employed by Riddell, and authored by at least two individuals who were business partners with Riddell.⁶⁶ Nevertheless, Riddell’s advertisements represented,

61. See *Riddell*, 724 F. Supp. 2d at 975-76 (W.D. Wis. 2010) (detailing advertisement statements based on Riddell Study).

62. See *id.* (quoting Riddell press release).

63. See *id.* (detailing where Riddell’s claims appeared).

64. See *id.* at 967 (introducing 2002-04 Riddell Study).

65. See *id.* at 967 (reporting on Riddell Study).

66. See *id.* at 967, 968 (describing conflicts of interest in Riddell Study); see also Defendant’s Amended Answer at 1, *Riddell*, 2010 WL 3051222 (W.D. Wis. June 17, 2009) (No. 3:08-cv-00711-BBC) (stating Schutt’s Declaratory Judgment Counterclaims). In its counterclaim, Schutt noted that the Vice President of the National Operating Committee on Standards for Athletic Equipment (NOCSAE), similarly, and several other prominent experts, were skeptical of Riddell’s claims to have developed concussion-reducing technology in the Revolution helmet. See *id.* at Counterclaim n.19 (“I do not think this article convincingly makes the case that the Riddell helmet is significantly better than other new helmets on the market. I strongly support the author’s suggestion for additional study by them and corroboration of their findings by others who are not tied to or funded by Riddell.”); see also Alan Schwarz, *Studies For Competing Design Called Into Question*, N.Y. TIMES (Oct. 27, 2007), <http://www.nytimes.com/2007/10/27/sports/football/27riddell.html?scp=1&sq=studies%20for%20competing%20design%20called%20into%20question&st=cse> [hereinafter “Schwarz, *Designs Questioned*”] (“The study has been strongly criticized by several prominent experts because it was commissioned by Riddell and because it tested new Revolution helmets against reconditioned traditional models of indeterminate age.”); Schwarz 1/4/11, *supra* note 7 (“[T]he authors of that [Riddell] study on multiple occasions have recommended further investigations, better controls and with larger numbers. If one is going to make

directly or indirectly, that the results of the 2002-2004 Riddell Study demonstrated “a 31percent reduction in concussions in players wearing Riddell Revolution helmets.”⁶⁷ Another issue with the Riddell Study was the manufacturer’s extrapolation of the study results to all helmets in the Revolution “family”; although the study tested only the Riddell Revolution helmet, Riddell made the reduction claim in advertisements for all Revolution products, not merely the

statements relative to the paper we wrote, it should be with the limitations that we emphasized, and not extrapolated to studies that we suggest should be done and haven’t been done yet.”) (quoting Dr. Joe Maroon, neurosurgeon at University of Pittsburg Medical Center and co-author of Riddell Study).

67. See *Riddell*, 724 F. Supp. 2d. at 969 (describing Schutt’s counterclaims and finding Riddell “relied heavily” on study in advertisements). Indeed, “most of the advertisements” referenced the *Neurosurgery* article. *Id.* Moreover, “numerous advertisements” included the “31% reduction in concussions” language. *Id.* Some advertisements gave more context to Riddell’s claims, such as:

‘[R]esearch has shown that players wearing the Riddell Revolution football helmet are 31% less likely to suffer a concussion than players wearing traditional football helmets.’ Some added that the study showed a reduced risk of concussion ‘up to 41%’ and others added that the 41% rate was only for players who had not previously suffered a concussion. Most of the advertisements also included a reference to the *Neurosurgery* article.

Id. Despite these claims and their support, skepticism about the advertisements and the concussion-reduction capability that Riddell touted therein remained. See Schwarz 10/21/10, *supra* note 13 (“Outside experts have criticized Riddell for overselling the protective properties of the Revolution and its successors.”); Schwarz 1/4/11, *supra* note 7 (reporting United States Senator Tom Udall made formal request for Federal Trade Investigation to commence against Riddell, “for its prominent claim that its popular Revolution models decrease concussion risk by 31 percent – which has been criticized by experts for years.”). For a further discussion of the “Riddell Study,” see *infra* notes 102-118 and accompanying text.

tested Revolution helmet.⁶⁸ It was to these facts, primarily, that Schutt objected.⁶⁹

The Riddell Study was referenced in several Riddell advertisements.⁷⁰ In March 2009, Riddell issued a press release that implied the Revolution *Speed* helmet was proven to reduce the risk of concussions by nearly a third: “The name Riddell is synonymous with football protection The Riddell Revolution helmet is the standard against which all football helmets are measured—shown to reduce the risk of concussion by nearly a third. The Revolution Speed . . . is taking the football world by storm.”⁷¹ In addition, Riddell sent out a rush mailer letter, citing “ground-breaking research,” which demonstrated “athletes who wear Riddell Revolution

68. See *Riddell*, 724 F. Supp. 2d at 969 (“Riddell used the phrase [research shows a 31% reduction in concussions in players wearing Riddell Revolution Helmets] in many advertisements for other helmets in the Revolution ‘family,’ including the ‘IQ,’ ‘IQ HITS,’ ‘Youth,’ ‘Speed’ and ‘Speed Youth’ helmets.”); *id.* (applying “published research” demonstrating concussion-reduction technology to Riddell Speed football helmet); see also Schwarz 1/4/11, *supra* note 7 (“Riddell uses the 31 percent figure to market its youth-size Revolutions, which were not studied at all.”). Schutt claimed there were important design and material differences that distinguished the other models from the Revolution, including differences in the design of the jaw strap, face masks, lining, and shell, which were thought to affect a helmet’s ability to prevent, or reduce, the risk of concussion. See *Riddell*, 724 F. Supp. 2d at 970 (enumerating material and design distinctions between Revolution and other models in Revolution family, “including different face guard mechanisms, materials used in the outer shell and liner, locking rear pads, mandible designs and padding structures”). Specific differences between the Revolution and other models in the Revolution family include (1) the “ABS” material used in the Revolution Youth helmets, as compared to the adult Revolution helmet, which uses “a more durable polycarbonate material;” (2) the shape of the padding in the IQ helmet; (3) the Speed helmet’s shell, face guard, mandible design, and liner; and (4) the quick-release face guard mechanisms in the Speed, IE, and the IQ HITS. *Id.* On the Revolution, “all high-stress” areas on the helmet, including the jaw flaps, front vent holes, and chinstrap and face guard attachment locations, were reinforced to mitigate the risk of cracking. See *id.* (detailing Revolution modifications). Riddell focused on these areas because the study indicated that changes to designs in these areas could affect the helmet’s ability to reduce concussions. *Id.*

69. See *Riddell*, 724 F. Supp. 2d at 969.

70. See *id.* The University of Pittsburg Medical Center study tested only the Riddell Revolution helmet, not any other helmet in Revolution family. See Collins, *supra* note 12 at 276 (introducing study of Riddell Revolution helmet, as compared to traditional football helmets).

71. See *Riddell*, 724 F. Supp. 2d at 969 (“The Riddell Revolution helmet is the standard against which all football helmets are measured – shown in published research to reduce the risk of concussion by nearly a third. The Revolution Speed football helmet – Riddell’s latest breakthrough innovation – is a combination of protection, comfort, and style”). Riddell made other statements about its superiority in PowerPoint presentations it gave to its sales representatives, such as: “Riddell’s Revolution Concussion Reduction Technology is its ‘flagship technology and the basis for every premium helmet in the line.’” *Id.* at 970.

Youth helmets were 31 percent less likely to suffer a concussion than athletes who wore traditional football helmets.”⁷²

Additionally, Riddell touted its superiority as the “flagship technology” in helmet protection in internal PowerPoint presentations.⁷³ Moreover, in July 2008, Riddell presented a PowerPoint to the NFL, which claimed the Revolution was the “only helmet shown to reduce risk of concussion on the playing field.”⁷⁴

Riddell made other statements that named Schutt, specifically.⁷⁵ These statements appeared in PowerPoint presentations given to sales representatives, and were not distributed publicly.⁷⁶ One such slide compared the Revolution “family” of helmets to Schutt’s high-end helmets, stating Schutt’s XP “doesn’t stack up.”⁷⁷

B. The Western District of Wisconsin’s Holding

On July 9, 2010, Riddell moved the Western District of Wisconsin to bifurcate the patent issues from the Lanham Act issues.⁷⁸ Thereafter, Riddell moved for summary judgment on Schutt’s counterclaims for false advertising under section 43(a) of the Lanham Act and deceptive trade practices under the Wisconsin Decep-

72. *See id.* (attributing results published in *Neurosurgery* article to Revolution Youth helmets). *But see* Schwarz 1/4/11, *supra* note 7 (“Riddell uses the 31 percent figure to market its youth-size Revolutions, which were not studied at all.”). As a result of this and similar claims regarding the Revolution Youth helmet, the Federal Trade Commission launched an investigation into Riddell and other helmet manufacturers’ advertising practices, noting that their advertisements “could violate the Federal Trade Commission Act, which prohibits misleading descriptions of the protective qualities of a safety device, particularly one used by children.” *Id.*

73. *See Riddell*, 725 F. Supp. 2d at 969-70 (stating Riddell made representations to sales representatives in PowerPoint presentations that claimed other helmets in Revolution family, including IQ HITS, Speed, IQ, Speed Youth, IQ Youth, Revolution Youth, and Revolution Little Pro, offered “Revolution Concussion Reduction Technology: shown in peer review study to reduce the chances of a concussion by 31%”). Riddell cited the 2002 study in support of these claims. *See id.* (noting Riddell supported its Revolution family helmets’ “31%-41%” concussion-reduction rate as “documented through a peer reviewed study”).

74. *See id.* (describing Revolution helmet as demonstrated to reduce risk of concussions).

75. *See id.* at 969-70 (providing “comparative” PowerPoint slides).

76. *See id.* at 976 (stating PowerPoint statements were “not advertisements at all, and Schutt has no evidence that sales force ever made similar statements to members of the public”).

77. *Id.* at 978 (providing specific example of alleged false statements regarding Schutt helmets).

78. *See* Motion to Bifurcate Claims, *Riddell*, 724 F. Supp. 2d 963 (W.D. Wis. July 9, 2010), (No. 308CV00711), 2010 WL 3940740 (moving court to bifurcate patent claims from Lanham Act claims).

tive Trade Practices Act.⁷⁹ Accordingly, the Court resolved the issues in separate opinions. The false advertisement and deceptive trade practices claims are the subject of this Note.⁸⁰

In its opinion, the District Court granted Riddell's motion for summary judgment.⁸¹ First, the court found, with one exception, that Schutt had failed to identify any literally false statements.⁸² Second, the court found that Schutt failed to show Riddell's statements caused harm.⁸³ Accordingly, Schutt's prayer for declaratory judgment on its counterclaims was dismissed.⁸⁴

III. BACKGROUND

Historically, helmet manufacturers have been cautious about making concussion-related claims of their equipment.⁸⁵ Riddell claimed their helmets could prevent the occurrence of concussions more so than helmets made by other manufacturers.⁸⁶ In doing so, Riddell ostensibly claimed that other helmets on the market were not as safe.⁸⁷ Predictably, competing manufacturers did not let Rid-

79. Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B); Wis. Stat. § 100.18; *see also Riddell*, 724 F. Supp. 2d 963, 966 (W.D. Wis. 2010) (providing procedural posture).

80. For a further discussion of Schutt's counterclaims, see *infra* notes 42-48 and accompanying text.

81. *See Riddell*, 724 F. Supp. 2d at 980 (stating "none of [Schutt's] Lanham Act claims survive summary judgment").

82. *See id.* at 974-75 (summarizing "Schutt has not provided any evidence that supports a conclusion that the results or methods of the concussion study are unreliable").

83. *See id.* at 966 (granting Riddell's motion for summary judgment on counterclaims for false advertising and deceptive trade practices and denying Schutt's prayer for relief).

84. *See id.* (denying Schutt's prayer for declaratory judgment on counterclaims).

85. *See Anderson*, *supra* note 15 ("None of the three major football helmet manufacturers . . . can make claims about concussion reduction or prevention."). Riddell, Schutt, and Adams USA, the three major football helmet manufacturers, concur that "no helmet is concussion-proof." *Id.* Moreover, prior to 2002, they tended to "shy away from words such as 'safer'" because of "liability issues." *Id.* (describing Riddell's cautious discouragement of University of Pittsburgh fullback's use of Revolution helmet, due to fear that helmet "might be disparaged as ineffective," if fullback, who had already suffered two concussions, suffered a third while wearing Revolution).

86. For a further discussion of the procedural posture of the *Riddell* case, see *supra* notes 35-84 and accompanying text.

87. *See Schwarz* 10/21/10, *supra* note 13 ("Everyone's afraid of being sued, because if you say that certain helmets are better, you're saying that millions of them out there now aren't safe.") (quoting Dr. Robert Cantu). Dr. Cantu is a renowned professor and researcher of neurosurgery, who studies sports concussions at the Boston University School of Medicine. *See* CHRISTOPHER NOWINSKI, HEAD GAMES: FOOTBALL'S CONCUSSION CRISIS vii (2007) (listing Dr. Cantu's acco-

dell get away with that indirect allegation.⁸⁸ But the response came from more than just Schutt; head injury doctors and scientists, competitors, legislators, and consumers objected to Riddell's claims.⁸⁹

A. The Science of Concussions

A concussion is a traumatic brain injury induced by sudden bodily impact that causes the brain to crash against the skull.⁹⁰ Concussions are common in contact sports; however, until recently, little was known about concussions, their long-term effects, or their prevention.⁹¹ Although researchers are studying how to prevent

lades: Chairman, Department of Surgery, Boston University School of Medicine; Chief, Neurosurgery Services, Director, Service Sports Medicine, Emerson Hospital, Concord, Massachusetts; Co-Director, Neurological Sports Injury Center, Brigham and Women's Hospital, Boston, MA; Neurosurgery Consultant, Boston College Eagles and Boston Cannon's Lacrosse teams). Dr. Cantu is also the Vice President of NOCSAE, the National Operating Committee on Standards for Athletic Equipment, which promulgates standards for helmet safety. *See id.* (introducing Dr. Cantu and NOCSAE). Although NOCSAE has successfully prevented skull fractures and brain bleeding caused by extreme forces, NOCSAE helmet standards do not address concussions. *See id.* (explaining that preventing concussions is different, and "trickier," than protecting against skull fractures). Nevertheless, Dr. Cantu has "been calling for a new standard to be written for football helmets for years," but to no avail. *Id.* According to Dr. Cantu, NOCSAE has not attempted to supplement its helmet standard to account for concussive impacts, because if it did, it would become vulnerable to lawsuits. *See id.* (expounding upon rationale for not attempting to address concussions in helmet standards: "it could open itself to lawsuits brought by players saying that their helmet did not prevent the injury").

88. Awareness and concern regarding head injuries in football and other contact sports have risen drastically in the last few years. *See, e.g.,* Emily Aronson, *Concussion Research Aims to Help Athletes, Study of the Brain*, PRINCETON UNIVERSITY NEWS (Oct. 17, 2011, 12:00 PM), <http://www.princeton.edu/main/news/archive/S31/80/06C59/index.xml?section=topstories#top> (noting growing practice of precautions and testing in sports medicine); ASSOCIATED PRESS, *States Consider Youth Concussion Laws*, ESPN.COM (Jan. 28, 2010, 10:14 AM), <http://sports.espn.go.com/espn/news/story?id=4865622> (exonerating nation-wide support of state-regulated youth concussion policies); *Concussions In the NFL*, ESPN.COM, http://espn.go.com/nfl/topics/_/page/concussions (last updated Sept. 7, 2011) (describing NFL efforts to regulate concussions). For a further discussion of the rising awareness and concern regarding head injury in contact sports, see *infra* notes 90-101 and accompanying text.

89. For a further discussion of the atmosphere that generated the response to Riddell's claim, see *infra* notes 90-191 and accompanying text.

90. *See What is a Concussion*, ESPN, http://espn.go.com/nfl/topics/_/page/concussions (last updated Sept. 7, 2011) (defining concussion); NCAA, *2011-12 NCAA Sports Medicine Handbook* 54, available at <http://www.ncaapublications.com/DownloadPublication.aspx?download=MD11.pdf> [hereinafter *Handbook*] (providing technical definition of concussion: "a complex pathophysiological process affecting the brain, induced by traumatic biomechanical forces").

91. *See Handbook*, *supra* note 90 at 53 (reporting higher incidence of concussions in "helmeted sports"); *see also* Schwarz 10/21/10, *supra* note 13 (noting uncertainty of how concussions occur).

concussions in contact sports, there is no workable solution right now.⁹²

Researchers have, however, discovered significant correlation between multiple concussions and decreased cognitive functioning.⁹³ The two major contemporary studies of the long-term effects of concussions are being conducted by Boston University's Center for the Study of Traumatic Encephalopathy and the Brain Injury Research Institute.⁹⁴ Dr. Robert Cantu, Vice President of the National Operating Committee on Standards for Athletic Equipment (NOCSAE), directs the Boston University study, and is assisted by Dr. Ann McKee and the Sports Legacy Institute, which is run by Chris Nowinski.⁹⁵ Dr. Bennet Omalu conducts the research at the Brain Injury Research Institute.⁹⁶

Dr. Omalu and the Boston University researchers have examined the brains of deceased athletes for signs of chronic traumatic encephalopathy (CTE), which they believe results from repeated concussive blows to the head.⁹⁷ To date, the researchers

92. See Schwarz 10/21/10, *supra* note 13 (asserting biochemists are “unsure of how to prevent concussions” in football).

93. See, e.g., David Cifu, *Repetitive Head Injury Syndrome*, MEDSCAPE REFERENCE (Nov. 16, 2010), <http://emedicine.medscape.com/article/92189-overview#a0107> (“Numerous studies . . . have shown that repeated brain injury can lead to chronic encephalopathy, termed *dementia pugilistica*.”); Gladwell, *supra* note 2 (discussing long term effects of multiple concussions); see also ASSOCIATED PRESS, *Athletes Donating Brains for Injury Study*, ESPN.COM (Oct. 12, 2010), <http://sports.espn.go.com/espn/news/story?id=5677532> (stating athletes with increased amounts of head trauma are more likely to produce CTE); Les Carpenter, ‘Brain Chaser’ Tackles Effects of NFL Hits, WASH. POST (Apr. 25, 2007), available at http://www.washingtonpost.com/wp-dyn/content/article/2007/04/24/AR2007042402480_pf.html (reporting significant trending of CTE in athletes, following Dr. Bennet Omalu’s discovery of CTE in three former NFL players).

94. See ASSOCIATED PRESS, *Athletes Donating Brains for Injury Study*, ESPN.COM (Oct. 12, 2010), <http://sports.espn.go.com/espn/news/story?id=5677532> [hereinafter “Brain Injury Study”] (describing BU Medical School and Sports Legacy Institute collaborative brain research program).

95. See Brain Injury Study, *supra* note 94 (describing collaborative brain research efforts at Boston University); see also Gladwell, *supra* note 2 (introducing activist Chris Nowinski, former college football player and professional wrestler who suffered six concussions during his athletic career); NOWINSKI, *supra* note 87, at 2-4 (describing Nowinski’s experience in college football and World Wrestling Entertainment and his six concussions, prompting his interest in publicizing risks of concussions). For a further discussion of Dr. Robert Cantu’s background and accolades, see *supra* note 87 and accompanying text.

96. See Gladwell, *supra* note 2 (crediting Dr. Omalu with first discovery of chronic traumatic encephalopathy, or “CTE,” in brain of former NFL player in 2002).

97. See *id.* (explaining CTE); see also Carpenter, *supra* note 93 (“The proteins appear when the brain is hit, but disappear as the healthy brain cells devour them, leading to recovery. Yet when the brain suffers too many blows, the brain cells can’t keep up with the protein and eventually give up and die, leaving just the red

have found “the telltale red flecks of abnormal protein,” indicating CTE, on all but one of the former athletes’ brains.⁹⁸ The findings indicate that “repeated concussions can, some twenty years after the fact, have devastating consequences if left unrecognized and untreated,” including an increased risk of depression, dementia, and suicide.⁹⁹ The recent death and bequest of former NFL player Dave Duerson’s brain to the study may add even more credence to the researcher’s theory.¹⁰⁰ Thus, the atmosphere leading to, and, even more so, following *Riddell*, was one that demanded increased concussion awareness, honest prevention efforts, and comprehensive management.¹⁰¹

B. The Riddell Study

1. *The Method*

In 2002, Riddell commissioned a study at the University of Pittsburgh Medical Center (UPMC) to compare the concussion

flecks.”); Alan Schwarz, *Pro Football; Expert Ties Ex-Player’s Suicide To Brain Damage From Football*, N.Y. TIMES (Jan. 18, 2007), <http://query.nytimes.com/gst/fullpage.html?res=9B06EFD81130F93BA25752C0A9619C8B63&pagewanted=print> [hereinafter Schwarz 1/18/07] (describing Dr. Omalu’s research, deaths of former football players, and subsequent brain analyses, which have revealed effects of “postconcussive brain dysfunction”).

98. See Carpenter, *supra* note 93 (listing findings of CTE in former football players); see also Gladwell, *supra* note 2 (noting discoveries of CTE in football players). But see Gladwell, *supra* note 2 (noting one former player’s brain did not show CTE and hypothesizing because deceased played running back position, and therefore sustained fewer successive head injuries than line position, and because he had only played in NFL for two years, CTE might not have been present).

99. See, e.g., Bill Dwyre, *Dave Duerson’s Suicide Could Be A Turning Point for NFL*, L.A. TIMES (Feb. 21, 2011), <http://articles.latimes.com/2011/feb/25/sports/la-sp-dwyre-dave-duerson-20110226> (describing Duerson’s suicide shot to the heart with note requesting brain be delivered to N.F.L. brain bank); Schwarz 1/18/07, *supra* note 97 (referring to multiple suicides by former NFL players whose brains contained signs of CTE).

100. See Dwyre, *supra* note 99 (“Now, Duerson has raised the stakes. He has apparently martyred himself for a cause. And if he properly identified his symptoms, and the Boston University doctors confirm this in the next several months, no amount of rationalizing or preservation on head-injury issues – past or present – will be acceptable.”). Duerson committed suicide on February 17, 2011, at the age of 50, following months of headaches, blurred vision, and deteriorating memory. *Id.* In a story of “unimaginable tragedy and incredible significance,” Duerson shot himself in the heart, not the head, because, as he revealed in his final note, he wanted his brain to be given to the NFL brain bank for evaluation. See *id.* (recalling Duerson’s suicide note); Karen Hawkins, *Duerson’s Family Sues NFL Over His Suicide*, ASSOCIATED PRESS (Feb. 23, 2012), <http://abcnews.go.com/Sports/wireStory/duersons-family-sues-nfl-suicide15776848#.T0baMiNGzwg> (announcing complaint filed against NFL due to Duerson’s suicide).

101. See Dwyre, *supra* note 100 (“This 2010 [NFL] season was the year of concussion awareness.”).

rates and recovery times for football players wearing the Riddell Revolution helmet, as compared to those wearing traditional helmets.¹⁰² The three-year study used ImPACT neurocognitive testing software to measure the concussion rates and recovery times.¹⁰³ In its Research Proposal, the study provided “directional hypotheses,” which suggested that athletes wearing the Revolution helmet would sustain fewer concussions, and would recover more quickly than the control group wearing traditional helmets.¹⁰⁴

Study participants were not selected at random; rather, the study focused on a particular group of approximately 2,000 high school players in the Pennsylvania Interscholastic Athletic Association.¹⁰⁵ Slightly more than half of the athletes wore the new Revolution helmets.¹⁰⁶ The remainder wore traditional helmets, drawn from the school’s inventory, which were not necessarily new.¹⁰⁷

After the first year of the study, the authors found that concussion rates among all athletes in the study were identical.¹⁰⁸ In 2003,

102. See *Riddell, Inc., v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 966 (W.D. Wis.) (describing how Riddell underwrote concussion study by providing salary support for study’s two leading authors, and noting that study’s third author was employed by Riddell). The study took place from 2002 until 2004. See *id.*; see also John Helyar, *Helmets Preventing Concussion Seen Quashed by NFL-Riddell*, BLOOMBERG (Mar. 18, 2013), <http://www.bloomberg.com/news/2013-03-18/helmets-preventing-concussion-seen-quashed-by-nfl-riddell.html> (stating Riddell invested \$336,000 in UPMC project, “aimed at demonstrating that the Revolution reduced concussions”).

103. See Helyar, *supra* note 102 (noting that three authors of study were co-owners of ImPACT, who also had business arrangement not to compete with Riddell).

104. See *id.* (defining “directional hypothesis” as “generated from a theory that would suggest that a relationship between two variables should go one way or the other”). Specifically, the directional hypothesis included in the Research Proposal provided:

- (1) Athletes wearing the Revolution will exhibit significantly fewer incidences of cerebral concussion compared to the [traditional helmet] group;
- (2) Athletes wearing the Revolution will exhibit fewer and shorter-duration-on-field markets of concussion severity as compared to control subjects; and
- (3) Post-concussion neurocognitive dysfunction and post-concussive symptoms will resolve earlier in athletes wearing the Revolution helmet relative to athletes not wearing this helmet.

Id.

105. See *id.* (defining study as “a prospective cohort study”).

106. See *id.* (explaining that Revolution helmets used in 2002 were new, but were refurbished and reused in subsequent years of study).

107. See *id.* (noting National Athletic Equipment Reconditioners Association refurbished and recertified any non-new helmets each year according to standards set by National Operating Committee on Standards for Athletic Equipment).

108. See *id.* (reporting that concussion rates between athletes wearing Revolution helmet and athletes wearing traditional helmets during 2002 season were “nearly identical”).

the second year of the study, the authors reported that concussion rates between the two groups of athletes were “not statistically significant.”¹⁰⁹ In the third and final year of the study, two reports were made. The first, an internal report, provided that, of the 2,207 three-year participants, 1,173 were fitted with Revolution helmets, and 1,034 with traditional helmets.¹¹⁰ Further, it provided that 5.29 percent of the athletes wearing the Revolution sustained cerebral concussions, as compared to 7.16 percent of those athletes wearing the traditional helmets.¹¹¹ However, the authors found that “the difference between the groups approached, but did not reach statistical significance.”¹¹²

The second, and final, report of the three-year study reported results from 2,141 study participants.¹¹³ By these numbers, the authors reported the concussion rates were 5.3 percent for athletes wearing Revolution helmets, and 7.6 percent for athletes wearing traditional helmets, which the authors deemed a “statistically significant difference.”¹¹⁴ Accordingly, the authors concluded, “there was a 2.3 percent decreased absolute risk for sustaining a concussion and a 31 percent decreased relative risk for athletes wearing the Revolution helmet.”¹¹⁵

2. *Publication*

Riddell submitted the results of the three-year study to *Neurosurgery* for publication.¹¹⁶ The article went through a peer review process, where it received many critiques from reviewing neurology

109. See *Riddell*, 724 F. Supp. 2d at 967-68 (adding that although concussion rates between study groups were not statistically significant, “the difference ‘approached’ statistical significance”).

110. See *id.* at 968.

111. See *id.*

112. See *id.*

113. See Helyar, *supra* note 102 (describing final report of three-year study). The final report disregarded data from sixty-six participants, all of whom wore traditional helmets. See *id.* Thus, the final report considered 2,141 athletes, 1,173 of whom were fitted with Revolution helmets, and 968 of whom were fitted with traditional helmets. See *id.*

114. See *id.* Moreover, two authors noted that the results “‘demonstrated a trend toward a lowered incidence of concussion,’ but the ‘limited size sample precludes a more conclusive statement of findings at this time.’” *Id.*

115. See *id.* (comparing concussion rates between two study groups and concluding Revolution helmet decreased risk of concussion by 31%). But see Schwarz 10/21/11, *supra* note 13 (quoting Dave Halstead, technical director of NOCSAE, who criticized decreased relative risk: “It’s a good helmet. But I don’t believe that 31 percent for a Yankee minute.”). For a further discussion of criticisms made by the study’s peer reviewers, see *infra* notes 119-126 and accompanying text.

116. See Schwarz 10/21/11, *supra* note 13 (categorizing publication as peer-reviewed journal in field of neurology).

experts regarding the methods, reliability, statistical significance, and neutrality of the study.¹¹⁷ Although the study was eventually published in 2006, several of the critical comments accompanied the printed article.¹¹⁸

When a study is not unanimously accepted, dissenting commentary may accompany the published article.¹¹⁹ Reviewers who were critical of the means of helmet selection were especially dismissive of the study's results.¹²⁰ One reviewer discounted comparison altogether: "It is well recognized that a new football helmet has a lower severity index rating than an older helmet We know

117. See *id.*; see also Collins, *supra* note 12 at 275-86 (publishing study).

118. See *Riddell*, 724 F. Supp. 2d at 969 ("The published article included comments appended to the study."). In his "dissent" over publication of the article, Dr. Robert Cantu, a leading Neurologist and Vice President of the National Operating Committee on Standards for Athletic Equipment (NOCSAE), the organization that creates the certification standard for football helmets and other athletic equipment, explained the rationale for his concern:

I have great respect for the Riddell Helmet and think it is as good as any helmet being made today. This article, however, does not convince me that it is superior.

First . . . [*Neurosurgery* peer] reviewers do not verify the authenticity of data and, occasionally, papers may be published over certain reviewers' objections. False This article, in my opinion, suffers from a serious, if not fatal, methodological flaw that precludes my not doubting the data, but doubting the significance of the data. The flaw is that we do not know the age of the helmets that comprised the non-Riddell group. We assume the Riddell helmets were either new or nearly new because the product is new. However, the helmets that the Riddell helmets were being compared against are of indeterminate age and were very likely significantly older It would be expected that if the newer Riddell helmets, therefore, are being compared against helmets that are significantly older, that the older helmet would not perform to as high a degree as the newer helmet. That is why today when parents or athletes ask me which is the best helmet to wear, I tell them I don't know which brand is best, but I know that a new helmet will be better than an old helmet and if recurring concussions are a concern that they should equip themselves with a new helmet.

Collins, *supra* note 12, at 284. For a further discussion of those comments that appeared in the published material, see *infra* notes 119-126 and accompanying text.

119. See Collins, *supra* note 12, at 284 (explaining that articles "may be published over certain reviewers' objections," in which case reviewers may "offer constructive suggestions in terms of how to make the article better").

120. See Collins, *supra* note 12, at 284 (noting "the study has several limitations in its design which may influence the results"). Another reviewer expressed concern over the selection of helmets, indicating the haphazard selection might have affected the study, so that it would be impossible, conclusively, to attribute the differences in results to one particular cause: "helmet selection was neither randomized or [sic] controlled, and that younger patients tended to use the older helmet type, and that group may be more susceptible to concussions." *Id.* Another, echoing similar concern over the study's "several limitations," agreed that one such limitation was the fact that "helmet selection was neither randomized, nor controlled." *Id.*

the Riddell helmets in this study are new but we have no mention of the age of the other helmets. This invalidates any comparison.”¹²¹ Another reviewer announced that the study “‘suffers from a serious, if not fatal methodological flaw,’ raising doubt about the ‘significance of the data’ because the age of the helmets was not known.”¹²²

Some reviewers were skeptical of the statistical import of the data.¹²³ One suggested that “the three years that were used in the study was needed to enroll enough subjects so that the results would attain statistical significance.”¹²⁴ Another was “not convinced that significant differences in technology exists between the Revolution and traditional helmet models.”¹²⁵ Finally, reviewers noted a “substantial conflict of interest” in the study, due to the fact that “each of the authors has a business relationship with either IMPACT or Riddell.”¹²⁶

121. *Riddell*, 724 F. Supp. 2d at 968 (quoting reviewer who declared mode of testing helmets “invalidate[d] any comparison”).

122. *See id.* at 969 (commenting upon study’s flaws). This comment appeared in the published version of the study. *Id.* Other criticisms of the study were published in Neurosurgery, including:

- (1) the alleged existence of conflicts of interest resulting from the counterclaim defendant’s funding of the study and its relationship with the owners of the diagnostic software used in the study; (2) the non-random sampling method used by the study’s authors; (3) the study’s failure to disclose information on the age and condition of the traditional helmets used as controls; (4) discrepancies between the number of participants in earlier reports and in the study’s final report; (5) what the authors considered to be the “preliminary” nature of the study; and (6) the study’s failure to address data collected in the years after the data discussed by the study.

Theodore Davis et al., *The Sixty-Fourth Year of Administration of the U.S. Trademark (Lanham) Act of 1946*, 102 THE TRADEMARK REP. 1, 219-20 (2012).

123. *See Riddell*, 724 F. Supp. 2d at 968 (criticizing statistical significance of data).

124. *Id.* (citing criticism from skeptics).

125. *Id.* (discussing further criticism of data).

126. *See id.* at 968, 969; Collins, *supra* note 12, at 285 (“Most importantly, each of the authors has a business relationship with either the computerized neurocognitive testing equipment company (IMPACT) or the helmet manufacturer (Riddell) that were being evaluated. *This fact represents a substantial conflict of interest, and the results should be interpreted accordingly.*”) (emphasis added).

C. False Advertising Under Lanham Act Section 43(a)

Claims of “false advertising” are brought under the Lanham Act, section 43(a).¹²⁷ To prevail on a false advertising claim, a plaintiff must prove five elements.¹²⁸ Section 43(a) provides:

(1) the defendant made a false statement of fact about its product or another’s product in a commercial advertisement, (2) the statement has a tendency to deceive or actually deceived a substantial segment of its audience, (3) the deception is material, that is, it is likely to influence purchasing decisions, (4) the defendant caused its false statement to enter interstate commerce, and (5) the plaintiff has been or is likely to be injured as a result, either by direct diversion of sales from itself to defendant or by a loss of good will that is associated with its products.¹²⁹

Under the first element, the false statement may be either: (1) literally false, as a factual matter; or (2) “literally true or ambiguous,” but “implicitly conveys a false impression,” or is misleading and likely to deceive consumers.¹³⁰ If the statement is literally false, the complaining party need not show evidence of consumer confusion or deception.¹³¹ Rather, the plaintiff need only demonstrate falsity and injury.¹³²

1. *Establishment Claims*

Under the Lanham Act section 43(a), a claim of literal falsity may challenge either an “establishment” or a “non-establishment” advertisement.¹³³ An establishment advertisement takes the form:

127. Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B) (asserting how false advertising claims are brought).

128. *See* *Hot Wax, Inc., v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999) (quoting Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B)) (providing five elements for proving false advertising under statute).

129. *Hot Wax*, 191 F.3d at 819 (discussing false advertising claim)

130. *Id.* at 820; *see also* *Thermal Design, Inc. v. Am. Soc. of Heating*, 775 F. Supp. 2d 1082 (E.D. Wis. 2011) (laying out first element of statute requirements).

131. *See Hot Wax*, 191 F.3d at 820 (“When the statement in question is actually false, the plaintiff need not show that the statement either actually deceived customers or was likely to do so. In contrast, when the statement is literally true or ambiguous, the plaintiff must prove that the statement is misleading in contact by demonstrated actual consumer confusion.”).

132. *See id.* (discussing requirements of first element).

133. *See* *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 952 (3rd Cir. 1993) (introducing two categories of literal falsity claims under Lanham Act). In *Riddell*, the challenged advertisements were establishment claims of literal falsity. *See* *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 971 (W.D. Wis. 2010) (noting challenged advertisements all refer to establishment claims).

“tests prove the asserted proposition.”¹³⁴ In other words, establishment claims represent to consumers that they are based upon tests that purport to establish the advertised claim.¹³⁵ A non-establishment claim, on the other hand, does not purport to be based on test results.¹³⁶ Where the defendant’s advertisement claims product superiority, a “plaintiff must affirmatively prove defendant’s product equal or inferior” to prove the claim is literally false.¹³⁷ A plaintiff may do this “‘only upon adducing’ evidence that affirmatively shows defendant’s claim to be false.”¹³⁸

A plaintiff may prove the literal falsity of an establishment claim by demonstrating one of two alternatives: (1) the tests are “not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made;” or (2) the study does not prove the proposition that is advertised.¹³⁹ A plaintiff may demonstrate that a test is not sufficiently reliable by either: (1) undermining the validity of the study; or (2) showing the results are undermined by other studies.¹⁴⁰

134. *Castrol*, 987 F.2d at 952 (defining establishment advertising claim); *see also Riddell*, 724 F. Supp. 2d at 971 (explaining that establishment claims are “presented in the form ‘tests show x’ (or ‘establish x’)”) (quoting *BASF Corp. v. Old World Trading Co., Inc.*, 41 F.3d 1081, 1090 (7th Cir. 1994)); *Castrol, Inc., v. Quaker State Corp.*, 977 F.2d 57, 62 (2nd Cir. 1992) (providing plaintiff must prove “literally false an advertised claim that tests prove defendant’s product superior” to prevail on establishment claim of false advertisement).

135. *See Castrol*, 987 F.2d at 952 (“[E]stablishment claims state to the consumer that they are based upon tests and, therefore, provide the consumer with the expectation that tests actually support the claim at issue.”).

136. *See Quaker State*, 977 F.2d 62, 63 (noting requirements for non-establishment claim).

137. *See id.* (establishing plaintiff’s burden).

138. *See id.* (quoting *Procter & Gamble Co. v. Chesebrough-Pond’s Inc.*, 747 F.2d 114 (2d Cir. 1984)) (identifying standard).

139. *See id.* (endorsing “not sufficiently reliable” test in Third Cir.); *see also Procter & Gamble Co. v. Chesebrough-Pond’s Inc.*, 747 F.2d 114, 119 (2nd Cir. 1984) (applying “not sufficiently reliable” test in Second Cir.); *Rhone-Poulenc Rorer Pharmaceuticals, Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514-15 (8th Cir. 1996) (using “not sufficiently reliable” test in Eighth Cir.); *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1138 (4th Cir. 1993) (adopting “not sufficiently reliable test” in Fourth Circuit); *Bracco Diagnostics, Inc., v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 468 (D.N.J. 2009) (“Moreover, if the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has met its burden of demonstrating literal falsity.”); *Riddell*, 724 F. Supp. 2d at 971 (“Establishment claims can be shown to be false by showing that the cited test or study ‘does not prove the proposition.’”) (quoting *BASF Corp. v. Old World Trading Co., Inc.*, 41 F.3d 1081, 1090 (7th Cir. 1994)).

140. *See Bracco*, 627 F. Supp. 2d at 384 (describing means for plaintiff to prove studies are not sufficiently reliable).

For example, in *Zeneca, Inc. v. Eli Lilly & Co.*,¹⁴¹ the plaintiff, the manufacturer of the drug Nolvadex (approved by the U.S. Food and Drug Administration (FDA) to reduce the risk of breast cancer), brought a false advertising claim against a competing manufacturer who claimed its drug, Evista, was also shown to reduce the risk of breast cancer.¹⁴² The defendant based its claim on the results of a clinical trial, published in a peer-reviewed journal, that proved the drug's effectiveness in reducing osteoporosis, and noted that further research was needed to determine its effect on breast cancer.¹⁴³ The District Court held that the study was unreliable as to defendant's claims that the drug reduced the risk of breast cancer.¹⁴⁴ Further, the court noted that because the results of the study were not disseminated in their entirety, the reviewers were unable to identify certain "critical flaws" in the study.¹⁴⁵ Finally, the *Zeneca* court found it persuasive that the FDA, "the agency responsible for determining the safety and efficacy of prescription drugs in

141. 1999 WL 509471 (S.D.N.Y. July 19, 1999).

142. *See id.* at *1 (providing facts).

143. *See id.* (detailing defendant's establishment claim). Moreover, the FDA had required the defendant to include in the label that Evista's effectiveness "in reducing the risk of breast cancer has not yet been established." *Id.*

144. *See id.* (finding study was not sufficiently reliable due to "nearly unanimous" consensus by FDA and "numerous experts" in relevant field that cited study did not prove drug reduced incidence of breast cancer due to study's flaws, e.g. study participants were not randomized on basis of risk factors; and study was not intended to consider effect of drug on breast cancer); *see also id.* at *30 (explaining "mere fact of publication in a peer-reviewed article does not prove that the claim in question is true"). The defendant argued that publication established "scientific proof" of the claims; however, the court held that publication "plain[ly] . . . does not establish reliability." *Id.* at *29.

145. *See id.* at *30 ("The peer reviewers . . . were not given the [study's] protocol and thus were not in a position to assess the flaws in the . . . study design as a breast cancer trial."). The court found that the study was unreliable because it suffered from several "critical flaws," including: (1) it was not designed to determine whether the drug could reduce breast cancer; (2) participants were not randomized; (3) participants were not selected for enrollment according to risk of developing breast cancer; (4) the short duration of the study did not indicate whether the preliminary results would continue to be seen; and (5) the study "protocol did not require annual mammograms or breast physical exams." *See id.* Because the reviewers were unable to examine these flaws, the published article did not note these limitations. *See id.* at *18-19, *29-30, *33 (listing peer reviewers' findings of "critical flaws"). The court reasoned, therefore, that proper dissemination was important to the public interest, especially regarding information about "highly significant drugs." *See id.* at *1 (objecting to stated industry practice that "peer reviewers as a rule are only given the manuscript of the article and nothing else"). Accordingly, the court determined, these flaws might have caused an imbalance in risk factors, meaning that the incidence of breast cancer might have been underdiagnosed. *See id.* at *33 (reasoning study's failure to account for certain flaws might have led to "false positive" results).

this country,” had not approved the drug for breast cancer risk reduction.¹⁴⁶

In *Bracco Diagnostics, Inc., v. Amersham Health, Inc.*,¹⁴⁷ the plaintiff, a vendor of x-ray equipment, brought a false advertising establishment claim against a competitor for advertisements that claimed clinical studies proved the superiority of its x-ray media products over the plaintiff’s products.¹⁴⁸ The court for the District of New Jersey found the claims that extrapolated the study results to apply to related, but untested, competing products were literally false.¹⁴⁹ Because the study made limited tests between the competitors’ products, the studies were not unreliable for establishing superiority claims about untested products; however, the court determined that the parties could properly claim that the study determined “that Visipaque *may* be better than a LOCM,” provided the party gave context to the statement.¹⁵⁰ In reaching its decision, the court, relying on the *Zeneca* court’s rationale, noted that the FDA’s rejection of the study’s primary conclusion was persuasive in finding the study unreliable.¹⁵¹

In a third case, *McNeil-PPC v. Pfizer*,¹⁵² the plaintiff, the market leader in sales of floss and dental cleaning products, sued the maker of Listerine mouthwash.¹⁵³ The plaintiff brought Lanham Act claims of false advertising for defendant’s commercial campaign that announced: “Listerine’s as effective as floss Clinical studies prove it.”¹⁵⁴ The results of the studies “indicated” that “Listerine was at least as good as dental floss in controlling interproximal gingivitis,” to which the authors and the American Dental

146. *See id.* at *34 (clarifying that failure to meet federal standards did not demonstrate, conclusively, that defendant’s claim was false, but was merely persuasive evidence).

147. 627 F. Supp. 2d 384, 468 (D.N.J. 2009) (explaining plaintiff’s claims).

148. *See id.* at 397 (reiterating plaintiff’s claims).

149. *See id.* at 469 (finding defendant’s statement that “Visipaque is better than all LOCM,” is an extrapolation which strays too far from the results and conclusions of the underlying . . . studies”).

150. *See id.* at 472 (requiring parties identify “which products, by brand name, were actually tested in the study” when making superiority claims and reasoning conclusions that do not “clearly and conspicuously” identify which products were actually tested present misleading messages to public).

151. *See id.* at 470-71 (justifying deference to FDA’s scientific findings and rejecting arguments that would require court to “second-guess the expert judgment of the FDA”).

152. 351 F. Supp. 2d 226 (S.D.N.Y. 2005).

153. *See id.* at 231 (introducing parties).

154. *See id.* (providing facts and Lanham Act claims).

Association (ADA) added: “when flossing was not done properly, and in individuals with mild to moderate gingivitis.”¹⁵⁵

The *McNeil* court found that the studies were “not sufficiently reliable” to prove that Listerine was as effective as floss in fighting mouth disease because the studies showed only that Listerine was “as effective as improperly-used floss.”¹⁵⁶ Additionally, the court found the literal claim in the advertisement was “overly broad” because the study samples were limited to individuals with mild to moderate gingivitis.¹⁵⁷ Therefore, the studies did not prove the products’ equivalent universal effectiveness; rather, they suggested equivalent effectiveness “only against plaque and gingivitis *in individuals with mild to moderate gingivitis*.”¹⁵⁸ The court noted the danger of the overly-broad claim was that consumers suffering from severe disease might be misled.¹⁵⁹

2. Injury

Under the Lanham Act, if a statement is literally false, a plaintiff must also show actual or likely injury occurring as a result of the statement, “either by direct diversion of sales from itself to defendant or by a loss of good will that is associated with its products.”¹⁶⁰ Because the Third Circuit had not decided a Lanham Act false advertising establishment claim issue, the District Court in *Riddell* relied on the Seventh Circuit’s decisions.¹⁶¹ In *L.S. Heath & Son, Inc. v. AT&T Information Systems, Inc.*, the Seventh Circuit Court held

155. *See id.* at 237-38 (hypothesizing user compliance and “behavioral or technical causes,” such as improper flossing techniques, contributed to studies’ surprising results); *id.* at 251 (noting study only included individuals with “mild to moderate gingivitis”).

156. *See id.* at 252 (reasoning studies therefore “proved only that Listerine is as effective as improperly-used floss”).

157. *See id.* at 251 (finding “literal claim in Pfizer’s advertisements is overly broad” and advertisements do not limit claim to cases of mild to moderate gingivitis).

158. *See id.* at 251-52 (quoting studies’ findings) (emphasis added).

159. *See id.* at 251 (“[C]onsumers who suffer from severe gingivitis or periodontitis . . . may be misled by the ads into believing that Listerine is just as effective as floss in helping them fight plaque and gingivitis, when the studies simply do not stand for that proposition.”).

160. *Hot Wax, Inc., v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999) (quoting Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B)).

161. *See Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 979-80 (W.D. Wis. 2010) (relying on Seventh Cir. decisions regarding false advertising establishment claim issue).

that a party claiming false advertising under the Lanham Act must show “a discernable competitive injury.”¹⁶²

In *Heath*, the plaintiff, a manufacturer of chocolate products (including the Heath bar), hired the defendant to install a new computer system for its business, and permitted the defendant to advertise plaintiff’s job in a national advertising campaign.¹⁶³ After the defendant ran the campaign, the plaintiff brought suit under the Lanham Act, claiming the defendant’s advertisement cast the plaintiff in a false light.¹⁶⁴

The Seventh Circuit held that the plaintiff was barred from bringing suit under the Lanham Act because the parties were not competitors in the computer industry; therefore, there was no “discernible *competitive* injury.”¹⁶⁵ The court relied on the Ninth Circuit’s interpretation of the purpose of the Lanham Act, finding: “the intent of the Act is to protect ‘against unfair *competition*.’”¹⁶⁶ Therefore, a complaining party must show that the injury resulted from an industry competitors’ misstatements.¹⁶⁷

D. Other Concussion-Related Activism

1. NOCSAE Standards

The operative, and only, standard for football helmet safety was written by NOCSAE in 1973.¹⁶⁸ NOCSAE is a nonprofit volunteer organization, comprised of coaches, medical personnel, and helmet makers, which oversees the certification of all football helmets in the United States.¹⁶⁹ NOCSAE certifies helmets according to an index that tests the amount of force that reaches the skull after a sixty-inch free fall.¹⁷⁰ However, NOCSAE does not oversee the testing, or enforce compliance with the standard, a practice that

162. See *L.S. Heath & Son, Inc. v. AT&T Info. Sys., Inc.*, 9 F.3d 561, 575 (7th Cir. 1999) (holding that “[i]n order to have standing to allege a false advertising claim, . . . the plaintiff must assert a discernible competitive injury”).

163. See *id.* at 565 (detailing facts of case).

164. See *id.* at 575 (stating plaintiff’s claim).

165. See *id.* (providing reasoning Seventh Circuit’s for holding) (emphasis added).

166. *Id.* (“In other words, the Act does not create a general, free-floating ‘tort of misrepresentation,’ unanchored to unfair *competition*.”) (citing *Halicki v. United Artists Communications*, 812 F.2d 1213, 1214 (9th Cir. 1987) (emphasis added)).

167. See *id.* (reiterating that parties must be in competition in order for plaintiff’s Lanham Act claim to survive).

168. See *History and Purpose*, NOCSAE, <http://nocsa.org/about-nocsa/history-and-purpose/> (last visited Jan. 30, 2012) (describing history and purpose of National Operating Committee on Standards for Athletic Equipment).

169. See Schwarz 10/27/07, *supra* note 1 (describing NOCSAE function).

170. See Schwarz 1/4/11, *supra* note 7 (revealing NOCSAE testing standard).

may cause helmets to “convey a level of concussion-related protection that the headgear is not shown to provide.”¹⁷¹ Moreover, adherence to the NOCSAE standard is voluntary.¹⁷²

In fact, the NOCSAE standard does not address concussions at all.¹⁷³ As concussions have become more of a focal point in contact sports, experts have grown critical of the outdated helmet standard, which was initially designed to prevent single, blunt force blows, of the type that would cause fatal skull fractures.¹⁷⁴ The standard has successfully reduced these types of single-blow fractures, but because there is little scientific data that provides how concussions can be prevented, applying the standard to concussions is more difficult.¹⁷⁵ There is a concern that attempting to compensate for the multiple concussive-type impacts that a helmet may sustain could compromise how effective the helmet is at withstanding, and preventing, single high impact blows.¹⁷⁶

2. State Legislation

Washington State pioneered the first law aimed at regulating when a youth may return to play after suffering a concussion.¹⁷⁷ Thirty states have followed suit.¹⁷⁸ Nine other states, including Cali-

171. *Id.* (expressing concern that “limited test standard” may convey false sense of protection).

172. *See id.* (stating NOCSAE “does not mandate adherence to its standard,” but it is used “voluntarily, by every level of football,” and suggesting NOCSAE has two functions: “to avoid skull fractures, and to avoid liability”).

173. *See* Schwarz 10/21/10, *supra* note 13 (describing limitation of standard).

174. *See id.* (“Helmet standards have not kept up with modern football.”) (quoting “industry insiders”).

175. *See id.* (indicating concussion prevention is more difficult to achieve successfully because brain can crash against skull “through a wide range of forces, some arriving straight to the head and others suddenly rotating it”).

176. *See id.* (asserting that “because football helmets have already prevented deaths so effectively for decades, and because football’s faster and more violent environment leaves biomechanics unsure of how to prevent concussions in the sport, NOCSAE has not asked helmet makers to even try” to adjust standards to prevent concussive forces). What is clear, however, is that requiring helmets to perform a variety of tests from different angles and with different levels of force would force manufacturers to focus on preventing different types of impacts. *See id.* (“[R]equiring headgear to perform across a spectrum of impacts would undoubtedly decrease the total number of injuries . . .”).

177. *See* WASH. REV. CODE ANN. § 28A.600.190 (West 2011) (providing Washington State concussion and head injury guidelines).

178. *See State Legislation*, THE CONCUSSION BLOG, <http://theconcussionblog.com/state-legislation/> (listing states with youth concussion laws as of January, 2012, which include: Alabama, Alaska, Arizona, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Missouri, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Utah, Vermont, and Virginia).

ifornia, Florida, Georgia, Nebraska, Ohio, Pennsylvania, Tennessee, Wisconsin, and Wyoming have also proposed concussion bills, which are now pending before their legislative bodies.¹⁷⁹

Many state concussion laws require baseline testing and an education component for coaches, parents, and athletes.¹⁸⁰ By mandating education, states have attempted to put the onus on trainers, coaches, parents, and even the students themselves to take responsibility for their own future interests.¹⁸¹ While these laws are largely reactive and do not attempt to prevent the risk of brain injury from contact sports, they represent an acknowledgement that a standard should be created to account for these known risks, and mitigate against further harm.¹⁸²

3. *Concussion-Related Lawsuits*

Research and scientific discovery surrounding concussions and their effects have led to a recent “flurry” of wrongful death lawsuits against the NFL and Riddell.¹⁸³ And there is no sign of stopping.¹⁸⁴ Nearly forty class action suits have been filed in federal court against the NFL since July 2011, involving over 850 former players, and the number continues to grow weekly.¹⁸⁵ Approximately one-

179. *Id.* (counting pending concussion bills).

180. *See, e.g.*, VA. CODE ANN. § 22.1-271.5 (West 2010). In Virginia, it is incumbent upon the Board of Education to develop and distribute “guidelines on policies to inform and educate coaches, student-athletes, and their parents or guardians of the nature and risk of concussions, criteria for removal from and return to play, and risks of not reporting the injury and continuing to play.” *Id.* § 22.1-271.5(A).

181. *See id.* (placing “greater responsibility” on coaches and trainers in determining whether and when an athlete returns to play).

182. *See, e.g.*, ASSOCIATED PRESS, *States Consider Youth Concussion Laws*, ESPN.COM (Jan. 28, 2010, 10:14 AM), <http://sports.espn.go.com/espn/news/story?id=4865622> [hereinafter *State Youth Laws*] (recalling death of Washington State high school student in fall 2009, shortly after Washington legislature passed § 600.190).

183. *See* Ken Belson, *NFL Faces Flurry of Concussion-Related Lawsuits*, SAN FRANCISCO CHRONICLE (Dec. 30, 2011), <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2011/12/30/SPVJ1MIDT9.DTL&feed=rss.sports> (surveying “more than a dozen” lawsuits alleging NFL and helmet manufacturers “deliberately concealed information about the neurological effects of repeated hits to the head”); *see also* In re NFL Players’ Concussion Injury Litigation, MDL No. 2323, 842 F. Supp. 2d 1378 (J.P.M.L. 2012) (Mem.) (granting transfer and consolidation of pretrial proceedings; naming several actions against NFL, including: Maxwell v. NFL; Pear v. NFL; Barnes v. NFL; Easterling v. NFL).

184. *See* Paul Anderson, *NFL Concussion Litigation Tracker*, NFL CONCUSSION LITIGATION, <http://nflconcussionlitigation.com/?p=262> (last visited Mar. 16, 2012) (chronicling lawsuit filings as frequently as every day, and questioning whether “we are anywhere close to seeing the end”).

185. *See id.* (blogging daily updates on concussion litigations).

third of the cases named Riddell as a defendant in addition to the NFL.¹⁸⁶

The suits generally allege that the NFL and Riddell have deliberately concealed information and distorted data regarding the neurological dangers of multiple hits to the head.¹⁸⁷ The suits ask for different remedies. One suit, for example, asks that the NFL and Riddell set up a medical monitoring program that would test players to determine whether concussions sustained in the NFL lead to problems later in life.¹⁸⁸ In at least one other suit, the plaintiffs seek acknowledgment that the Riddell Study was a farce.¹⁸⁹ Specifically, the *Jacobs v. NFL* complaint alleges: “Riddell has long been aware of medical issues concerning concussions,” yet it sponsored a “worthless” study to support its claims that the Revolution helmet reduced the incidence of concussions.¹⁹⁰ When the multidistrict suits are consolidated, the federal district court that hears the case will have to consider the Western District of Wisconsin’s decision in *Riddell v. Schutt*.¹⁹¹

IV. NARRATIVE ANALYSIS

This part features two sections, the first of which describes the District Court’s analysis of Schutt’s false advertising counterclaim,

186. See *id.* (calculating involvement of Riddell in concussion-related lawsuits).

187. See Ken Belson, *For N.F.L., Concussion Suits May Be Test for Sport Itself*, N.Y. TIMES (Dec. 29, 2011), <http://www.nytimes.com/2011/12/30/sports/football/nfl-faces-retired-players-in-a-high-stakes-legal-battle.html?pagewanted=all> (describing “multifront legal challenge to . . . game itself”); see also Thom Loverro, *Maxwell v. NFL Case Could Hit League Hard*, WASHINGTON EXAMINER.COM (July 27, 2011, 7:05 PM), <http://washingtonexaminer.com/2011/07/thom-loverro-maxwell-v-nfl-case-could-hit-league-hard/40539> (claiming that NFL and Riddell have known for decades “that multiple blows to the head can lead to long-term brain injury, including memory loss, dementia and depression,” but deliberately concealed these dangers).

188. See *Tony Dorsett on NFL: “They Use You Up,”* ESPN (Feb. 2, 2012), http://espn.go.com/nfl/story/_/id/7532284/plaintiffs-depict-nfl-apatetic-concussions (asking for relief in form of medical monitoring program for former players who have suffered concussions).

189. See *Jacobs v. NFL*, 2011 WL 6371825 (S.D.N.Y. Dec. 20, 2011) (Trial Pleading) (naming Riddell as defendant in class action complaint and alleging Riddell knew *Neurosurgery* study did not prove anything).

190. See *id.* at *25 (noting that Dr. Robert Cantu has “publicly criticized the study as being worthless”).

191. 724 F. Supp. 2d 963 (W.D. Wis. 2010). For a further analysis of the Western District of Wisconsin’s decision, see *infra* notes 196-293 and accompanying text.

brought under the Lanham Act Section 43(a).¹⁹² The false advertising analysis is divided into two sub-sections, which examine, initially, the court's approach to the literal falsity prong under the two available tests.¹⁹³ Subsequently, the false advertising section describes the District Court's analysis of Schutt's alleged injury.¹⁹⁴ The second section examines Schutt's counterclaim of deceptive trade practices under the Wisconsin Deceptive Trade Practices Act.¹⁹⁵

A. Schutt's Counterclaims for False Advertising

Under the first prong of the Lanham Act section 43(a), the suing party must show that the defendant made "a false statement of fact . . . in a commercial advertisement about its own or another's product."¹⁹⁶ The nature of the "false statement" may be: (1) literally false; or (2) literally true, but implicitly conveys a false impression, or is likely to deceive customers.¹⁹⁷ Where the objectionable statement purports to prove, or "establish," a particular proposition by relying upon the results of a scientific study, the cause of action

192. *See id.* at 971-80 (analyzing false advertising under § 43(a)(1)(B)). For a further discussion of the court's treatment of these claims, see *infra* notes 196-293 and accompanying text.

193. *See id.* at 971 (presenting alternative iterations of literally false establishment claims as stated by Seventh Circuit and Second Circuit). For a further discussion of the court's application of the Second Circuit test, see *infra* notes 210-236 and accompanying text.

194. *See id.* at 979-80 (addressing Schutt's alleged injury). For a further discussion of the court's brief treatment of Schutt's injury counterclaims, see *infra* notes 237-293 and accompanying text.

195. *See* Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B); Wis. Stat. § 100.18. *See also* Riddell, Inc. v. Schutt Sports, Inc., 724 F. Supp. 2d 963, 966 (W.D. Wis. 2010) (detailing Schutt's counterclaims).

196. Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B) (stating elements for false advertising). To prevail on a claim for false advertisement under the Lanham Act, a plaintiff must show:

- (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product;
- (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience;
- (3) the deception is material, in that it is likely to influence the purchasing decision;
- (4) the defendant caused its false statement to enter interstate commerce; and
- (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to a defendant or by a loss of goodwill associated with its products.

Riddell, 724 F. Supp. 2d at 971 (quoting *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999)).

197. *See Riddell*, 724 F. Supp. 2d at 971 (providing plaintiff's burden under § 42(a)(1)(B) and requiring "false statement" be either "literally false as a factual matter," or "literally true or ambiguous but implicitly convey[s] a false impression or is misleading in context or likely to deceive consumers").

is called an “establishment claim.”¹⁹⁸ Unless the statement in question is literally false, the plaintiff must also introduce evidence of customer confusion to prove the second alternative.¹⁹⁹ In the absence of actual confusion, the plaintiff must demonstrate that the establishment claim is literally false.²⁰⁰

To prove an establishment claim is literally false, a plaintiff has two alternatives.²⁰¹ The plaintiff must show either: (1) the study was not sufficiently reliable; or (2) even if a cited study was reliable, it did not, in fact, “establish the proposition asserted by the defendant,” and was therefore “simply irrelevant.”²⁰² The majority of circuit courts have endorsed the “not sufficiently reliable” test, first employed by the Second Circuit; however, the Seventh Circuit has not.²⁰³ Therefore, the Second Circuit test was not binding upon the Western District of Wisconsin.²⁰⁴

In *Riddell*, football helmet manufacturer Schutt brought a section 43(a) false advertisement counterclaim against its competitor, Riddell, for commercial advertisements that stated concussion rates were thirty-one to forty-one percent lower for wearers of the Riddell Revolution helmet.²⁰⁵ The advertisements cited the results of a concussion study in support of the claim.²⁰⁶ Accordingly, the District Court analyzed the objectionable statements as establishment

198. See *Hot Wax*, 191 F.3d at 820 (“When the statement in question is actually false, the plaintiff need not show that the statement either actually deceived customers or was likely to do so. In contrast, when the statement is literally true or ambiguous, the plaintiff must prove that the statement is misleading in context by demonstrating actual consumer confusion.”). For a discussion of the ways a party may prove the falsity of an establishment claim, see *infra* notes 197-293 and accompanying text.

199. See *Riddell*, 724 F. Supp. 2d at 971 (noting test).

200. See *Hot Wax*, 191 F.3d at 820 (stating when objectionable statement is “actually false,” plaintiff need not introduce extrinsic evidence of actual confusion).

201. See *Proctor & Gamble Co. v. Chesebrough-Pond’s Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (establishing Second Circuit test for establishment claims). *But see Riddell*, 724 F. Supp. 2d at 971-72 (noting Seventh Circuit had not ruled on several tests for “establishment claims”).

202. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992); *see also Riddell*, 724 F. Supp. 2d at 973 (listing alternatives for establishing literal falsity of Riddell’s establishment claims).

203. See *Chesebrough-Pond’s*, 747 F.2d at 119 (providing Second Circuit test: whether cited study or test is “sufficiently reliable to permit one to conclude with reasonable certainty that [the test] established the proposition for which it was cited”).

204. See *Riddell*, 724 F. Supp. 2d at 971-72 (noting Seventh Circuit had not ruled on several tests for “establishment claims”).

205. See *id.* (stating issue before W.D. Wis.).

206. See *id.* (providing facts).

claims.²⁰⁷ The court determined that Schutt did not introduce evidence of actual consumer confusion, and was therefore required to prove that the advertisements were literally false in order to prevail.²⁰⁸ Accordingly, the court reviewed the establishment claim for literal falsity by employing both prongs of the literal falsity analysis, albeit somewhat reluctantly in regards to the Second Circuit test.²⁰⁹

1. *Reliability of the Study*

The District Court reluctantly applied the Second Circuit test to determine whether the establishment claim was founded upon a “not sufficiently reliable study,” and was therefore literally false.²¹⁰ The Second Circuit “not sufficiently reliable” test, set forth in *Chesebrough-Pond’s*, provides: “an establishment claim can be literally false even if the cited test or study does prove the proposition, if the test was ‘not sufficiently reliable to permit one to conclude with reasonable certainty that the test established the proposition’ for which it was cited.”²¹¹ The District Court defined “reasonable certainty” as: “whether the methods and findings of the cited study are acceptable to the relevant scientific community.”²¹² Moreover, the Court noted: “rejection by the authors of a study or a regulatory agency is evidence that the study is not acceptable to the relevant scientific community.”²¹³

207. *See id.* (detailing court’s initial determinations of Schutt’s claim).

208. *See id.* at 971 (finding Schutt provided no evidence of consumer confusion).

209. *See id.* (“[F]or the purpose of this opinion, I will assume that the ‘not sufficiently reliable’ test applies.”)

210. *See id.* (noting concerns with logic of Second Circuit test); *see also Chesebrough-Pond’s*, 747 F.2d 114, 119 (2d Cir. 1984) (establishing standard for establishment claims as “sufficiently reliable to permit one to conclude with reasonable certainty that [the test] established the proposition for which it was cited”). For a further discussion of the Second Circuit test, see *supra* note 139 and accompanying text.

211. *Riddell*, 724 F. Supp. at 971.

212. *Id.* at 972; *compare with Zeneca, Inc. v. Eli Lilly and Co.*, 1999 WL 509471, at *1 (S.D.N.Y. July 19, 1999) (finding claims were literally false because cited study was not sufficiently reliable due to “nearly unanimous” consensus by FDA and numerous experts in relevant field that cited study did not prove drug reduced incidence of breast cancer, study participants were not randomized on basis of risk factors, and study was not intended to consider effect of drug on breast cancer, but rather on osteoporosis); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 397 (D.N.J. 2009) (holding study results were unreliable when findings were extended to similar media other than specific media tested); *McNeil-PPC v. Pfizer*, 351 F. Supp. 2d 266, 236-38, 251-52 (S.D.N.Y. 2005) (stating conclusions that product “was at least as good as” competitor’s were unreliable because study authors’ statements indicated study results might have been due to factors other than product’s superiority).

213. *Riddell*, 724 F. Supp. at 973.

Although the majority of circuit courts, and the parties in *Riddell*, compelled the Western District of Wisconsin to apply the Second Circuit test, the Court emphasized that the test was not binding in the Seventh Circuit.²¹⁴ Moreover, the District Court remained wary of the test's logic, noting an "apparent tension" within the Second Circuit test.²¹⁵ The Court explained that, under the Second Circuit test, if a court were to determine that a study, cited in an establishment claim, was "not sufficiently reliable," the test would deem the study literally false, notwithstanding that the study did, in fact, truly demonstrate the stated proposition.²¹⁶ The Court struggled to reconcile that result with the plain meaning of "literally false," and suggested that, if a cited test were unreliable, then claims as to what that test established would be "merely deceptive or misleading, not literally false."²¹⁷ In that case, the Court proposed, a plaintiff should introduce evidence of actual confusion to satisfy the "false statement" prong of section 43(a).²¹⁸

Despite its misgivings, the Court applied the Second Circuit test, and held that Schutt failed to show the study was literally false.²¹⁹ The Court found that Schutt did not meet its burden of proving the study was unreliable because it did not show that the methods employed were unacceptable to the relevant scientific community.²²⁰ In its analysis, the Court distinguished *Zeneca*, in

214. *See id.* at 971-72 (noting "not sufficiently reliable" test is not binding as "the Court of Appeals for the Seventh Circuit has not had the opportunity to apply [it]").

215. *See id.* at 971 (questioning whether "'not sufficiently reliable' test should be applied in this case").

216. *See id.* at 971-72 (finding test "leads to a strained reading of the phrase 'literally false'").

217. *See id.* at 972 (addressing tension between plain meaning of "literally false" and "a conclusion that a statement in the form 'text shows x' is literally false even if the test *really does* show x").

218. *See id.* (suggesting that if test *does* show x, stating so is not "literally false" and statement is merely deceptive or misleading if underlying study is unreliable, not literally false, in which case plaintiff would require evidence of actual consumer confusion to satisfy first prong of § 43(a)); *see also id.* at 971 (explaining "false statement" under § 43(a) must be either: (1) "literally false as a factual matter," or (2) "literally true or ambiguous but implicitly convey[s] a false impression or is misleading in context or likely to deceive consumers"); *see also Hot Wax*, 191 F.3d at 820 ("When the statement is literally true or ambiguous, the plaintiff must prove that the statement is misleading in context by demonstrating actual consumer confusion."). For a further discussion of a complaining party's burden of proof where a false statement is literally true, but misleading in context, see *supra* notes 130-131, 197, and accompanying text.

219. *See Riddell*, 724 F. Supp. 2d at 972 (applying Second Circuit test "for the purpose of this opinion" only).

220. *See id.* at 974 (determining Schutt failed to demonstrate study methods were unreliable).

which a plaintiff made an establishment claim that a study, published in a peer-reviewed journal, proved plaintiff's drug reduced the risk of breast cancer.²²¹ In *Zeneca*, the District Court held, notwithstanding publication in a peer-reviewed journal, the study was unreliable; therefore, the establishment claims were literally false.²²² In that case, the plaintiff showed that the peer reviewers did not assess the full data set and analyses of the study; thus, they were unable to identify certain flaws within the study design itself and were therefore unable to properly assess its reliability.²²³

In this case, the Court found that Schutt merely "recite[d] objections made by reviewers."²²⁴ This was problematic for two reasons.²²⁵ First, the reviewers' objections did not pertain to the particular methods used in the study.²²⁶ The objections concerned: (1) conflicts of interests between the testers and the funders of the study; (2) not randomized or controlled study design; (3) unclear age of traditional helmets; and (4) speculation about the statistical significance and the reason for the three-year trial period.²²⁷ The Court reasoned that these concerns casted doubt on the study's results, but they did not amount to an outright rejection of the study's methods.²²⁸

Second, the Court conceded that publication, alone, does not prove the reliability of a study; however, "the fact that a peer-reviewed article was approved for publication is some evidence that the study *is* reliable," and that the objections were not so serious as

221. See *Zeneca, Inc. v. Eli Lilly & Co.*, 1999 WL 509471, at *1 (S.D.N.Y. July 19, 1999) (providing facts).

222. See *id.* (finding study was not sufficiently reliable due to "nearly unanimous" consensus by FDA and "numerous other experts" in relevant field that cited study did not prove drug reduced incidence of breast cancer due to study's flaws, e.g. study participants were not randomized on basis of risk factors; and study was not intended to consider effect of drug on breast cancer); see also *id.* at *30 (recognizing "mere fact of publication of a peer-reviewed article does not prove that the claim in question is true").

223. See *id.* ("The peer reviewers . . . were not given the [study's] protocol and thus were not in a position to assess the flaws in the . . . study design as a breast cancer trial.").

224. See *Riddell*, 724 F. Supp. 2d at 975 (theorizing Schutt produced enough evidence to doubt study results, but not enough to show study was not acceptable to relevant scientific community).

225. See *id.* (stating reviewers' objections did not pertain to specific methods used in study in question).

226. See *id.* at 972 (noting reliability of study is determined by acceptance of study's methods with "reasonable certainty").

227. See *id.* at 974 (illustrating reviewers' concerns with study design).

228. See *id.* (stating Schutt failed to show study results were unreliable).

to make the study unreliable.²²⁹ Therefore, Schutt had to overcome the presumption of reliability by the mere publication of a study in a peer-reviewed journal.²³⁰ However, by relying solely on the dissenting reviewers' commentary, with no further support to the contrary, Schutt was unable to overturn the presumption.²³¹ Therefore, because Schutt did not provide any evidence to support "a conclusion that the results or methods of [Riddell's] concussion study are unreliable, Schutt failed to show literal falsity under the "not sufficiently reliable" alternative.²³²

Finally, the Court noted that rejection by the authors of the study, or a responsible regulatory agency, would be persuasive evidence that the study was not acceptable to the relevant scientific community.²³³ The Court noted that in *Bracco*, the FDA, which was responsible for monitoring the x-ray media field, "rejected the study's primary endpoint as not meaningful or reliable."²³⁴ Moreover, in *McNeil*, the authors of the study stated that the study was limited to its explicit facts, and could not be extrapolated beyond them.²³⁵ Therefore, if a regulatory agency or the study's authors rejected Riddell's establishment claim, it would create a presumption that the Riddell Study was unreliable. However, the Court found that Schutt failed to provide evidence of either type of rejection.²³⁶

2. *What the Advertisements Stated the Study Showed*

Alternatively, a plaintiff may prove an establishment claim is literally false by demonstrating that even if a cited study was reliable, it did not, in fact, "establish the proposition asserted by the

229. *Id.* (citing *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 593 (1993)) (emphasis added); *see also id.* (concluding "fact of publication over peer reviewers' objections is evidence that those objections were not serious enough to make the study unreliable").

230. *See id.* ("[T]he fact that a peer-reviewed article was approved for publication is some evidence that the study is reliable.").

231. *See id.* ("[A] party seeking to attack the reliability of a peer-reviewed article should do more than recite objections made by reviewers.").

232. *See id.* at 975 (discussing implications of lack of evidence by Schutt with regards to literal falsity analysis).

233. *See id.* at 973 ("Rejection by the authors of a study or a regulatory agency is evidence that the study is not acceptable to the relevant scientific community.").

234. *See id.* (acknowledging why FDA rejected study in *Bracco*).

235. *See McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 226, 231 (S.D.N.Y. 2005) (reporting study showed Listerine was "at least as good as dental floss in controlling interproximal gingivitis" *when flossing was not done properly*) (emphasis added).

236. *See Riddell*, 724 F. Supp. 2d at 974-75 (summarizing "Schutt has not provided any evidence that supports a conclusion that the results or methods of the concussion study are unreliable").

defendant,” and is therefore “simply irrelevant.”²³⁷ Schutt attempted to prove this by attacking three different types of Riddell advertisements: (1) advertisements using the study in connection with Riddell helmets other than the Revolution; (2) advertisements using the Riddell Study that were directed at age groups other than high school students; and (3) advertisements that claimed superiority of Riddell’s helmets over Schutt’s helmets.²³⁸

a. Statements About the Riddell “Family”

First, Schutt challenged Riddell advertisements that applied the results of the Riddell Study to helmets other than the Revolution.²³⁹ These advertisements took several forms: (a) statements that “research shows a 31-41 percent reduction in concussions in players wearing Riddell Revolution helmets;” (b) statements that the “technology” in the Revolution family of helmets “has been shown to reduce the incidence of concussion;” (c) one statement that “research shows that wearers of Riddell Revolution *Youth* helmets were 31 percent less likely to suffer a concussion than traditional helmet wearers;” and (d) “statements that appear only in PowerPoint presentations to [the internal Riddell] sales force.”²⁴⁰

The court treated most of the statements that referred to other helmets in the Revolution family quickly.²⁴¹ With respect to statement (a), the court rejected Schutt’s contention that the statements were literally false because they appeared in advertisements for non-Revolution helmets.²⁴² The court determined that the statements embodied the precise findings of the study, and were therefore not literally false, regardless of the context in which they appeared.²⁴³

237. *See* *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992) (discussing alternative method to prove establishment claim); *see also* *Riddell*, 724 F. Supp. 2d at 973 (reciting alternatives for establishing literal falsity of Riddell’s establishment claims).

238. *See* *Riddell*, 724 F. Supp. 2d at 975 (listing Schutt’s three allegations of literal falsity under “study does not establish what the advertisement claims it does” prong).

239. *See id.* at 975 (analyzing alleged falsity of Riddell’s advertisements that used study in connection with helmets other than Revolution helmet).

240. *Id.*

241. *See id.* at 975-76 (stating three of Schutt’s challenges to Riddell’s statements “can be addressed quickly”).

242. *See id.* (treating Schutt’s first argument).

243. *See id.* (determining “first group is exactly what the study shows,” and dismissing claim even though statement was “nestled into advertisements for helmets other than the Revolution”).

The District Court determined that the only literally false statement was (c), which concerned the Riddell Revolution *Youth* helmet.²⁴⁴ The court found this statement was literally false for the simple reason that the Riddell study did not involve the *Youth* helmets.²⁴⁵ Statements in category (d), which appeared in the PowerPoint presentations, were, according to the court, “not advertisements at all.”²⁴⁶ Moreover, the court reasoned that because there was no evidence that these statements were actually disseminated to the public, they were not literally false.²⁴⁷

The court devoted more time to statements in category (b), which concerned the technology in the Revolution family of helmets.²⁴⁸ The issue was whether the technology in the Revolution, which was shown to reduce concussions, was “equally present in all the different helmets in the ‘family,’” such that Riddell could claim that all Revolution-line helmets had been shown to reduce concussions.²⁴⁹ Schutt argued that the concussion-reduction technology in the Revolution helmet—proven to reduce concussions—was not the same technology used in all Revolution family helmets.²⁵⁰ Schutt contended that the Revolution’s technology was not ubiquitous among all helmets in the Revolution line because they all had different design features, “including difference in shell, face guard, padding, lining, and other features,” that might change their ability to reduce concussions.²⁵¹ Because not every Revolution line helmet had been tested and shown to reduce concussions, it was therefore false for Riddell to claim that all helmets in the Revolution line contained concussion reduction technology.²⁵²

The court was not persuaded by Schutt’s argument. It found that Schutt did not prove these design differences affected the hel-

244. *See id.* at 976 (“[T]he study did not involve Youth helmets, so the statement that it did is literally false . . .”).

245. *See id.* (interpreting Riddell’s “correction” of rush mailer in which third statement appeared as acknowledgment of literal falsity).

246. *See id.* (reasoning presentations were not advertisements because “Schutt has no evidence that sales force ever made similar statements to members of the public”).

247. *See id.* (declaring merely presenting statements to sales force internally did not constitute false advertising).

248. *See id.* at 975 (analyzing alleged falsity of Riddell’s advertisements that used study in connection with helmets other than Revolution helmet).

249. *See id.* at 976 (deliberating over whether Revolution concussion technology was ubiquitous throughout entire Revolution family).

250. *See id.* (presenting Schutt’s argument).

251. *See id.* (describing Schutt’s contention).

252. *See id.* (recounting Schutt’s rationale).

hats' ability to reduce concussions.²⁵³ The court noted that Schutt carried the burden of showing, conclusively, the literal falsity of the advertisements, and it failed to do so.²⁵⁴ Therefore, the court held the advertisements that used the Riddell Study in connection with helmets other than the Revolution were not literally false.²⁵⁵

b. Statements Targeted at Non-High School Students

Second, Schutt challenged advertisements that targeted age groups other than high school students.²⁵⁶ Schutt claimed these statements were literally false because the Riddell Study "was not designed to be applied to those age groups."²⁵⁷ Schutt contended that when an advertised claim is directed at groups outside of a study's sample, the claim is overly broad; following *McNeil*, "an advertisement claim that is 'overly broad' is literally false."²⁵⁸

The District Court distinguished *McNeil*, noting the *McNeil* court found the "overly broad" claim misleading, as distinct from "literally false."²⁵⁹ Accordingly, the District Court found that the advertisements might have been misleading, but were not literally false.²⁶⁰ This was true, the court found, even though the study "may

253. *See id.* ("What Schutt submits instead are general assertions that design differences to areas like the shell or the face guard *can* change concussion results. However, this does not explain why the actual design differences in this case would be expected to do so."). The court's test was whether design differences between the Revolution family of helmets were so significant that they constituted an altogether different "technology" than that encompassed in the Revolution helmet; a technology that the Riddell Study did not test, and therefore did not prove to aid in reducing the risk of concussion. *See id.* (detailing court's rationale).

254. *See id.* (asserting Schutt had burden to show literal falsity and formulating test for determining falsity of statements that technology used in Revolution line of helmets reduced incidence of concussion).

255. *See id.* (determining Schutt had "established literal falsity of only one statement related to the use of the concussion study with other helmets . . .").

256. *See id.* at 976-77 (presenting Schutt's second allegation of literal falsity).

257. *See id.* at 976-77 (alleging "study does not establish what the advertisement claims it does").

258. *See id.* at 977; *see also* *McNeil-PPC v. Pfizer*, 351 F. Supp. 2d 226, 251 (S.D.N.Y. 2005) (ruling "the two studies do not stand for the proposition that Listerine is as effective as floss against plaque and gingivitis" because literal claim was "overly broad").

259. *See Riddell*, 724 F. Supp. 2d at 977 (distinguishing on grounds that *McNeil* court "did not hold that the claim was literally false because it was overly broad; instead, the [*McNeil*] court reasoned that 'consumers . . . may be misled . . .'" (quoting *McNeil*, 351 F. Supp. 2d at 251 (reasoning "consumers who suffer from severe gingivitis or periodontics . . . may be misled by the ads into believing that Listerine is just as effective as floss in helping them fight plaque and gingivitis . . ."))).

260. *See id.* ("[A]n overly broad claim is misleading, which is different from its being literally false.").

not have been intended to apply outside this [high school student sample] group” because the study did not include limiting language.²⁶¹ The court reasoned that advertisements with broad statements do not become literally false simply by being directed at audiences outside of the tested population because such consumers are not “required” to conclude that their peers were tested; rather, they are invited, or misled, to such belief.²⁶²

c. Superiority Statements

Finally, Schutt challenged advertisements that allegedly used the study to compare, and claim superiority over, Schutt’s helmets.²⁶³ These “comparative” advertisements included both direct and indirect, or “unqualified,” claims.²⁶⁴ Schutt argued these advertisements were literally false for two reasons. First, Schutt contended that the internal PowerPoint presentations to the Riddell sales force, which made direct comparisons between Schutt and Riddell helmets, were literally false because the helmets had never been tested against each other.²⁶⁵ Second, Schutt challenged Riddell’s advertisements that made unqualified comparative claims without providing the proper point of comparison.²⁶⁶

Schutt’s “direct comparison” argument claimed Riddell’s PowerPoint “training materials” demonstrated that Riddell was disseminating literally false statements through its sales representatives.²⁶⁷ This argument relied on *Zeneca*.²⁶⁸ In *Zeneca*, the plaintiff sued a competing manufacturer for false advertising for claims that its drug, Evista, was also shown to reduce the risk of breast cancer.²⁶⁹ The *Zeneca* court found that the studies were unreliable for establishing that claim, and reasoned that evidence of “scripts” or “verbatim” that contained these false statements, which the defen-

261. *See id.* (rationalizing that absence of limiting language does not require conclusion there were no limitations in Riddell Study).

262. *See id.* (differentiating between requiring conclusion and suggesting implication).

263. *See id.* at 975 (listing Schutt’s third allegation of literal falsity under “study does not establish what the advertisement claims it does” prong).

264. *See id.* at 977-78 (describing Schutt’s argument).

265. *See id.* (noting Schutt’s challenge that any comparison between Riddell and Schutt helmets was improper because helmets had never been tested against each other).

266. *See id.* at 978 (stating Schutt’s contention that Riddell’s claims did not include traditional helmets as proper comparison).

267. *See Riddell*, 724 F. Supp. 2d at 978.

268. *See Zeneca Inc. v. Eli Lilly and Co.*, No. 99-1452, 1999 WL 509471, at *8-9 (S.D.N.Y. July 19, 1999).

269. *See id.* at *1 (providing facts).

dant issued to its sales representatives, demonstrated the statements were, in fact, being disseminated.²⁷⁰

In this case, the court rejected Schutt's "direct comparison," argument by distinguishing *Zeneca*, noting that "verbatim" and notes written immediately after representatives' visits with clients were good evidence that the exchanges did occur.²⁷¹ On the other hand, in this case, there was no evidence that the PowerPoint presentations were actually given to Riddell representatives, or that the messages within these presentations were endorsed as verbatim sales scripts.²⁷² Again, the court's rationale turned on the distinction between misleading and literally false statements, stating that while these "tools" might "suggest that sales representatives were trained to mislead, they fail to suggest that representatives were trained to make literally false statements."²⁷³

Schutt's "unqualified," or "indirect," comparative claims argument asserted Riddell's claims were "necessarily" false by implication.²⁷⁴ Specifically, Schutt objected to: (1) "Revolution Helmets reduce concussions 31 percent;" and (2) "Riddell Revolution helmet is the standard against which all football helmets are measured—shown in published research to reduce the risk of concussion by nearly a third."²⁷⁵ As principal competitors in the football equipment market, Schutt alleged that Riddell's unqualified superiority claim necessarily, and falsely, implied that the Revolution was superior to Schutt's high-end helmets.²⁷⁶ Schutt relied on *Castrol*, where defendant's claims that the product "outperforms any leading motor oil" necessarily implied superiority over plaintiff's competing product.²⁷⁷ The *Castrol* court held "a

270. See *Riddell*, 724 F. Supp. 2d at 978 (objecting to advertisements that stated "Reasons Why Riddell Helmets are Superior to Schutt Helmets . . . With RCRT, Speed reduces the chances of concussion by 31%/41%. XP doesn't stack up"); see also *Zeneca*, 1999 WL 509471, at *8-9 (reiterating defendant's objectionable claim that "Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer").

271. See *Riddell*, 724 F. Supp. 2d at 978 (distinguishing *Zeneca*, 1999 WL 509471).

272. See *id.* at 977-78.

273. *Id.* at 978.

274. See *id.*

275. *Id.*

276. See *id.* at 978-979.

277. See *id.* at 978 (noting Schutt's argument "that a claim of superiority may necessarily implicate a principal competitor even when the competitor is not named" was supported by case law) (citing *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 948 (3d. Cir. 1993)).

claim of superiority may necessarily implicate a principal competitor even when the competitor is not named.”²⁷⁸

In this case, the District Court rejected Schutt’s “unqualified,” or “indirect,” comparison argument.²⁷⁹ The court acknowledged the validity of the *Castrol* holding, but found that because Schutt only objected to the implied superiority as it concerned Schutt’s high-end products, the *Castrol* holding was irrelevant.²⁸⁰ The court formulated the issue as: whether an unqualified statement necessarily implied superiority over “a particular product of the competitor’s.”²⁸¹ Here, the court found the “reduce concussions” claim did not necessarily implicate Schutt’s high-end products because there was “no context” indicating the comparison was specific to the high-end products.²⁸² Again, the court found that while this might have been misleading, it was not false.²⁸³

Moreover, the court found that there were two ways to interpret “Revolution helmet is the standard against which all football helmets are measured:” either, the Revolution has been shown to prevent concussions better than “all helmets;” or, the Revolution is “the ‘gold standard’ in helmets because it has been shown to prevent concussion” through testing.²⁸⁴ Therefore, because of this ambiguity, the court found that the advertisements were not “necessarily false.”²⁸⁵

B. Injury

Under the Lanham Act, if a statement is literally false, a plaintiff must also show actual or likely injury occurring as a result of the statement, “either by direct diversion of sales from itself to defendant or by a loss of good will that is associated with its products.”²⁸⁶ In this case, the District Court determined that only one of Rid-

278. *Castrol*, 987 F.2d at 947-48.

279. *See Riddell*, 724 F. Supp. 2d at 978-79 (questioning whether Riddell’s claims implicated Schutt’s high-end products in addition to standard helmets).

280. *See id.* (stating further that Schutt suffered no actual injury resulting from Riddell’s advertisements).

281. *Id.* at 979.

282. *See id.* (acknowledging that lack of framing could mislead)

283. *See id.* (commenting on odd language of advertisement)

284. *See id.* (laying out two ways Court could have interpreted advertisement).

285. *See id.* (restating falsity-by-implication test as “whether the ‘consumer will unavoidably receive a false message’ from the advertisement in its entirety”) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 587 (3d Cir. 2002)).

286. *Hot Wax, Inc., v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999) (quoting Lanham Act, § 43(a)(1)(B), 15 U.S.C. § 1125(a)(1)(B)).

dell's advertisements was literally false: the rush mailer stating that *Youth* helmets were shown to reduce concussions.²⁸⁷ The court found this statement was literally false for the simple reason that the Riddell study did not involve *Youth* helmets.²⁸⁸ However, the court found no evidence that Schutt had suffered injury from the rush mailers, as required to recover under the Lanham Act.²⁸⁹ Accordingly, the court held that none of Schutt's Lanham Act claims survived summary judgment.²⁹⁰

Moreover, despite the finding of one literally false advertisement, the court determined that there was no basis for injunctive relief because Riddell "already removed the reference to Youth helmets from the rush mailer and there is no suggestion they intend to use that language" in future advertisements.²⁹¹ The court added that its decision in Riddell's favor was "not because Riddell's advertisements were particularly open and honest, but rather because Schutt tried to take the easiest evidentiary path to success: literal falsity."²⁹² Finally, the court reiterated the distinction it made, throughout the opinion, between misleading or deceptive advertisements and literal falsity, conceding that Riddell's advertisements were, if anything, misleading and deceptive.²⁹³

V. CRITICAL ANALYSIS

The *Riddell* case presented a difficult issue for the Western District of Wisconsin.²⁹⁴ First, there was no on-point "literally false" establishment claim precedent for the court to follow because *Riddell* was the inaugural establishment claim case in the Seventh Cir-

287. See *Riddell*, 724 F. Supp. 2d at 979 (noting that despite one literally false claim, none of Schutt's claims pass summary judgment).

288. See *id.* at 976 ("[T]he study did not involve Youth helmets, so the statement that it did is literally false . . .").

289. See *id.* at 980 ("Schutt has failed to identify any loss of its own or any profit of plaintiffs that might be related to the single false advertisement identified.").

290. See *id.* (holding, despite finding of one literally false advertisement, "none of [Schutt's] Lanham Act claims survive summary judgment").

291. See *id.* at 980 (expounding on technical falsity in Riddell's advertising).

292. See *id.* (acknowledging Riddell was not blameless).

293. See *id.* (noting challenged statements were "at most . . . misleading or deceptive"). Although the District Court could not provide relief for a merely misleading advertisement, in January 2011 United States Senator Tom Udall of New Mexico asked the Federal Trade Commission "to investigate whether Riddell's claim of a 31 percent reduction in concussions was misleading." See Helyar, *supra* note 102 (noting FTC investigation is ongoing).

294. See *id.* at 971-72 (noting Seventh Circuit did not provide guiding precedent for establishment claim issues and stating misgivings with applying existing tests).

cuit.²⁹⁵ Second, as the court shrewdly noted, the Second Circuit’s “not sufficiently reliable” test contains a logical flaw, which may impeach its suitability as a test for literal falsity.²⁹⁶

A. Riddell’s “Establishment Claims” Were Literally False

1. *The Riddell Study Was Not Sufficiently Reliable*

The Western District of Wisconsin found that Schutt failed to show that the Riddell Study was “not sufficiently reliable” to prove, with reasonable certainty, that it established the proposition for which it was cited in Riddell’s advertisements; namely, that the Revolution has been proven to reduce the risk of concussions by 31 to 41 percent.²⁹⁷ This holding is questionable for two reasons: first, persuasive case law provides that publication in a peer-reviewed journal does not create a presumption of validity; second, the court did not consider the positions of NOCSAE, the Federal Trade Commission (FTC), or the Consumer Product Safety Commission (CPSC), the entities with responsibility for regulating the consumer product industry.²⁹⁸

a. Schutt Did More Than Merely “Recite Objections”²⁹⁹

The District Court challenged Schutt to “do more than recite objections made by reviewers.”³⁰⁰ Ultimately, the court determined that Schutt failed to meet the *Zeneca* criteria for rejecting a peer-reviewed study for three reasons: first, the study’s publication cre-

295. *See id.* at 971 (explaining Seventh Circuit has not decided establishment claim involving scientific study or test).

296. *See id.* at 971-72 (reciting court’s concerns with Second Circuit test).

297. *See Proctor & Gamble Co. v. Chesebrough-Pond’s*, 747 F.2d 114, 119 (2d Cir. 1984) (providing Second Circuit test: whether cited study or test is “sufficiently reliable to permit one to conclude with reasonable certainty that [the test] established the proposition for which it was cited”); *see also Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 974 (W.D. Wis. 2010) (holding Schutt failed to demonstrate study methods were unreliable).

298. *See Zeneca Inc. v. Eli Lilly Co.*, No. 99-1452, 1999 WL 509471, at *30 (S.D.N.Y. July 19, 1999) (stating “fact of publication of a peer-reviewed article does not prove that the claim in question is true”); *see also Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 470-71 (D.N.J. 2009) (declining to “second-guess the expert judgment of the FDA”); *Zeneca*, 1999 WL 509471 at *34 (finding “it is appropriate to consider the views of . . . the agency responsible for determining the safety and efficacy of prescription drugs in this country”).

299. *See Riddell*, 724 F. Supp. 2d at 975 (finding Schutt merely “recite[d] objections made by reviewers,” which was not enough evidence to show study was not acceptable to relevant scientific community).

300. *See id.* at 974 (challenging Schutt to demonstrate that “reviewers were not in a position to identify certain flaws in the protocol used in the study, were not given the results of trials showing different results and were not given the comments of the FDA”) (citing *Zeneca*, 1999 WL 509471, at *29-30).

ated a presumption of reliability; second, the reviewers' objections did not pertain to the particular methods used in the study; and third, Schutt did not provide persuasive evidence of the authors' rejection of the study's claims.³⁰¹ However, the court's determination was improper.

First, the court maintained that publication in a peer-reviewed journal made the Riddell Study presumptively valid.³⁰² In contrast, the *Zeneca* decision developed from the position that "publication of a peer-reviewed article does *not* prove that the claim in question is true."³⁰³ Because the *Riddell* court presumed the validity of the study, it gave little weight to the particular objections; instead, it justified its position by treating the fact that the study was published—*despite* reviewers' objections—as indicative of how insignificant these objections were.³⁰⁴

Second, because it presumed the study's validity, the District Court did not recognize that the reviewers' objections pertained to the particular methods used in the Riddell Study.³⁰⁵ In both studies, the reviewers cited common concerns, including: (1) participants were not randomized; (2) participants were not selected for enrollment based on certain known risk factors; (3) the length of the study; and (4) the limited data samples.³⁰⁶ In *Zeneca*, the study was found unreliable because reviewers were unable "to identify certain flaws in the protocol" of the study and "were not given the

301. *See id.* (distinguishing *Zeneca*, where "the reviewers were not in a position to identify certain flaws in the protocol used in the study, were not given the results of trials showing different results and were not given the comments of the FDA 'concerning the inadequacies of the . . . results'") (quoting *Zeneca*, 1999 WL 509471, at *29-30).

302. *See id.* (concluding "fact of publication over peer reviewers' objections is evidence that those objections were not serious enough to make the study unreliable") (citing *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 593 (1993)) (emphasis added).

303. *Zeneca*, 1999 WL 509471, at *30 (emphasis added).

304. *See Riddell*, 724 F. Supp. 2d at 974 ("Nonetheless, the fact that a peer-reviewed article was approved for publication is some evidence that the study is reliable."). *But cf. Zeneca*, 1999 WL 509471 at *30 ("[T]he mere fact of publication in a peer-reviewed article does not prove that the claim in question is true.").

305. *See Riddell*, 724 F. Supp. 2d at 969 (noting "serious, if not fatal, methodological flaw" of Riddell Study, articulated by Vice President of NOCSAE, organization responsible for certification standard of football helmets); *see also Zeneca*, 1999 WL 509471, at *30 (noting that because study results were not disseminated in their entirety, reviewers could not identify certain of study's "critical flaws").

306. *See Riddell*, 724 F. Supp. 2d at 969 (acknowledging, but not crediting, peer reviewer criticism). For a further discussion of the "critical flaws" in the *Zeneca* study, *see supra* note 144 and accompanying text. For a further discussion of the reviewers' findings of "fatal" flaws in the Riddell Study, *see supra* notes 118-126 and accompanying text.

results of trials showing different results.”³⁰⁷ The *Riddell* court’s determination ignored the parallel between peer reviewers’ “nearly unanimous” findings of “serious, if not fatal” flaws in the Riddell Study, and those “critical flaws” that persuaded the *Zeneca* court to find the breast cancer study unreliable.³⁰⁸ Under the *Zeneca* rule, this evidence was sufficient to find the study unreliable; however, the *Riddell* court interpreted the evidence as merely “reciting authors’ objections”.³⁰⁹ *Zeneca* stated the general “rule” that peer reviewers are not provided complete study data and analyses.³¹⁰ This general practice was restated in the dissenting commentary published with the Riddell Study in *Neurosurgery*, where one of the authors noted that reviewers were forced to make certain assumptions about the Riddell Study’s methodology for testing non-Riddell helmets of various age.³¹¹ Additionally, as in *Zeneca*, the *Riddell* reviewers were not given the results of trials showing different results for helmets of varied age.³¹²

Third, the District Court should have considered the limitations that authors and peer reviewers placed on the Riddell Study.³¹³ Several previous decisions have endorsed this as persuasive evidence of unreliability. In *Zeneca*, the court found it persuasive, notwithstanding its publication, that the study specifically noted that further research was needed to determine Evista’s effect

307. *See id.* (challenging Schutt to demonstrate that “reviewers were not in a position to identify certain flaws in the protocol used in the study, were not given the results of trials showing different results and were not given the comments of the FDA . . .”) (citing *Zeneca*, 1999 WL 509471, at *29-30).

308. *See Riddell*, 724 F. Supp. 2d at 969 (noting “serious, if not fatal, methodological flaw” of Riddell Study, articulated by Vice President of NOCSAE, organization responsible for certification standard of football helmets).

309. *See Riddell*, 724 F. Supp. 2d at 974 (stating that defendant failed to add anything to bolster or challenge validity of study).

310. *See Zeneca*, 1999 WL 509471, at *29 (“[P]eer reviewers as a rule are given only the manuscript of the article and nothing else.”).

311. *See Collins*, *supra* note 12, at 284 (stating “reviewers do not verify the authenticity of data” of articles published in *Neurosurgery*). The reviewers of the Riddell Study conjectured about the protocol that was used, and noted it in their commentary. *See id.* One example was helmet age: “we assume the Riddell helmets were either new or nearly new However, the helmets that the Riddell helmets were being compared against are of indeterminate age” *See id.*

312. *See id.* (speculating about results of testing and implying reviewers were not shown results of tests done on helmets of varying age: “it would be expected if the newer Riddell helmets, therefore, are being compared against helmets that are significantly older, that the older helmet would not perform to as high a degree as the newer helmet”).

313. *See Collins*, *supra* note 12, at 284 (limiting study’s reliability because, e.g., “helmet selection was neither randomized, nor controlled,” haphazard selection of helmets made it impossible to attribute, conclusively, differences in results to one particular cause).

on breast cancer.³¹⁴ Additionally, in *McNeil*, the court found that Listerine could not make claims that extrapolated the particulars of the study to apply beyond the precise conditions tested; thus, Listerine could not claim to be “at least as good” as floss in protecting against mouth disease when the study’s authors had limited the conclusion to apply only when flossing was not done properly.³¹⁵ The facts were similar in *Riddell*.³¹⁶

The authors of the Riddell Study recommended, “on multiple occasions,” that further investigation was needed to determine the Revolution’s effect on concussions.³¹⁷ One author noted: “if one is going to make statements relative to the paper we wrote, it should be with the limitations that we emphasized, and not extrapolated to studies that we suggest should be done and haven’t been done yet.”³¹⁸ The suggested areas of study included: controlling for the age of the helmet; the age of the athlete; level of experience, skill; amounts of playing time; and any prior incidence of concussion.³¹⁹ Under *Zeneca* and *McNeil*, stated limitations by a study’s authors confine the scope of permissible establishment claims to the precise population studied.³²⁰

b. NOCSAE, FTC, and CPSC Did Not Endorse Riddell’s Establishment Claims

Despite the absence of mandatory precedent, the District Court should have acknowledged the weight that other courts have given to a regulatory agency’s rejection of a particular establishment claim because of broader public safety concerns.³²¹ In *Zeneca*,

314. See *Zeneca*, 1999 WL 509471, at *1 (noting FDA had required defendant to include in label that drug’s effectiveness “in reducing the risk of breast cancer has not yet been established”).

315. See *McNeil-PPC, Inc. v. Pfizer, Inc.*, 351 F. Supp. 2d 226, 231 (S.D.N.Y. 2005) (reporting study showed Listerine was “at least as good” as floss only when flossing was not done properly).

316. See *Riddell*, 724 F. Supp. 2d at 969 (providing authors’ commentary on study’s flaws).

317. See Schwarz 1/4/11, *supra* note 7 (quoting University of Pittsburgh Medical Center neurosurgeon and Riddell Study co-author Dr. Joe Maroon stating “the authors of that [Riddell] study on multiple occasions have recommended further investigations, better controls and with larger numbers”).

318. *Id.*

319. See Collins, *supra* note 12, at 282 (listing “significant limitations” to study).

320. See *Zeneca Inc. v. Eli Lilly Co.*, 1999 WL 509471, at *1 (S.D.N.Y. July 19, 1999) (limiting establishment claims to precisely what studies proved); *McNeil*, 351 F. Supp. at 231 (same).

321. See, e.g., Lehrer, *supra* note 59 (providing another iteration of broader public safety concern with concussions in football: “these cognitive deficits have a

the court found it persuasive that the FDA, the agency that regulates the safety of prescription drugs, had not approved the defendant's drug for the reduction of the risk of breast cancer.³²² Additionally, in *Bracco*, deciding that a superiority claim of one product over all x-ray media equipment, even equipment that was not tested, was literally false without more context.³²³ In reaching its decision, the *Bracco* court endorsed the rationale in *Zeneca*, noting that the FDA's rejection of the study's conclusion was persuasive evidence that the overall study was unreliable.³²⁴

The *Riddell* court did not address the issue of federal and private regulatory bodies declining to endorse Riddell's establishment and superiority claims.³²⁵ Three entities, the FTC, the CPSC, and NOCSAE were publicly critical of Riddell's "misleading safety claims and deceptive practices."³²⁶ The FTC and CPSC are legislative agencies that are responsible for ensuring the honesty of manu-

real-world impact: when compared with similar students without a history of concussions, athletes with two or more brain injuries demonstrate statistically significant lower grade-point averages"); Schwarz 10/27/07, *supra* note 1 ("Concussion is the big elephant in the room right now when it comes to helmets . . ."); Schwarz, *Designs Questioned*, *supra* note 66 (objecting to Riddell's establishment claims and demonstrating public interest concern: "People are running around with that [Revolution advertisement] selling helmet, and it has not been shown that it makes a difference. People get a false sense of security, and you have to hope that children are not suffering from the promotion of numbers that are not accurate") (quoting Dr. Michael Levy, neurosurgeon at Children's Hospital in San Diego); Schwarz 1/4/11, *supra* note 7 (calling for formal FTC investigation into "misleading descriptions of the protective qualities" of Revolution helmet, and reasoning that "[a]thletes, coaches and parents today are increasingly aware of the danger of concussion, and this awareness influences decisions about buying new and reconditioned football helmets Athletes who have already suffered a concussion – as well as their coaches and parents – may be particularly susceptible to misleading marketing claims about helmet safety").

322. See *Zeneca*, 1999 WL 509471, at *34.

323. See *Bracco Diagnostics, Inc., v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 472 (D.N.J. 2009) (requiring parties to identify "which products, by brand name, were actually tested in the study" when making superiority claims).

324. See *id.* at 470-71 (rejecting arguments that would require court to "second-guess the expert judgment of the FDA").

325. See Frommer, *supra* note 59 (stating that, as to Riddell's claim that "research shows a 31 percent reduction in the risk of concussion in players wearing the Riddell Revolution": "there is actually very little scientific evidence to support that claim") (quoting Senator Tom Udall, member of Senate Commerce Committee and Consumer Protection Subcommittee, which oversees work of Consumer Product Safety Commission); Schwarz 10/21/10, *supra* note 13 ("[The Revolution is] a good helmet. But I don't believe that 31 percent for a Yankee minute.") (quoting technical director of NOCSAE, Dave Halstead); see also Schwarz, *Designs Questioned*, *supra* note 66 ("I think that the Revolution is a good helmet – one of the safest, if not the safest, out there. But I have problems with that particular study. The helmet is not shown to do what they say it does.") (quoting Halstead).

326. See Schwarz 1/4/11, *supra* note 7 (noting Riddell's "prominent" establishment claim "has been criticized by experts for years").

facturers and the safety of consumer products.³²⁷ NOCSAE is the entity that sets the standard for football helmet testing.³²⁸ The FTC and CPSC were each, separately, asked to investigate Riddell's claims.³²⁹ The Court, however, did not consider the objective, consumer-oriented, criticism in its analysis.³³⁰

2. *The Study Did Not Prove What Riddell Claimed It Established*

The court's treatment of Schutt's alternative argument for literal falsity is, generally, legally sound; however, the court's strict application of logical principles ignores the important policy of consumer protection in a particularly sensitive area of consumer and legislative concern.³³¹ The court should have considered these broader concerns in its opinion; although they might not have changed the outcome, they would have acknowledged a developing area of law.³³² Because of this lack of foresight, the *Riddell* court's dismissal of the counterclaims on summary judgment is not likely to be followed in the future.³³³

The court's treatment of the first group of advertisements, which claimed the technology in the Revolution "family" was shown

327. See *About the Federal Trade Commission*, FEDERAL TRADE COMMISSION, <http://www.ftc.gov/ftc/about.shtm> (last visited Mar. 22, 2012) (describing FTC as agency that prevents "business practices that are . . . deceptive or unfair to consumers"); *About CPSC*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, <http://www.cpsc.gov/about/about.html> (last visited Mar. 22, 2012) (providing overview of CPSC function as commission "charged with protecting the public from unreasonable risks of injury or death from thousands of types of consumer products under the agency's jurisdiction").

328. See NOCSAE, *History and Purpose*, ABOUT NOCSAE, <http://www.nocsa.org/about/history.html> (last visited Jan. 30, 2012) (describing NOCSAE history and purpose).

329. See Frommer, *supra* note 59 (announcing congressman's request for formal investigation of misleading safety claims by CPSC).

330. For a further discussion of the potential impact of the court's decision on future concussion-related lawsuits, see *infra* notes 362-370 and accompanying text.

331. See, e.g., Lebowitz & Mzhen, *Players Sue NFL and Helmet Manufacturer Over Head Injuries*, WASHINGTON DC INJURY LAWYER BLOG, http://www.washingtondcinjurylawyerblog.com/2011/11/players_sue_nfl_and_helmet_man.html (Nov. 3, 2011) (stating "concussions in sports . . . have received heightened scrutiny recently in both the media and in Congress").

332. See, e.g., H.R. 1347, 111th Cong. (2nd Sess. 2010) (seeking to create and implement new guidelines for the prevention and treatment of concussions in school-aged children).

333. See, e.g., *In re NFL Players' Concussion Injury Litigation*, MDL No. 2323, 842 F. Supp. 2d 1378 (J.P.M.L. 2012) (Mem.) (order transferring and consolidating cases for pretrial proceedings) (anticipating lawsuits against NFL and Riddell that claims Riddell Study was "worthless").

to reduce concussions, was brief.³³⁴ Initially, the court held that the advertisement for the Riddell Revolution *Youth* helmets was literally false.³³⁵ Consequently, the court should have followed the injunction issued in *Bracco*, in which the defendant was ordered to formally correct the literally false statement.³³⁶ Following *Bracco*, the court should have enjoined Riddell to correct its misstatement in the rush mailer.³³⁷ Although the statement had already been corrected internally, the false perception was never corrected with the public.³³⁸

Secondly, and more importantly, the court failed to recognize the impossibility of the burden it ascribed to Schutt of demonstrating, conclusively, that design differences between the Riddell helmets affected their ability to reduce concussions.³³⁹ Schutt showed that the design differences “can” affect a helmet’s ability to “reduce” a concussion, but it could not have met the court’s standard of “conclusive” proof because scientists do not know how, precisely, to prevent concussions in contact sports.³⁴⁰

It is now commonly known that these traumatic brain injuries are caused by sudden impacts that send the brain crashing against the skull.³⁴¹ Although the NOCSAE helmet standard, which both Riddell and Schutt use to orient their helmet manufacturing, does not have a concussion component, research has indicated that certain measures may reduce concussions; one example was the more

334. See *Riddell, Inc., v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 975 (W.D. Wis. 2010) (analyzing alleged falsity of Riddell’s advertisements that used study in connection with helmets other than Revolution helmet).

335. See *id.* at 975-76 (referring to statement that wearers of Riddell Revolution *Youth* helmets were 31% less likely to suffer concussion than traditional helmet wearers and concluding that “the study did not involve Youth helmets, so the statement that it did is literally false”).

336. See *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 397 (2009) (ordering “an injunction and damages for post and future corrective advertising . . . to prevent future violations of the Lanham Act”).

337. See *id.* (issuing injunction).

338. *Riddell*, 724 F. Supp. 2d at 980 (finding injunction inappropriate because Riddell “already removed the reference to ‘Youth’ helmets from the rush mailer and there is no suggestion they intend to use that language”).

339. See *id.* at 976 (finding fault with Schutt’s “general assertions that design differences to areas like the shell or the face guard *can* change concussion results”).

340. See Schwarz 10/21/10, *supra* note 13 (asserting biochemists are “unsure of how to prevent concussions” in football). Definitive concussion prevention is so elusive because the brain can crash against skull “through a wide range of forces, some arriving straight to the head and others suddenly rotating it.” *Id.* Thus, it is difficult to adequately accommodate and defend against such varied threats.

341. See *What is a Concussion*, *supra* note 90 (defining concussion); Schwarz 10/21/10, *supra* note 13 (noting uncertainty of how concussions occur).

rounded facemask design of the Riddell Revolution, and more padding along the sides of the helmet.³⁴² Considering these facts and the findings of the Riddell Study, it is reasonable to conclude that a helmet that does not provide the precise protection of the Revolution would not prevent concussions with the same effectiveness.

The court's treatment of the second group of advertisements, those which were directed to age groups outside of the Riddell Study sample, determined that they were not literally false because, while the advertisements were misleading, they were not literally false.³⁴³ The court reasoned that Riddell's advertisements stated, simply, that the concussion study showed decreased concussion rates, without mentioning, or limiting, its application to the sample population.³⁴⁴

This rationale ignores important policy considerations. Initially, it ignores the policy provided in *McNeil* and *Zeneca*.³⁴⁵ Additionally, it ignores the ultimate goal of protecting consumers from harm by parsing words in its meticulous analysis of "misleading" and "literally false."³⁴⁶

Both the *McNeil* and *Zeneca* courts understood this policy.³⁴⁷ The *McNeil* court noted that the danger of the "overly broad" claim that Listerine was "as good as" floss was the effect it might have on consumers.³⁴⁸ The court reasoned that consumers suffering from

342. See Schwarz 10/21/10, *supra* note 13 ("Helmet standards have not kept up with modern football.") (quoting "industry insiders"); see also Anderson, *supra* note 15 (describing Riddell's facemask design feature, intended to "deflect some hits rather than absorb them," thought in previous helmets to contribute to incidence of concussion). For a further discussion of concussion-related design differences, see *supra* notes 39-42 and accompanying text.

343. *Riddell*, 724 F. Supp. 2d at 977 (discussing advertisements intended for age groups other than high school students).

344. See *id.* (concluding that "[b]ecause the study showed decreased concussion rates, the advertisement claims are not literally false").

345. See *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226, 251-52 (S.D.N.Y. 2005) (finding studies did not prove products' equivalent universal effectiveness, but instead indicated comparable effectiveness "only against plaque and gingivitis in individuals with mild to moderate gingivitis" because study samples were limited to individuals with mild to moderate gingivitis); *Zeneca Inc. v. Eli Lilly and Co.*, No. 99-1452, 1999 WL 509471, at *19 (S.D.N.Y. Jul. 19, 1999) (noting "disservice" to affected women of allowing advertisements of Evista as breast cancer-reducing drugs when claim had not been conclusively demonstrated).

346. See *Riddell*, 724 F. Supp. 2d at 978, 979, 980 (differentiating between "misleading" and "literally false").

347. See *McNeil*, 351 F. Supp. 2d at 251 (describing policy of not misleading affected consumers); *Zeneca*, 1999 WL 509471, at *19 (noting policy of not misleading public regarding "highly significant" drugs).

348. See *McNeil*, 351 F. Supp. 2d at 251 (illustrating consumer protection goal).

severe mouth disease might be misled into believing they were protecting themselves by using Listerine, when studies had not demonstrated Listerine's comparable effect on individuals with severe mouth disease.³⁴⁹ Further, in *Zeneca*, the court justified its limitation on claims that Evista had been shown to reduce the risk of breast cancer by considering the "disservice" this would be to "the millions of women who fear the disease."³⁵⁰

In *Riddell*, the court did not consider the broader ramifications of its decision. The court could have noted the "risk compensation effect" that "better" protective equipment provides, which describes the typical reaction to improved safety gear: an increase in the riskiness of behavior, but it did not.³⁵¹ Additionally, the court could have drawn parallels to *Zeneca* by acknowledging the growing awareness and fear of concussions, but it did not.³⁵² Instead, the court treated Schutt's counterclaims on summary judgment, applying a purely legal analysis.³⁵³ Had the court permitted the parties to introduce evidence of the effect of claims on consumers, or the medical dangers of overly broad claims about equipment, the holding might have been different.

3. *Injury: To Whom?*

The court found that Schutt failed to prove competitive harm or injury.³⁵⁴ Under the Lanham Act for false advertising, to prove that a statement is literally false, a plaintiff must also show actual or likely injury occurring as a result of the statement, "either by direct diversion of sales from itself to defendant or by a loss of good will that is associated with its products."³⁵⁵ The court applied the legal principles properly here; Schutt failed to demonstrate competitive

349. *See id.* ("[C]onsumers who suffer from severe gingivitis or periodontitis . . . may be misled by the ads into believing that Listerine is just as effective as floss in helping them fight plaque and gingivitis, when the studies simply do not stand for that proposition.")

350. *Zeneca*, 1999 WL 509471, at *19 (quoting Eli Lilly's internal instructions about Evista and providing another example of importance of protecting consumers).

351. *See* Lehrer, *supra* note 59 (describing "risk compensation effect"). For a further discussion of the risk compensation effect, see *infra* notes 356-362 and accompanying text.

352. *See, e.g.*, Dell'Antonia, *supra* note 8 (reporting on "Football and the Fear of Concussions").

353. *See* *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 981 (W.D. Wis. 2010) (dismissing Schutt's counterclaims on summary judgment).

354. *See id.* at 980 (dismissing Schutt's counterclaims on summary judgment).

355. *Hot Wax, Inc., v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999) (quoting Lanham Act, § 43(a)(1)(B), 15 U.S.C.A. § 1125(a)(1)(B)).

harm, and was therefore barred from recovery under the Lanham Act.³⁵⁶

However, assuming, as the court found, that Riddell's rush mailer advertising the *Youth* helmet was literally false, the policy reasons for finding against Riddell outweigh Schutt's failure to demonstrate competitive harm. By condoning the perpetuation of advertisements claiming a specialized anti-concussion helmet, proven to "reduce the incidence of concussions," the court implicitly effectuated the risk compensation phenomenon.

Moreover, the court missed an opportunity to send a message to all leagues and affiliates that have been, and will increasingly be, affected by further discoveries of the dangers of concussions.³⁵⁷ The point was not that Schutt failed to prove injury from Riddell's false statement; rather, the point was that youths might have seen the flyer, convinced their conscientious parents to buy the helmet, and proceeded to make headfirst tackles under the belief that they were wearing an anti-concussion helmet.³⁵⁸ By dismissing the counterclaims on summary judgment, the court never considered the broader implications of Riddell's advertisement, and therefore failed to provide for the protection of youths.³⁵⁹

VI. IMPACT

*You ever been in a car crash? Done bumper cars? You know when that hit catches you off guard and jolts you, and you're like, what the hell? Football is like that. But ten times worse. It's hell.*³⁶⁰

The days of football players taking big hits, sniffing smelling salts, and running back onto the field may finally be over.³⁶¹ Con-

356. *See id.* (providing plaintiff must demonstrate advertisement is literally false and has caused injury for recovery under Lanham Act).

357. *See* Belson, *supra* note 187 (entitling article "*For N.F.L., Concussion Suits May Be Test for Sport Itself*" and describing "multifront legal challenge to . . . game itself"); Loverro, *supra* note 187 (reporting "*Maxwell v. NFL Case Could Hit League Hard*"); Wise, *supra* note 4 (noting "[NFL]'s concussion policy and its culture change, expressing regret for generations of coaches and players").

358. *See* Lehrer, *supra* note 59 (stating "every year, we get more and more parents showing up with some fancy helmet and telling us this is the one their kid has to use" due to alleged concussion-reduction capabilities).

359. *See, e.g.,* Frommer, *supra* note 59 (requesting FTC look into "helmet claims" and writing that "issues involving serious health concerns—especially those for children and young adults—are a 'high priority for the commission'") (quoting FTC Chairman Jon Leibowitz).

360. Wiedeman, *supra* note 1 (quoting Kris Jenkins, recently retired NFL defensive lineman).

361. *See* Sauser, *supra* note 6 (describing "significant rule changes" enacted in 2010-2011 season in response to "greater awareness of head injuries," including more serious penalties and fines for helmet-to-helmet and defenseless player hits).

ussion awareness has grown tremendously in recent years.³⁶² Football, undoubtedly, is a sport of “hit, hit, hit,” but its true impact on those who play is largely unknown.³⁶³ The existence of the Riddell Study—withstanding its limitations—and concussion-oriented helmets demonstrate how prominent this recent expansion of concussion consciousness has become.³⁶⁴ On the other hand, these efforts may symbolize the efforts of Riddell and other similarly situated parties, such as the NFL, to direct concussion-related research, selectively and misleadingly disseminate the results of concussion studies, and attempt to protect themselves from the seemingly imminent liability that such parties face.³⁶⁵

The *Riddell* court chose to decide the case on the basis of legal reasoning alone, and did not consider the weight that this concussion consciousness carried. Perhaps the fact that the District Court was able to do this without accounting for the public policy concerns of football and the associated health risks shows just how far concussion consciousness has come since the 2010 decision.³⁶⁶ Indeed, in the three years since *Riddell* was decided, efforts to develop a strategy to decrease the risk of brain injury from contact sports have increased dramatically.³⁶⁷ The focus has been on rule changes and better equipment, yet it is generally acknowledged that equip-

362. See Leibowitz, *supra* note 331 (stating “concussions in sports . . . have received heightened scrutiny recently in both the media and in Congress, with many statistics suggesting the number of concussions has increased significantly”).

363. See generally Greg Bishop, *In Year of Hut, Hut, Hut, the 49ers Hit, Hit, Hit*, N.Y. TIMES (Jan. 17, 2012), <http://www.nytimes.com/2012/01/18/sports/football/for-49ers-defense-its-hit-hit-hit.html> (stating San Francisco 49er’s slogan has become “hit everything, hit anything, hit hard, hit first, hit often”).

364. See Schwarz 10/27/07, *supra* note 1 (“Contemporary helmet manufacturers have made a point of improving protection against concussions.”).

365. See, e.g., *In re NFL Players’ Concussion Injury Litigation*, MDL No. 2:12-02323 (J.P.M.L. 2012) (Compl.) (suing NFL for allegedly concealing health threats of playing professional football and Riddell for making inadequate helmets and exaggerating protection provided by Revolution models); see also Helyar, *supra* note 102 (noting Riddell’s \$336,000 investment in UPMC project “aimed at demonstrating that the Revolution reduced concussions”).

366. See Leslie Leuke, Comment, *High School Athletes and Concussions: More Than a Game at Stake*, 32 J. LEGAL MED. 483, 485 (2011) (attributing recent publicity “to former sports players’ reports of post-concussion difficulties and new studies that have rebutted the presumption that because athletes seem to recover from concussions so rapidly, concussions’ long-term effects are minimal”).

367. See *State Legislation*, THE CONCUSSION BLOG, <http://theconcussionblog.com/state-legislation/> (last visited Apr. 8, 2013) (listing thirty states enacting youth concussion laws between 2009 and 2012, and nine states with bills pending); Cailyn M. Reilly, *The NCAA Needs Smelling Salts When It Comes to Concussion Regulation in Major College Athletics*, 19 UCLA ENT. L. REV. 245, 260-61, 278-79 (2012) (discussing concussion management policies in professional sports leagues and several NCAA member conferences).

ment, alone, cannot solve the problem. In fact, it is extremely unlikely that any helmet can ever prevent concussions; certainly, “no current helmet . . . or other piece of equipment can significantly prevent concussions from occurring.”³⁶⁸

While the answer to stopping brain injury in contact sports remains unclear, it is clear that a future court decision on these or similar concussion-related legal issues will have to incorporate the broader policy concerns surrounding concussions in its analysis.³⁶⁹ In particular, when the Eastern District of Pennsylvania hears *In re NFL Players’ Concussion Injury Litigation*, in which Riddell has been named a co-defendant, the court must consider how the concussion enlightenment affects Riddell’s liability for exaggerating the protection that its helmets provide.³⁷⁰ *In re NFL Players’* does not make any Lanham Act claims against Riddell, but many of the claims in the complaint are based on the UPMC study, its flaws, and the exaggerated advertising that ensued, which were at issue in *Riddell*.³⁷¹

In conclusion, a future court should find that because of the catastrophic long-term health effects of concussions—many of which have come to light in the three years since *Riddell* was decided—Riddell will be held liable for disseminating favorable results from flawed studies that ostensibly support its claims about the effectiveness of its helmets at preventing concussions—but are objectively exaggerated and inaccurate—and failing to warn consumers—candidly and adequately—about the risks of traumatic brain injury inherent to contact sports that no helmet can ever eliminate. The court should ground its ruling in two important public policies: first, the policy of preserving the mental health of amateur and professional athletes over the economic gains of helmet manufacturers, and, second, the public interest in acknowledging the link

368. Lehrer, *supra* note 59.

369. See, e.g., *In re NFL Players’ Concussion Injury Litigation*, No. 2:12-03337, MDL No. 2323, 2012 WL 5212950 (E.D. Pa. June 13, 2012) (Trial Pleading) (incorporating policy concerns of head trauma into complaint). See also *NFL Head Injuries Draw Public Concern*, WASH. POST, http://www.washingtonpost.com/page/2010-2019/WashingtonPost/2012/06/07/National-Politics/Polling/release_91.xml?uid=z058LrCoEeGw96SQqoz3hw (last visited April 29, 2013).

370. See *In re NFL Players’ Concussion Injury Litigation*, MDL No. 2323, 842 F. Supp. 2d 1378 (J.P.M.L. 2012) (Mem.) (order transferring and consolidating cases for pretrial proceedings, anticipating consolidation of NFL brain injury law suit in Eastern District of Pennsylvania).

371. See, e.g., *NFL Players’ Concussion Injury Litigation*, 2012 WL 5212950 at *76–80 (pleading facts relevant to causes of action against Riddell and claiming that “the Riddell Defendants do not acknowledge a link between repeat concussions and later life cognitive problems” and “the Riddell Defendants have never warned Plaintiff or retired players of the long-term health effects of concussions”).

between repeat concussions and later cognitive problems so that a long-term collaborative solution can eventually be reached.