The Governor's Council for Judicial Appointments

State of Tennessee

Application for Nomination to Judicial Office

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INTRODUCTION

The State of Tennessee Executive Order No. 34 hereby charges the Governor's Council for Judicial Appointments with assisting the Governor and the people of Tennessee in finding and appointing the best and most qualified candidates for judicial offices in this State. Please consider the Council's responsibility in answering the questions in this application questionnaire. For example, when a question asks you to "describe" certain things, please provide a description that contains relevant information about the subject of the question, and, especially, that contains detailed information that demonstrates that you are qualified for the judicial office you seek. In order to properly evaluate your application, the Council needs information about the range of your experience, the depth and breadth of your legal knowledge, and your personal traits such as integrity, fairness, and work habits.

This document is available in word processing format from the Administrative Office of the Courts (telephone 800.448.7970 or 615.741.2687; website http://www.tncourts.gov). The Council requests that applicants obtain the word processing form and respond directly on the form. Please respond in the box provided below each question. (The box will expand as you type in the word processing document.) Please read the separate instruction sheet prior to completing this document. Please submit original (unbound) completed application (*with ink signature*) and eight (8) copies of the form and any attachments to the Administrative Office of the Courts. In addition, submit a digital copy with electronic or scanned signature via email to debra.hayes@tncourts.gov, or via another digital storage device such as flash drive or CD.

THIS APPLICATION IS OPEN TO PUBLIC INSPECTION AFTER YOU SUBMIT IT.

PROFESSIONAL BACKGROUND AND WORK EXPERIENCE

1. State your present employment.

I am employed at Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C. in the Memphis office. I have been employed by this firm and its predecessors since March 6, 1972.

2. State the year you were licensed to practice law in Tennessee and give your Tennessee Board of Professional Responsibility number.

I was licensed to practice law in 1972. My BPR# 7973.

3. List all states in which you have been licensed to practice law and include your bar number or identifying number for each state of admission. Indicate the date of licensure and whether the license is currently active. If not active, explain.

Tennessee. I was admitted on March 25, 1972. My license is currently active.

4. Have you ever been denied admission to, suspended or placed on inactive status by the Bar of any state? If so, explain. (This applies even if the denial was temporary).

No.

5. List your professional or business employment/experience since the completion of your legal education. Also include here a description of any occupation, business, or profession other than the practice of law in which you have ever been engaged (excluding military service, which is covered by a separate question).

I have practiced law at this firm for 43 years. I briefly had a 40% ownership in Big Shelby, Inc. d/b/a Ms. Kitty's from May of 1973 through May of 1976. Ms. Kitty's operated a popular nightspot at 531 South Cooper, near Overton Square. I sold my interest in May of 1976.

6. If you have not been employed continuously since completion of your legal education, describe what you did during periods of unemployment in excess of six months.

N/A

7. Describe the nature of your present law practice, listing the major areas of law in which you practice and the percentage each constitutes of your total practice.

My present law practice involves business disputes and litigation which occupies 100% of my time.

- In recent years, a major portion of this practice has consisted of advising clients and supervising attorneys in other states in litigation to enforce, modify, or have declared void employment covenants not to compete relating to employees and competing firms.
- I recently represented a Memphis-based medical laboratory that performs laboratory analysis of blood and tissue samples in its laboratory here in Memphis for healthcare providers throughout the United States. A competitor filed arbitrations in Dallas, Texas against three former employees and an executive as well as litigation in the federal court in Dallas and ultimately in the federal court here in Memphis. For a number of years these cases involved a substantial part (50-60%) of my time.
- During that time I also handled other business disputes relating to competition issues and advised numerous clients of my partners on issues in these areas, including researching the law of the applicable state or jurisdiction and drafting enforceable covenants not to compete and giving opinions as to the enforceability of covenants not to compete drafted by competitors.
- I also represented a petroleum distributor which distributes quick lube products that was accused of misbranding and commingling the products. This litigation lasted approximately three years in federal court here in Memphis, and also involved federal litigation in Delaware and Texas. The case also involved mediation in Delaware and was ultimately settled. During that applicable time period that case occupied approximately 25-30% of my time.
- The remainder of my practice is involved in the field of antitrust. I recently advised national counsel in a case pending in chancery court in west Tennessee in which major oil and gas companies were sued claiming price fixing at the wholesale level. Federal antitrust law does not provide for a cause of action for indirect purchasers. I assisted counsel with briefs in the trial court, Court of Appeals and Tennessee Supreme Court relating to this doctrine and the federal preemption doctrine, relating to the Federal Energy Regulatory Commission's preemption in this area of the law.
- Competition issues including non-competition restrictions and antitrust in litigation, arbitration, and counseling clients constitutes 80% of my present practice and appellate work the remaining 20%.
- During the course of my career I have generally taken at least 2-3 cases in chancery court

to trial each year and handled 5-10 injunction matters in chancery court each year.

8. Describe generally your experience (over your entire time as a licensed attorney) in trial courts, appellate courts, administrative bodies, legislative or regulatory bodies, other forums, and/or transactional matters. In making your description, include information about the types of matters in which you have represented clients (e.g., information about whether you have handled criminal matters, civil matters, transactional matters, regulatory matters, etc.) and your own personal involvement and activities in the matters where you have been involved. In responding to this question, please be guided by the fact that in order to properly evaluate your application, the Council needs information about your range of experience, your own personal work and work habits, and your work background, as your legal experience is a very important component of the evaluation required of the Council. Please provide detailed information that will allow the Council to evaluate your qualification for the judicial office for which you have applied. The failure to provide detailed information, especially in this question, will hamper the evaluation of your application.

When I began practicing with Heiskell, Donelson, Adams, Williams and Wall in 1972, I was the 14th lawyer. As a result, I tried cases in General Sessions, Circuit, and Chancery Court, as well as assisting my mentors, William F. Kirsch, Jr. and Longstreet Heiskell, in federal court cases.

- My mentors exposed me to antitrust cases starting with a price discrimination and attempt to monopolize case brought by a local office coffee service against a nationwide competitor. Next, I assisted Mr. Kirsch in a class action brought by a franchisee of Holiday Inns against the franchisor for violations of the Sherman Act by requiring that franchisee purchase certain equipment such as locks, springs, mattresses and logo signs from the franchisor. This experience led me to develop a specialty in the law of competition, which includes the federal and state antitrust laws, the Federal Trade Commission's proceedings, enforcement or defense against enforcement of restrictive covenants not to compete in employment agreements, and certain regulatory proceedings by both the State of Tennessee, the Federal Trade Commission and the antitrust section of the Justice Department.

- I represented a nationwide baking company in defense of a price discrimination case brought in federal court in Greenville, Mississippi.

- During the energy crisis in the mid-1970s, Congress enacted the Petroleum Marketing Practices Act, which gave certain rights to lessees of gas stations. I represented a jobber or distributor, which was an independent business that distributed products for a national oil company to service stations operators who leased the property owned by a major oil companies through subleases with my client. I tried a number of cases, including jury trials, relating to the price increases sought to be imposed by the oil companies which could not be passed on effectively to the sublessee dealers.

- I have defended clients in administrative actions brought by the antitrust section of the State of Tennessee's Attorney General's Office involving alleged milk price fixing, alleged agreements to set uniform prices by body shops that do repair work for a major insurance company in Tennessee; a proceeding against the homebuilders of Jackson for allegedly boycotting for sale by owner agents; a proceeding against a number of mental healthcare providers for allegedly agreeing on a uniform price to be proposed to the State of Tennessee for the services which, if successful, would have resulted in a federal debarment from financial reimbursement to Medicare or Medicaid and seriously eroded ability of the State of Tennessee to provide mental health services.

- I represented the City of Memphis Light Gas and Water Division in a suit brought in federal court in Nashville by cable companies alleging antitrust violations because the utilities throughout the state charged a uniform rate for the cable companies to string their wires on existing utility poles, notwithstanding the fact that most utilities enjoyed governmental immunity and were not in geographic competition with one another.

- I participated with one of my partners in Jackson, Mississippi in the defense of a healthcare provider from Nashville who had acquired a multi-specialty clinic from a major competitor in the Vicksburg market. The complaint alleged an attempt to monopolize in violation of the Sherman Act which the Federal Trade Commission had declined to pursue. We prevailed at the trial.

- I tried a case in federal court in Memphis brought pursuant to the Lanham Act for false advertising. I represented a major manufacturer of oil dry products which is a silica-based substance similar to cat litter in a suit against a competitor who refused to place the OSHA warning labels on the product relating to inhalation of the silica dust.

- I represented a group of urologists who purchased a lithotripter to dissolve kidney stones without surgery in a proceeding brought by the Federal Trade Commission exploring whether or not the doctors' referral practice to this machine constituted a restraint of trade.

- I have had an extensive chancery practice involving competition cases relating to the enforcement or denial of enforcement of covenants not to compete based upon current Tennessee Supreme Court law guidelines. I have generally tried 2-5 of these cases per year. I also have tried similar cases in the chancery courts of Davidson and Knox Counties.

- I have also tried a wide range of jury trials in circuit court in Shelby County including will contests, defective residential construction, personal injury, and products liability.

- I have tried jury cases in federal court in Arkansas involving personal injury, trade secrets, and violations of securities law.

- I have also defended a fraud case against a major employer before a jury in the circuit court of Hardin County, Tennessee involving allegations brought by a purchaser at auction of a defunct industrial site who did not pay for the property due to alleged

environmental defects which were not disclosed. I prevailed in that jury case.

- I defended an employee in a federal case brought in Nashville who was hired by a competitor. Even though he had no non-competition agreement, the former employer alleged that he "would inevitably disclose" trade secrets. I prevailed in that case.

- I obtained a substantial jury verdict on a counterclaim in federal court before a jury in Memphis relating to fictitious rebates claimed by the former distributor of the national lighting retailer.

- Beginning in 1980, when Leo Berman, Jr. and his father joined our firm, I assisted Mr. Bearman in the defense of two very serious medical malpractice cases. The first involved an alleged failure to diagnose breast cancer by a general practitioner and the second involved brain damage to an infant at a local children's hospital. Thereafter, I began trying jury cases for Mr. Bearman's insurance clients. For a period of approximately 6 years tried approximately 5 jury cases per year.

- I have also represented businesses in trade secrets litigation in federal court in Chicago, Illinois, and chancery court in Mississippi through appeals to the Supreme Court of Mississippi.

- I represented a Memphis-based broker dealer in a chancery court suit against an employee who had joined a competitor but had taken the entire list of securities purchasers of zero-coupon bonds.

- I have had substantial class action experience in the Holiday Inn case referenced above, in a suit brought against a national automobile manufacturer for the sale of new cars exposed to a tornado, and for a national funeral home and cemetery owner based upon the sale of burial policies.

- I have participated along with my partner, Grady Garrison, in the defense of a local architecture firm relating to alleged copyright infringement on architectural designs of apartment complexes in federal court in Memphis.

- I have represented a Memphis-based fast food franchisor in Sherman Act antitrust actions alleging tying arrangements brought in federal court in Little Rock, Arkansas and in Memphis, Tennessee.

- I have had numerous chancery cases relating to business disputes, including the sale of an office building in Bartlett, the sale of farmland in Cross County, Arkansas, and a dispute over a lease of substantial warehouse space in Memphis.

- I have also handled condemnation cases for a local municipality involving improvements to the area adjacent to Poplar Pike with a brick wall. I have tried jury cases in circuit court in Memphis involving executive compensation.

- I have defended cases in circuit court involving alleged violations of the Tennessee

Human Rights Act involving sexual harassment and another involving derogatory statements made based upon ethnicity.

- I have defended a garment manufacturer against a clothing supplier based in west Tennessee in federal court in Jackson, Tennessee.

- I have tried numerous cases in the chancery court involving breach of contract of every nature and description from defective landscaping, delivery of non-conforming goods under the Uniform Commercial Code.

- I defended a hardwood lumber mill on a breach of contract case in chancery court involving the quality of lumber exported to Germany.

- I defended a local vendor of conveying equipment sold to an air express company in Memphis, Tennessee in a suit brought by the State of Tennessee in chancery court claiming that the conveyors were personal property and should be taxed. The Court ruled that due to the nature of these conveyors, the conveyors constitute fixtures and were not taxable. The Court of Appeals affirmed.

- I have represented broker dealers in securities cases that have ranged from a suit by a local housing authority against a national firm alleging unsuitable investments in long-term treasury bonds, suits by the FDIC against broker dealers for alleged unsuitable investments brought in federal court both in Memphis and in Nashville, suits relating to unsuitability brought against a national banking client located here in Memphis in federal court in Louisville and in Nashville, as well as multi-district litigation in New Orleans.

- I have represented a Memphis-based broker dealer in AAA arbitration in Chattanooga which ultimately was appealed to the chancery court, the Court of Appeals and the Supreme Court, which ruled that the scope of appeal in arbitrations was limited by the Uniform Arbitration Act and the Federal Arbitration Act.

- I have handled many securities arbitrations brought by customers against broker dealers for allegedly unsuitable investments, churning or unauthorized trades.

- I also defended a businessman in northwest Tennessee who has extensive farm land, grain elevators, a television station and agricultural equipment dealerships in an investigation undertaken by the antitrust division of the Attorney General's Office of the State of Tennessee which did not result in formal charges or proceedings being brought.

- I also defended a case brought in circuit court under the state antitrust laws. A number of chiropractors sued the PPO affiliated with a local Memphis-bases hospital for being excluded from their panel of physicians. My client was granted summary judgment based on the plaintiff's counsel's misreading of the state antitrust statute, which does not require a PPO to include all specialists, but can reasonably limit the number of specialists in a particular area admitted to its panel. The Tennessee Court of Appeals and Supreme Court affirmed.

- I also defended an international transportation company in a suit brought in Chancery Court in Nashville claiming underpayment of over-the-road drivers of tractor trailers. The Chancery Court declined to certify the class and the Court of Appeals affirmed.

- I represented a local tent and awning manufacturer in a suit before the Tennessee Claims Commission against the State of Tennessee for nonpayment for tarps sold to the University of Memphis to cover portions of the seating at the Liberty Bowl for televised game events. I also filed suit in federal court for that same client in an interpleader action to require the manufacturer who sold backyard awnings to a vendor in Massachusetts which were made with my client's material to indemnify my client.

- I brought suit in federal court for a local gas station operator who had purchased the property he leased from a major oil company from the lessor to the oil company to recover unpaid rents.

- I defended in circuit court a national funeral home and cemetery company alleging that a funeral home owned by the client had inadvertently switched a burial urn.

- As I mentioned in answer to question 7 above, I have represented a Memphis-based laboratory in connection with arbitrations and lawsuits relating to proceedings brought by competitors relating to enforcement of non-compete agreements brought in Dallas, Texas and in another case brought in San Antonio, Texas by another competitor.

- I was retained by a national medical device company to monitor a circuit court trial herein Memphis involving an allegedly defective stent in order to handle any appeal that might be necessary. No appeal was filed.

- I defended a national retail chain in a suit brought in federal court here for alleged false arrest when security employees detained and charged the plaintiff with shoplifting but failed to show up in municipal court. The charges were then dismissed and the plaintiff brought a claim for false arrest. I received a defense jury verdict.

- I defended individuals who served on the board of directors of a general insurance agency in Arkansas. The underwriter or insurance company sought to obtain a judgment against the directors individually because the company had failed to remit premiums it had collected from trucking companies. I received a defense verdict in federal court here in Memphis which was affirmed by the Sixth Circuit Court of Appeals.

- During the time that Larry Godwin was director of police services for the City of Memphis, I regularly defended him in suits brought by plaintiffs against him in his individual as well as official capacity. These suits ranged from allegations of excessive force to a dispute over the elimination of an honorary title of 30 year captain. I was successful in obtaining dismissal and summary judgments in all of these cases.

- I recently concluded a trial in probate court in which I represented the only child of the deceased who was also the executor of the estate. He used a power of attorney to defeat specific requests that had been made to distant relatives. I was successful in defending a

claim concerning one of approximately 6 major transactions which had been notarized and witnessed by a local bank officer after interviewing bedridden testator and determining that he was competent and authorized the transaction.

- I also referenced in the answer to question 7 above the suit brought in federal court against a distributor of quick lube oil products relating to alleged commingling of the products.

- In addition to litigation, I am actively engaged in counseling clients relating to compliance with antitrust laws and personnel issues relating to trade secrets, covenants not to compete, and compliance with the law generally. These include a trade association of manufacturers in Memphis relating to such items as utility rates, water treatment, and other common issues. These include a major fiberglass manufacturer located in Fayette and Shelby Counties, Tennessee. The clients also include wealth management firms, banks, broker dealers, petroleum distributors, and others.

- I have advised a major Memphis corporation concerning retention of counsel in criminal matters relating to their employees in Wisconsin, businessmen charged with insider trading by the Securities and Exchange Commission or the criminal division of the Department of Justice, compliance with Federal Trade Commission rules relating to volume discounts, and other matters generally related to competition.

- In addition, I continue to take pro bono matters as they become available through the firm.

9. Also separately describe any matters of special note in trial courts, appellate courts, and administrative bodies.

See answer to questions 11 and 12.

In addition, I recently represented my ex-wife concerning insurance coverage with the State of Tennessee for her ongoing treatment for ovarian cancer. The State contended that the treatment recommended by the doctors was experimental and not covered under the plan.

With the assistance of my daughter, who is an attorney, we sued the state in an administrative law proceeding and received a confidential favorable settlement through mediation before an administrative law judge who was not assigned to the actual case.

On October 10, 1990, I was awarded a $2,809,822.00 jury verdict on a counter-claim on behalf of a lighting manufacturer against a distributor who was receiving illegal rebates based upon fictitious invoices.

10. If you have served as a mediator, an arbitrator or a judicial officer, describe your experience (including dates and details of the position, the courts or agencies involved, whether elected or appointed, and a description of your duties). Include here detailed description(s) of any noteworthy cases over which you presided or which you heard as a judge, mediator or arbitrator. Please state, as to each case: (1) the date or period of the proceedings; (2) the name of the court or agency; (3) a summary of the substance of each case; and (4) a statement of the significance of the case.

I have been engaged as a private mediator in business disputes since approximately 1995. I generally conduct at least three mediations during the course of a year.

I have also served as an arbitrator in securities cases for many years, first with the National Association of Securities Dealers and later for FINRA. These cases have usually involved claims of sale of unsuitable securities, unauthorized trades, and churning.

Because of the number of these cases and the fact that the firm does not continue to maintain files on these cases, I cannot state with particularity the number of cases or the issues in each case.

I was appointed by Chancellor Goldin a special master in a dispute between transportation companies relating to a group of employees who left and formed their own company and were alleged to have solicited the prior employers customers in violation of restrictive agreements.

I served as special judge for Chancellor Neal Small for several days when his brother was suffering kidney failure. I have served as special judge in the Circuit and General Sessions courts.

11. Describe generally any experience you have of serving in a fiduciary capacity such as guardian ad litem, conservator, or trustee other than as a lawyer representing clients.

I represented a client who was a conservator of his mother in the Probate Court of Shelby County, Tennessee for approximately 26 or 27 years until his mother died.

In addition, Probate Court Judge Benham appointed me conservator a mentally impaired young adult in a very egregious case. His mother had applied for Social Security disability based upon his late father's disability earnings. After several years the benefits were awarded in the form of two checks totaling approximately $155,000. By that time the mother had cancer and was in hospice. A dishonest nephew had her sign a power of attorney and used that power of attorney to steal the funds.

I sued the dishonest nephew and obtained a judgment and recovered approximately $10,000 of the remaining proceeds. I continue to serve as conservator on a pro bono basis.

12. Describe any other legal experience, not stated above, that you would like to bring to the attention of the Council.

In 1985 I was faced with a very unusual case. Two Memphis practitioners who filed Jones Act cases for injured seamen in federal courts up and down the Mississippi River were about to be sanctioned by the then Ethics Commission for violating the new advertising guidelines which required a television ad to have both a written and audible disclaimer. My clients ads were brief and only had the written disclaimer. A competing plaintiff's attorney had filed a complaint. If they were sanctioned that meant that they would be unable to be admitted in the various federal district courts that border the Mississippi River.

I was not in favor of the lawyer advertising, but my research convinced me that these restrictions were overly broad and violated commercial free speech. I attempted to negotiate with my friend Mike Cody, who was the Attorney General, but ultimately had to sue the Tennessee Supreme Court in federal court for injunctive relief.

The Court decided to review its own motion and adopted the present rule. See *In Re: Goldin*, 689 S.W.2d 869 (Tenn. 1985).

13. List all prior occasions on which you have submitted an application for judgeship to the Governor's Council for Judicial Appointments or any predecessor commission or body. Include the specific position applied for, the date of the meeting at which the body considered your application, and whether or not the body submitted your name to the Governor as a nominee.

On August 20, 2014, I applied for Part III of Chancery Court for the Thirtieth Judicial District at Memphis. I was one of the three candidates recommended to Governor Haslam. The Governor selected Bo Carr.

I ran for Part I of the Shelby County Chancery Court on August 7, 2014. I received over 38,000 votes but lost to the incumbent.

In March of 2013, I submitted an application to the Shelby County Commission to be considered for appointment for the vacancy created in Shelby County Probate Court by the retirement of Judge Benham. After seeing the other more qualified probate practitioners that had filed for the position, I did not pursue the appointment.

In May of 2008 I applied for the vacancy on the Court of Appeals created by the death of Judge Frank Crawford. I was not selected as one of the three names to be sent to the governor.

EDUCATION

14. List each college, law school, and other graduate school that you have attended, including dates of attendance, degree awarded, major, any form of recognition or other aspects of your education you believe are relevant, and your reason for leaving each school if no degree was awarded.

I graduated in 1968 from Southwestern at Memphis, now Rhodes College, with a bachelor of arts with distinction in economics. I had attended Christian Brothers College, now Christian Brothers University, my freshman year of 1964-65. I graduated from Vanderbilt University School of Law Class of 1971. I was one of the top 10 graduates in a class of approximately 115 students. I also received an award from Professor Bill Harbison from the International Academy of Trial Lawyers for my participation in the mock trial advocacy court.

PERSONAL INFORMATION

15. State your age and date of birth.

67. DOB: 9/27/46. Age: 68.

16. How long have you lived continuously in the State of Tennessee?

My family is from Memphis. I have resided in Tennessee since approximately 18 months of age and left only for law school and military service.

17. How long have you lived continuously in the county where you are now living?

Since 1948 with the exception of law school and military service.

18. State the county in which you are registered to vote.

Shelby County.

19. Describe your military service, if applicable, including branch of service, dates of active duty, rank at separation, and decorations, honors, or achievements. Please also state whether you received an honorable discharge and, if not, describe why not.

I served in the United States Army Reserve from 1968 through 1970. I was on active duty with the United States Army from July-November 1969. From 1970-1974 I served in the Tennessee Air National Guard. In the Nashville unit I was assigned to flight operations. I had the honor of serving under Col. John Tune and accompanied him to an operation named Ember Dawn in 1973 to the Arctic Testing Station at Delta Junction, Alaska. I received a commendation for participation in this mission. I was honorably discharged as a Sergeant E-5 on April 30, 1970.

20. Have you ever pled guilty or been convicted or are you now on diversion for violation of any law, regulation or ordinance? Give date, court, charge and disposition.

No.

21. To your knowledge, are you now under federal, state or local investigation for possible violation of a criminal statute or disciplinary rule? If so, give details.

No.

22. Please state and provide relevant details regarding any formal complaints filed against you with any supervisory authority including, but not limited to, a court, a board of professional responsibility, or a board of judicial conduct, alleging any breach of ethics or unprofessional conduct by you.

I have been practicing for 43 years. I have only had one complaint filed with the Board of Professional Responsibility, No. 15461-9-LC, which was filed in September of 1995 and dismissed on March 18, 1997. The complainant was a client who operated a local package delivery service using small compact cars equipped with two-way radios. He had purchased the assets of a competitor, including certain radios in which the competitor perfected a security interest to secure payment of the purchase price. My client defaulted and the competitor filed an ex parte temporary injunction in Chancery Court prohibiting use of the radios and ultimately obtained the radios. My client ultimately filed a disciplinary complaint against me, opposing counsel, and the chancellor handling the case. All were dismissed. He subsequently filed a civil lawsuit against my firm, not naming me as a defendant, which was dismissed by the circuit judge, the Court of Appeals, and the Supreme Court. Ultimately the Supreme Court on its own initiative entered an order barring the clerk from accepting any more filings from the client.

23. Has a tax lien or other collection procedure been instituted against you by federal, state, or local authorities or creditors within the last five (5) years? If so, give details.

No.

24. Have you ever filed bankruptcy (including personally or as part of any partnership, LLC, corporation, or other business organization)?

No.

25. Have you ever been a party in any legal proceedings (including divorces, domestic proceedings, and other types of proceedings)? If so, give details including the date, court and docket number and disposition. Provide a brief description of the case. This question does not seek, and you may exclude from your response, any matter where you were involved only as a nominal party, such as if you were the trustee under a deed of trust in a foreclosure proceeding.

I was the plaintiff in a divorce case filed in the Circuit Court for the 30th Judicial District at Memphis, styled William Michael Richards vs. Janet Charlene Leach Richards, No. 104383RD1. The divorce was uncontested and a property settlement and child support arrangements were agreed upon. The final decree of divorce was entered on July 16, 1986.

I also sued an automobile financing entity for failure to notify me that my stepson, the debtor on a consumer installment loan that I had guaranteed, let his automobile insurance lapse resulting in a default when he wrecked the vehicle and totaled it.

26. List all organizations other than professional associations to which you have belonged within the last five (5) years, including civic, charitable, religious, educational, social and fraternal organizations. Give the titles and dates of any offices that you have held in such organizations.

I have been a member of the Lawyers Journal Club, which is a group of Memphis lawyers that meets once a month to present learned papers. Prior to the applicable time period, I was active in the Boys Clubs of Memphis, as well as the Tennessee and Memphis Bar Associations. I am currently a member of the Antitrust Section of the American Bar Association. I am a graduate of the Leadership Memphis class of 1981. As a member of the Phoenix Club supporting the Boys Clubs of Memphis, I received the Mednikow Award for Outstanding Service to the Boys Clubs.

I am a Fellow in the Tennessee Bar Foundation, a member of the Tennessee Supreme Court Historical Society, and a former member of the American Inns of Court, Leo Bearman, Jr. Chapter.

I serve as a volunteer judge in the Rhodes College Annual Mock Trial Competition.

27. Have you ever belonged to any organization, association, club or society that limits its membership to those of any particular race, religion, or gender? Do not include in your answer those organizations specifically formed for a religious purpose, such as churches or synagogues.

    a. If so, list such organizations and describe the basis of the membership limitation.

    b. If it is not your intention to resign from such organization(s) and withdraw from any participation in their activities should you be nominated and selected for the position for which you are applying, state your reasons.

No.

ACHIEVEMENTS

28. List all bar associations and professional societies of which you have been a member within the last ten years, including dates. Give the titles and dates of any offices that you have held in such groups. List memberships and responsibilities on any committee of professional associations that you consider significant.

I am a member of the Lawyers Journal Club, as well as the American, Tennessee and Memphis Bar Associations. I am a past vice-president for West Tennessee of the Tennessee Bar Association and president of the Young Lawyers Division of the then Memphis and Shelby County Bar Association in 1979. I am also a Fellow in the Tennessee Bar Foundation, a member of the Tennessee Supreme Court Historical Society, and a former member of the American Inns of Court, Leo Bearman, Jr. Chapter. I hold an a.v. rating from Martindale and Hubbell.

29. List honors, prizes, awards or other forms of recognition which you have received since your graduation from law school that are directly related to professional accomplishments.

In 1985 I received the Sam A. Myar Junior Memorial Award in recognition of outstanding service to the legal profession and the community. I was selected one of the Best Lawyers in America for 2014-15 in the areas of Antitrust, Arbitration, and Mediation. The Best Lawyers in America named me Best Layers 2014 Memphis Litigation-Antitrust "Lawyer of the Year." I have been named in Best Lawyers in America since 2007 for Antitrust and Alternate Dispute Resolution.

30. List the citations of any legal articles or books you have published.

Tennessee Bar Journal, Recent Developments in the Law of Competition in Tennessee, Vol. 35, No. 2, February 1999;

Antitrust Law 360, Sixth Circuits Narrow Path For Plaintiffs Under Twombly and Iqbal, published August 11, 2011.

31. List law school courses, CLE seminars, or other law related courses for which credit is given that you have taught within the last five (5) years.

Federal Bar Association, November 18, 2005 Federal Practice Seminar. I presented "How to Conduct an Investigation Post-Enron."

Lawyers Journal Club, March 23, 2013, "12(b)(6) Motions in the Sixth Circuit After Twombly and Iqbal."

Lawyers Journal Club, "Scope of Arbitration: A Review of State and Federal Antitrust Laws."

32. List any public office you have held or for which you have been candidate or applicant. Include the date, the position, and whether the position was elective or appointive.

I ran for Chancery Court Part I in the August 7, 2014 elections against an incumbent. I received slight over 38,000 votes and was defeated by the incumbent opponent, who has held the office since 1998.

See response to question 13 above.

33. Have you ever been a registered lobbyist? If yes, please describe your service fully.

No.

34. Attach to this questionnaire at least two examples of legal articles, books, briefs, or other legal writings that reflect your personal work. Indicate the degree to which each example reflects your own personal effort.

Attached is an Expedited Petition for Declaratory Order filed before the State of Tennessee in an administrative law proceeding relating to cancer treatment for my ex-wife. Also enclosed are two related memoranda. Submission "A".

My daughter, Jamie Whitney, who is a lawyer in Austin, Texas, compiled the medical authorities. I drafted the entire brief and memoranda incorporating her medical authorities.

Secondly, attached is an article previously referenced that I recently submitted to the Antitrust 360 publication which is routinely read by antitrust practitioners throughout the United States. I drafted the entire article. Submission "B".

Thirdly, attached is the brief I filed in the Tennessee Supreme Court in the Conservcare/Amodeo case. Submission "C".

ESSAYS/PERSONAL STATEMENTS

35. What are your reasons for seeking this position? ***(150 words or less)***

Complex civil cases are the core of the Chancery Court docket. I have tried many complex civil business litigation cases in chancery, circuit, and federal trial courts, and have argued substantial cases in the federal appellate courts, the Tennessee Court of Appeals, and the Tennessee Supreme Court. With decades of experience, I possess a clear understanding of the law and have

seen the influence and far reaching effects the judicial system has on the lives of those involved. I will respect the dignity of each person. I will hear the facts of each case and apply the law. I will issue written findings of fact and conclusions of law promptly.

36. State any achievements or activities in which you have been involved that demonstrate your commitment to equal justice under the law; include here a discussion of your pro bono service throughout your time as a licensed attorney. ***(150 words or less)***

I was elected President of the Young Lawyers' Section of the Memphis and Shelby County Bar Association in 1979. I instituted the first "phone-a-thon" in which young lawyers manned telephones at night to answer legal questions and give legal advice to indigent clients. This program that I instituted has continued in some form to the present. The Young Lawyers Section received an Award of Merit from the American Bar Association for instituting this public service.

My firm requires that all lawyers provide at least 100 hours annually of pro bono representation. I have met or exceeded this goal.

As listed in the answer to question 11, I currently serve as a conservator to a mentally impaired young adult by virtue of appointment by Judge Benham in Cause No. D-5963 in the Probate Court.

Federal Judge Robert McCrae appointed me to represent two indigent prisoners in separate cases. The first involved a pro se lawsuit filed by an inmate at Ft. Pillow in the maximum security unit alleging that he had been brutally beaten without cause. He suffered some severe injuries. However, as the proof developed it turns out that he and other inmates were attempting to storm the pod in his unit and were subdued by the guards. A jury returned a verdict that the actions of the guards were legal under the circumstances. The second case involved an appointment to defend a prisoner at the Shelby County Correction Facility who allegedly attacked a fellow prisoner at the jail at 201 Poplar. The prisoner, who was a cross-dressing transsexual, suffered head injuries and ultimately died. The coroner testified that an attack could have caused these injuries or they may have been caused by a fall in his cell. The jury returned a verdict against my client.

37. Describe the judgeship you seek (i.e. geographic area, types of cases, number of judges, etc. and explain how your selection would impact the court. ***(150 words or less)***

Part III of the Chancery Court of Shelby County, Tennessee is one of three parts or divisions of the Chancery Court. The Chancery Court in Memphis hears adoptions, divorces, contract actions, title disputes, corporate shareholder claims, business disputes, suits for accountings, and all matters traditionally handled by separate courts of equity. I have tried numerous cases in this court since my admission to the bar in 1972 and feel that this is an opportunity to give back to the community. I will treat litigants, lawyers and witnesses with respect and promptly render

written findings of fact and conclusions of law in each case.

38. Describe your participation in community services or organizations, and what community involvement you intend to have if you are appointed judge? ***(250 words or less)***

I have actively handled on a pro bono basis many cases over my career. I have never refused an appointment to represent an indigent client on a pro bono basis and have never withdrawn from a case when a client did not have sufficient funds to pay me. If appointed to the Chancery Court I will encourage practitioners to do the same and give back to the citizens of Shelby County.

39. Describe life experiences, personal involvements, or talents that you have that you feel will be of assistance to the Council in evaluating and understanding your candidacy for this judicial position. ***(250 words or less)***

As a native Memphian, I began at an early age getting to know my fellow Memphians. From junior high school through my graduation from Southwestern (Rhodes College) I delivered the morning newspaper to their homes 365 days of the year, rain or shine. I worked hard and earned college tuition and along with a scholarship, graduated with honors from Rhodes College and Vanderbilt Law School. This contributed to a diligent work ethic that continues today. I will dedicate the same resolve to the task at hand as Chancellor. I believe my training and experience enables me to fill this promise.

40. Will you uphold the law even if you disagree with the substance of the law (e.g., statute or rule) at issue? Give an example from your experience as a licensed attorney that supports your response to this question. ***(250 words or less)***

As I explained in detail in the answer to question 12, in 1985 I was forced to sue the Tennessee Supreme Court on the issue of restrictions of commercial free speech related to lawyer advertising. Keep in mind that at that time most lawyers and virtually all of the larger law firms found lawyer advertising distasteful. I felt the same way. However, after I read the existing case law detailing the balance between lawyer advertising and unconstitutional restrictions on commercial free speech, I nevertheless took the case. After obtaining injunctive relief in federal court, the Tennessee Supreme Court decided to review its own rule and modified the rule consistent with the First Amendment grant of commercial free speech. The Court, through the Board of Professional Responsibility, still polices advertising to prevent false and deceptive advertising.

REFERENCES

41. List five (5) persons, and their current positions and contact information, who would recommend you for the judicial position for which you are applying. Please list at least two persons who are not lawyers. Please note that the Council or someone on its behalf may contact these persons regarding your application.

A. Lewis R. Donelson, founder, Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.
B. David Popwell, President and Chief Operating Officer First Tennessee Bank
C. Ham Smythe, Chairman Yellow Cab Company
D. Brook Lathram, Attorney Bass, Berry & Sims
E. Glen Reid, Attorney Wyatt, Tarrant & Combs

AFFIRMATION CONCERNING APPLICATION

Read, and if you agree to the provisions, sign the following:

I have read the foregoing questions and have answered them in good faith and as completely as my records and recollections permit. I hereby agree to be considered for nomination to the Governor for the office of Judge of [Court] Part III of the Chancery Court of Tennessee for the Thirtieth Judicial District at Memphis, and if appointed by the Governor, agree to serve that office. In the event any changes occur between the time this application is filed and the public hearing, I hereby agree to file an amended questionnaire with the Administrative Office of the Courts for distribution to the Council members.

I understand that the information provided in this questionnaire shall be open to public inspection upon filing with the Administrative Office of the Courts and that the Council may publicize the names of persons who apply for nomination and the names of those persons the Council nominates to the Governor for the judicial vacancy in question.

Dated: April 30th, 2015.

Michael Richards
Signature

When completed, return this questionnaire to Debbie Hayes, Administrative Office of the Courts, 511 Union Street, Suite 600, Nashville, TN 37219.

THE GOVERNOR'S COUNCIL FOR JUDICIAL APPOINTMENTS
ADMINISTRATIVE OFFICE OF THE COURTS

511 UNION STREET, SUITE 600
NASHVILLE CITY CENTER
NASHVILLE, TN 37219

TENNESSEE BOARD OF PROFESSIONAL RESPONSIBILITY
TENNESSEE BOARD OF JUDICIAL CONDUCT
AND OTHER LICENSING BOARDS

WAIVER OF CONFIDENTIALITY

I hereby waive the privilege of confidentiality with respect to any information that concerns me, including public discipline, private discipline, deferred discipline agreements, diversions, dismissed complaints and any complaints erased by law, and is known to, recorded with, on file with the Board of Professional Responsibility of the Supreme Court of Tennessee, the Tennessee Board of Judicial Conduct (previously known as the Court of the Judiciary) and any other licensing board, whether within or outside the State of Tennessee, from which I have been issued a license that is currently active, inactive or other status. I hereby authorize a representative of the Governor's Council for Judicial Appointments to request and receive any such information and distribute it to the membership of the Governor's Council for Judicial Appointments and to the Office of the Governor.

William Michael Richards

Type or Print Name

William Michael Richards

Signature

April 30, 2015

Date

#7973

BPR #

Please identify other licensing boards that have issued you a license, including the state issuing the license and the license number.

None

A

BEFORE THE STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JANET LEACH RICHARDS,

Petitioner,

v. No.: 17.06 - 112820J

TENNESSEE DEPARTMENT OF HEALTH;
SUSAN R. COOPER, MSN, RN,
COMMISSIONER,

Respondent.

EXPEDITED PETITION FOR DECLARATORY ORDER PURSUANT TO T.C.A. § 4-5-223 and T.C.A. § 56-7-2352(c)(1) and T.C.A. § 56-7-2352(c)(7)

COMES NOW Petitioner Janet Leach Richards and respectfully seeks expedited review of an adverse decision regarding health insurance coverage in this petition for declaratory order pursuant to T.C.A. § 4-5-223 and T.C.A. § 56-7-2352(c)(1) and T.C.A. § 56-7-2352(c)(7) and states as follows:

I.
PARTIES

1. Petitioner Janet Leach Richards (hereinafter "Professor Richards") is a professor emeritus at the University of Memphis Cecil C. Humphreys School of Law, where she taught for over thirty-two (32) years.

2. Respondent Tennessee Department of Health and Susan R. Cooper, MSN, RN, Commissioner, (hereinafter, collectively, "the Commissioner") are responsible for interpreting and administering insurance plans for employees of the State of Tennessee, including Professor Richards, consistent with the applicable law.

II.
FACTS

3. Professor Richards was diagnosed with Stage IV ovarian cancer in 2002. Since then, aggressive treatment has enabled her to live an active life and continue teaching law school until her recent retirement in May of 2011. Professor Richards' prior successful treatment has consisted of, among other things, high dose chemotherapy and a stem cell transplant. Now her cancer has reoccurred.

4. Professor Richards is being treated by Dr. Mark E. Reed at The West Clinic in Memphis, Tennessee. Dr. Reed is board-certified in Gynecological Oncology. He has personally treated Professor Richards

since her initial diagnosis almost a decade ago. Dr. Reed's prior treatment decisions have allowed Professor Richards to achieve three prior clinical remissions of her ovarian cancer.

5. Dr. Reed has determined that Professor Richards' bone marrow is no longer able to tolerate standard dose chemotherapy as a result of her previous intensive treatment regimen. *See* Physician Progress Note, attached hereto as Exhibit A, at A-6. Additionally, Dr. Reed has determined that Professor Richards' recurrent cancer is unlikely to respond well to standard dose chemotherapy because the cancer is slow-growing. *Id.* Dr. Reed has considered and ruled out multiple other treatment possibilities, including surgical options, because of significant likely adverse side effects. *Id.*

6. Dr. Reed has determined that the most effective treatment for Professor Richards would be small, daily ("metronomic") doses of an oral chemotherapy drug, Hycamtin (topotecan) (which has been effective on Professor Richards in standard doses on two prior occasions), coupled with a second oral drug, Votrient (pazopanib). *Id.* The metronomic dosage of these chemotherapy drugs will be better tolerated and will more effectively address the tumor's slow growth over time (as compared with standard dosage chemotherapy). *Id.*

7. Insurance coverage is necessary to allow Professor Richards access to these chemotherapy drugs. The market cost of each of these drugs is between $6,000 to $8,000 per month, meaning that the cost of the combined treatment will be between $12,000 and $16,000 each month. In order to effectively treat her cancer, Professor Richards will need to fill these prescriptions regularly for a period of at least six months, possibly longer. Professor Richards has recently retired and is on a fixed income. Absent appropriate insurance coverage, the cost of this chemotherapy regimen is prohibitive.

8. Professor Richards' insurance carrier, CVS CareMark, declined coverage of the prescribed drugs, and the Commissioner subsequently declined to order coverage of the treatment prescribed by Dr. Reed on the grounds that it was not a "widely accepted medical regimen" according to the acting Medical Director. *See* Commissioner's Letter of May 18, 2011, attached hereto as Exhibit B.

9. Tennessee law does not limit coverage to "widely accepted medical regimen[s]" but instead requires coverage if the therapy prescribed is "recognized for treatment of the indication in one (1) of the standard reference compendia, ***or*** in the medical literature." T.C.A. § 56-7-

2352(c)(1) (emphasis added). Medical literature is defined by statute as "published scientific studies published in any peer-reviewed national professional journal." *Id.* at (b)(2). The statute further authorizes the Commissioner to "direct any person who issues an insurance policy to make payments required by this section." *Id.* at (c)(7).

10. Professor Richards has identified for the Commissioner (and attaches hereto and incorporates by reference) multiple scientific studies published in peer-reviewed, national professional journals identifying metronomic topotecan and/or pazopanib as effective in treatment of recurrent, slow-growing ovarian cancer. *See generally* Exhibit C. Additionally, topotecan is listed as an ovarian cancer treatment in two of the compendia recognized by the statute. *See* Exhibits E, F.

11. Accordingly, Professor Richards requests a declaratory order pursuant to T.C.A. § 4-5-223, T.C.A. § 56-7-2352(c)(1), and T.C.A. § 56-7-2352(c)(7) that (1) finds Professor Richards' proposed treatment regimen is a covered off-label treatment regimen under Tennessee law and (2) declares that the Commissioner shall direct Professor Richards' insurance carrier, CVS CareMark, to cover and provide this prescribed treatment, and (3) provides all other relief to which Professor Richards may be entitled.

III.
APPLICABLE LAW

12. In 1997, the legislature enacted T.C.A. § 57-7-2352 to address inequities in the interpretation of health insurance coverage. The statute was further expanded by amendment in 2010.

13. In enacting and expanding this statute, the legislature made extensive findings concerning the efficacy and necessity of off-label prescription drugs, particularly in treating various cancers. *See* T.C.A. § 57-7-2352 (a)(1)—(9). The legislature found that "[a]pproximately fifty percent (50%) of cancer drug treatment is for off-label indications." *Id.* at § (a)(6). The legislature further noted that "denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness." *Id.* at (a)(4).

14. The legislature's unequivocal policy judgment is that consistent insurance coverage for off-label uses of prescription drugs is essential to the "necessary and appropriate treatment of a person being treated for a life-threatening illness." *Id.* As a result, the statute unequivocally mandates insurance coverage for off-label uses in the broadest possible language. Specifically, the statute provides as follows:

56-7-2352. Coverage for off-label uses of approved drugs. - **(a)** The general assembly finds and declares the following:

. . .

(6) Off-label use of an FDA-approved drug is legal when prescribed in a medically appropriate way and is often necessary to provide needed care. Approximately fifty percent (50%) of cancer drug treatment is for off-label indications. The FDA and the federal department of health and human services recognize the wide variety of effective uses of FDA-approved drugs for off-label indications. Information on the appropriate off-label use of FDA-approved drugs is obtained from compendia published by the United States Pharmacopeial Convention, the American Medical Association, and the American Society of Hospital Pharmacists. ***In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications.***

. . .

(8) Reimbursement for off-label indications of FDA-approved drugs is ***necessary to conform to the way in which appropriate medical treatment is provided, to make needed drugs available to patients,*** and to contain health care costs; and

. . .

(b) As used in this section, unless the context requires otherwise:

(1) "Insurance policy" means any individual, group, or blanket policy written by a medical expense indemnity corporation, a hospital service corporation, a health care service plan contract, or a private insurance plan issued, amended, delivered or renewed in this state, or that provides such insurance for residents of this state;

(2) "Medical literature" means published scientific studies published in any peer-reviewed national professional journal; and

(3) "Standard reference compendia" means:

(A) The United States Pharmacopeia Drug Information;

(B) The American Medical Association Drug Evaluations; or

(C) The American Hospital Formulary Service Drug Information.

(D) The National Comprehensive Cancer Network Drugs and Biologics Compendium;

(E) The Thomson Micromedex DrugDex; or

(F) The Gold Standard/Elsevier Clinical Pharmacology.

(c)(1) No insurance policy or contract regulated under this title that provides coverage for drugs ***shall exclude coverage*** of any such drug for a particular indication on the ground that the drug has not been approved by the FDA for that indication, ***if the drug is recognized for treatment of the indication in one (1) of the standard reference compendia, or in the medical literature;*** provided, that nothing in this section shall be construed to authorize the commissioner of health to approve any drug or direct any person that issues an insurance policy to make payments for the drug for a particular indication unless the drug is recognized for treatment of the indication in one (1) of the standard reference compendia or in the medical literature.

(2) Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

. . .

(7) The commissioner of health shall have the authority to direct any person who issues an insurance policy to make payments required by this section.

T.C.A. § 56-7-2352(a)—(c) (emphasis added).

IV.
ARGUMENT

The legislature has mandated that off-label use of drugs, particularly in cancer treatment, must be covered provided that such use is recognized for the treatment at issue in medical compendia or in the medical literature as defined in the statute. T.C.A. § 56-7-2352(c)(1). By using the disjunctive, "or," the legislature has made clear that satisfaction of either requirement establishes coverage. *Id.*

Professor Richards is entitled to coverage of Hycamtin (topotecan) pursuant to the "medical compendia" provisions of the statute, and is entitled to coverage of both Hycamtin (topotecan) and Votrient (pazopanib) pursuant to the "medical literature" provision of the statute.

A. Professor Richards has Established Coverage for Topotecan Based on the Statute's "Medical Compendia" Clause

The statute specifically identifies certain publications that fit the definition of "medical compendia," including the American Hospital Formulary Service Drug Information and the Thomson Micromedex DrugDex. T.C.A. § 56-7-2352(b)(3). One of the drugs requested for Professor Richards' treatment, Hycamtin (topotecan), is referenced for treatment of recurring ovarian cancer in both of these publications. *See* Exhibit D, Richards Letter of May 23, 2011 at D-3 and footnotes 3 and 4;

Exhibit E, AHFS entry for Topotecan Hydrochloride at E-1; Exhibit F, DrugDex entry for Topotecan Hydrochloride at F-1. In fact, "ovarian cancer" is the ***first*** indication listed for topotecan in the AHFS compendium, which specifically notes that topotecan is useful "in patients with disease that has recurred or progressed . . . ." Exhibit E at E-1. This is the exact indication for which Professor Richards is requesting coverage. Accordingly, the statute clearly mandates coverage for topotecan in this case. T.C.A. § 56-7-2352(c)(1).

B. Professor Richards has Established Coverage for Both Topotecan and Pazopanib Under the Statute's "Medical Literature" Clause

The statute defines "medical literature" as "published scientific studies published in ***any peer-reviewed national professional journal.***" T.C.A. § 56-7-2352(b)(2). (emphasis added). Thus, the statute mandates coverage for any off-label use that is supported by scientific studies published in a peer-reviewed national professional journal. *Id.* at § 56-7-2352(c)(1).

The public policy behind this statutory language is a good one. An insurer should not be allowed to second-guess a treating physician, particularly one treating a life-threatening illness such as cancer, so long as a course of treatment is supported by peer-reviewed journals. *Id.* at §56-7-2352(a)(4),(6). As the statute points out, "scientific studies of off-label use

of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications." *Id.* at § 56-7-2352(a)(6).

The statute's reliance on peer-reviewed journals mirrors the best practices identified by the medical community. The American Society of Clinical Oncology (ASCO) notes "the growth of peer-reviewed medical journals that provide credible support of off-label uses not yet included in the compendia," explaining that peer-reviewed medical journals "have become significant sources of credible information about medically appropriate off-label uses, and they . . . should be recognized as legitimate sources of coverage data." American Society of Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications*, 24 JOURNAL OF CLINICAL ONCOLOGY 3206, 3207 (2006), attached hereto at A-9.

Professor Richards has identified several scientific studies evaluating metronomic topotecan, pazopanib, and these two drugs in combination for treatment of ovarian cancer, each of which is published in a peer-reviewed national professional journal. *See* Exhibit C. Accordingly, Professor Richards has established coverage for these drugs under the statute. T.C.A. § 56-7-2352(c)(1).

i. Professor Richards' Treatment Plan is Recognized in the Medical Literature

The statute provides a clear, objective standard under which pharmaceutical coverage cannot be denied. T.C.A. § 56-7-2352(c)(1). Professor Richards has more than met this standard. Professor Richards provided Commissioner Cooper with ***seven*** different scientific studies, published in peer-reviewed national professional journals over a period of more than a decade, that recognize Hycamtin (topotecan) and Votrient (pazopanib) for the treatment of recurrent ovarian cancer, both as single agents and in combination. *See generally* Exhibit C.

Topotecan, in particular, has a substantial history in the medical literature concerning recurrent ovarian cancer. As noted above, topotecan has twice been effective in reducing Professor Richards' cancer growth in the past, and repeat treatments with this particular drug have been found to be effective in the medical literature. For example, a 1998 case study evaluated the efficacy of repeat treatments of topotecan in ovarian cancer patients previously treated with this drug and found "[t]opotecan re-treatment caused a greater than 50% reduction of CA 125 levels" in the patients studied. Dunton CJ, et al., *Secondary response of ovarian tumors to topotecan*, GYNECOL. ONCOL. 1998 Jun; 69(3): 258-9 (reprinted here at C-

56). Accordingly, "[t]he case studies reported here suggest that repeat treatment with topotecan can be beneficial." *Id.*

Professor Richards' treating oncologist has prescribed oral topotecan rather than standard-dose intravenous topotecan. *See* Exhibit A. This treatment method is well-documented in the medical literature. In particular, a 2001 study of oral topotecan in patients with recurring ovarian cancer found that oral topotecan is as effective as standard-dose intravenous topotecan but tends to have a lower toxicity than the standard dosage. Clarke-Pearson DL, et al., *Oral topotecan as single-agent second-line chemotherapy in patients with advanced ovarian cancer*, J CLIN ONCOL. 2001 Oct 1;19(19): 3967-75 (reprinted here at C-34—35). Another 2001 study, which compared the efficacy of oral topotecan to standard intravenous topotecan in a total of 266 patients with recurring ovarian cancer, *see* C-3, noted that "[t]he relative reduction in toxicity associated with oral topotecan and its ease of administration suggests a potential for prolonged treatment with this compound. Such a strategy might improve survival in these patients because there have been reports of longer duration of therapy being associated with a reduction in mortality." Gore M, et al., *A randomized trial of oral versus intravenous topotecan in patients with relapsed epithelial ovarian cancer*, EUR J. CANCER, 2002; 38(1): 57 (reprinted here at C-6).

This study explained that prolonged oral dosing is desirable "because of the cell cycle-specific mechanism, convenience of administration, and favorable toxicity profile." *Id.*

Another study of metronomic topotecan published in 2009 indicated that metronomic topotecan, as opposed to standard-dose therapy, can "result in reduced normal tissue toxicity and minimize 'off-treatment' exposure resulting in an improved therapeutic ratio." Merritt WM, et al. *Anti-angiogenic properties of metronomic topotecan in ovarian carcinoma.* CANCER BIOL. THER. 2009 Aug;8(16): 1596-603 (reprinted here at C-9). This study specifically found metronomic topotecan was effective in reducing ovarian cancer tumor growth. *Id.* at C-11. "Metronomic dosing of cytotoxic agents function as "antiangiogenic" [inhibiting the growth and spread of cancer cells] because the frequent, low dose administration appears to differentially target endothelial cells." *Id.* at C-9. Furthermore, the study noted that metronomic topotecan may be particularly effective in combination with other therapeutic agents. *Id.* at C-13.

Two recent studies have done just that, combining metronomic topotecan with pazopanib. *See* Merritt WM, et al., *Bridging the gap between cytotoxic and biologic therapy with metronomic topotecan and pazopanib in ovarian cancer*, MOL. CANCER THER. 2010 Apr; 9(4): 985-95 (reprinted here

at C-17), and Hashimoto K, et al., *Potent preclinical impact of metronomic low-dose oral topotecan combined with the antiangiogenic drug pazopanib for the treatment of ovarian cancer*, MOL CANCER THER. 2010 Apr; 9(4): 996-1006 (reprinted here at C-44). This is the same drug combination Professor Richards' treating oncologist has prescribed. *See* Exhibit A at A-1.

Pazopanib is an FDA-approved oral angiogenesis inhibitor, meaning it retards the growth and spread of cancer cells. Friedlander M, et al., *A Phase II, open-label study evaluating pazopanib in patients with recurrent ovarian cancer*. J. GYNECOL ONCOL. 2010 Oct; 119(1): 32-7 (reprinted here at C-38). Current medical literature regarding ovarian cancer recognizes that "angiogenesis plays a critical role in the growth of ovarian tumors and is therefore a potentially viable therapeutic target. For example, several studies have established an inverse correlation between angiogenesis and OS [overall survival] and PFS[progression free survival] in women with advanced OC [ovarian cancer]." *Id.* (internal citations omitted).

A Phase II clinical trial published in 2010 evaluated pazopanib's effectiveness on recurrent ovarian cancer, finding the drug was "relatively well tolerated, with toxicity similar to other small-molecule, oral angiogenesis inhibitors, and demonstrated promising single-agent activity in

patients with recurrent ovarian cancer." *Id.* at C-37. Specifically, the study concluded that pazopanib is "had antitumor activity in patients with recurrent OC." *Id.* at C-41.

The 2010 studies noted above, combining pazopanib with topotecan in metronomic doses, each found this combination effective in the treatment of ovarian cancer—the exact diagnosis at issue here. *See* Merritt, *Bridging the Gap* at C-21; Hashimoto, *Potent Preclinical Impact* at C-44. In particular, the Merritt study found "pazopanib therapy effectively inhibits VEGFR-2 activity, and results in significant reduction in tumor growth in combination with metronomic topotecan." *Id.* at C-22. This study noted that metronomic therapy of combined topotecan and pazopanib actually shows superior antiangiogenic (growth-inhibiting) effects on ovarian cancer tumors compared to standard dosage treatments. *Id.* at C-24—25. "The findings in the current study provide evidence that metronomic therapy with pazopanib may provide a unique therapeutic strategy for cancer patients, offering potent antitumor activity with less treatment-delaying toxicity." *Id.* at C-25.

The Hashimoto study similarly noted "[m]etronomic oral topotecan showed excellent antitumor activity, the extent of which was significantly enhanced by concurrent pazopanib, which itself had only modest activity, with 100% survival values of the drug combination after six months of

continuous therapy." *Id.* at C-44. This study further projected that, due to the minimal toxicity of this treatment regimen, "the therapy could be maintained for half a year without any obvious toxic side effects." *Id.* at C-45.

ii. These Scientific Studies Meet the Statutory Standard for Coverage

There can be no doubt that topotecan and pazobanib are "recognized for treatment" of recurrent ovarian cancer in "published scientific studies published in any peer-reviewed national professional journal." T.C.A. § 56-7-2352(b)(2); (c)(1); *see generally* Exhibit C. Commissioner Cooper's letter of May 18, 2011, attached hereto as Exhibit B, acknowledges the existence of the medical literature provided by Professor Richards and her treating physician and in no way suggests any of these published, peer-reviewed studies fail to meet the statutory definition of "medical literature." Rather, the Commissioner characterized these studies as "preliminary" and denied Professor Richards' request for treatment on the inappropriate grounds under the statute that "this treatment is not recognized as ***a widely accepted medical regimen*** . . . ." *Id.* at B-1.[1]

[1] The Commissioner is not allowed to substitute her personal judgment or the judgment of the Acting Medical Director for the unambiguous statutory language, but in any event Professor Richards disputes the characterization of this relatively substantial body of robust and well-controlled medical studies, including multiple Phase II trials incorporating over a decade of cumulative research, as "preliminary." *See generally* Exhibit C. Though the combination of topotecan with pazopanib is a relatively new treatment development for ovarian cancer, this combination has been favorably explored in peer-reviewed scientific publications. *See* Exhibit C at C-21 *et seq.*, C-44 *et seq.* Moreover, the use of each of these drugs,

The Commissioner has clearly applied the wrong legal standard in denying Professor Richards' request. Nothing in the plain language of the statute excludes "preliminary" studies from its definition of "medical research," nor does the statute require that an off-label use be "widely accepted" so long as it is supported by scientific, peer-reviewed publications. T.C.A. § 57-7-2352(b)(2), (c)(1). In fact, it is precisely because off-label use is not necessarily "widely accepted" or "final" that the Tennessee legislature left the appropriateness of off-label uses to the sound discretion of the treating physician, so long as the proposed use is supported by at least one peer-reviewed national professional journal. *See* T.C.A. § 56-7-2352(a)(1)—(9) (articulating "the wide variety of effective uses of FDA-approved drugs for off-label uses" and the delays and expense inherent in the process of finalizing FDA approvals of additional uses).[2]

topotecan and pazopanib, in metronomic doses to treat recurrent ovarian cancer is well-documented. *See generally* Exhibit C.

[2] The legislature could certainly have included the "widely accepted" limiting language created by the Commissioner; the statute clearly limits coverage for drugs that have not received any FDA approval or that the FDA has determined are contraindicated for the proposed treatment. T.C.A. § 56-7-2352(b)(3)—(5). However, the statute contains no such limiting language regarding off-label uses of FDA-approved drugs that are supported by medical literature. On the contrary, the express policy judgments articulated in the statute suggest that off-label uses for FDA-approved prescription drugs must be covered by insurance when peer-reviewed medical literature indicates such treatment is medically appropriate. *Id.* at § 56-7-2352(a)(1)-(9).

iii. The Plain and Unambiguous Language of the Statute Requires Coverage

The plain language of the statute does not require or permit the Commissioner to create a new, discretionary standard or make judgment calls on whether the proposed treatment is "recognized as a widely accepted medical regimen." Exhibit B at B-1. Rather, the statute unequivocally states:

> ***No insurance policy . . . that provides coverage for drugs shall exclude coverage of any such drug for a particular indication*** on the ground that the drug has not been approved by the FDA for that indication, ***if the drug is recognized for treatment of the indication*** in one of the standard reference compendia or ***in the medical literature.***

T.C.A. § 56-7-2352(c)(1) (emphasis added). This is not a weighing of the scientific literature; it is simply a determination of whether or not scientific literature approving the treatment exists. *Id.*

iv. The Legislative History of the Statute Supports Professor Richards' Request

A Tennessee Attorney General's opinion further illustrates the narrow scope of the decision before the Commissioner by describing the evolution of the off-label statute's dispute resolution process in some detail. Tenn. Op. Atty. Gen. No. 03-157, 2003 WL23099757 (Tenn. A.G.), attached hereto as Exhibit G at G-6—7. At one point in the legislative process, the proposed (but never enacted) version of the statute placed enforcement in the

hands of the Commissioner of Commerce and Insurance (not the Commissioner of Health) along with a seven-member advisory panel of medical experts who were in fact tasked with subjectively evaluating whether individual off-label uses were medically appropriate based on their professional expertise. *Id.* This panel of medical experts included 3 medical oncologists, two specialists in the management of AIDS patients, one heart disease specialist, and one physician selected by the Tennessee medical association. *Id.* at G-6. It should be noted, however, that even then their advisory role was triggered only for requests for "off-label uses not included in any of the three (3) standard references or in the medical literature." *Id.*

In contrast, the statute as enacted places an objective, easily verifiable decision solely in the hands of the Commissioner of Health, without any consultation with such experts in the medical field. T.C.A. § 56-7-2352(c)(6). The reason medical experts are not needed under the statute as enacted is because the statutory language neither requires nor authorizes the Commissioner to weigh the medical efficacy or general acceptance of the proposed treatment. *Id.* at (c)(1). Instead, the statute imposes a nondiscretionary, objective standard that simply requires the Commissioner to determine whether an applicant has submitted evidence of "scientific studies published in any peer-reviewed national professional journal" in

which the requested drug is "recognized for the treatment of the indication." T.C.A. §§ 56-7-2352(b)(2), (c)(1), (c)(7). The answer to that question is "yes" or "no" and requires no consideration of whether the treatment has obtained "wide acceptance."

v. Professor Richards' Treatment Plan is Covered Under the Statute

When the language used by the legislature is clear, additional terms may not be added or implied. As the Tennessee Supreme recently stated in *Colonial Pipeline Co. v. Morgan,* 263 S.W.3d 827, 836 (Tenn. 2008):

> When a statute is clear, we apply the plain meaning without complicating the task. Our obligation is simply to enforce the written language.

Professor Richards has met the statutory burden and is entitled to coverage of these drugs. Commissioner Cooper acknowledged the existence of the medical literature required by the statute in her letter of May 18, 2011 in which she states, "While some very preliminary studies have been undertaken . . . ." *See* Exhibit B at B-1. Preliminary studies, so long as they are published in national, peer-reviewed scientific publications, satisfy the statute. T.C.A. § 56-7-2352(b)(2), (c)(1). Moreover, one of the drugs prescribed for Professor Richards' treatment, Hycamtin (topotecan), is recognized for the treatment of recurrent ovarian cancer in at least two of the

medical compendia listed by the statute. *See* Exhibit E; Exhibit F; T.C.A. § 56-7-2352(b)(3), (c)(1).

The legislature gave the Commissioner the power to address insurers' noncompliance with the mandates of the off-label statute by providing in T.C.A. § 56-7-2352(c)(7): "The commissioner of health shall have the authority to direct any person who issues an insurance policy to make payments required by this section." Because Professor Richards has demonstrated her eligibility for coverage, the statute makes it incumbent upon the Commissioner to enforce the legislative intent by directing CVS Caremark to provide coverage for Hycamtin and Votrient. *Id.* Accordingly, the Commissioner should issue an order directing coverage for Professor Richards' use of these medically necessary and appropriate treatments.

V.
CONCLUSION

The drugs prescribed for Professor Richards provide the safest and most effective treatment option in the professional opinion of her treating oncologist, a board-certified specialist in gynecological cancers who has safely and effectively treated Professor Richards through three separate recurrences of her ovarian cancer over a period of almost a decade. Insurance coverage of these drugs is necessary for Professor Richards to

receive this treatment, because the private cost of this regimen exceeds $7,000 per month and treatment is expected to continue for a period of at least six months.

Both topotecan and pazopanib are recognized by scientific journals for their efficacy in treatment of ovarian cancers. *See generally* Exhibit C. Additionally, topotecan is recognized for treatment of ovarian cancer by two of the medical compendia identified in the statute. *See* Exhibits E, F. Accordingly, the proposed off-label use of these drugs is covered by the mandate set forth in T.C.A. § 56-7-2352(c)(1).

Professor Richards respectfully submits that the administrative reviewers, both connected with the plan administrator and outside reviewers, imposed a hurdle of medical necessity that is inconsistent with both the statutory language and the clear public policy mandated by the legislature in enacting T.C.A. § 56-7-2352. In light of the medical literature and recognized medical compendia supporting the proposed treatment, the medical judgment of Professor Richards' long-term treating oncologist, and the prohibitive cost of these drugs absent coverage, the commissioner should order the plan to cover and provide these drugs.

Professor Richards requests expedited review of this petition as Dr. Reed prescribed these drugs at the beginning of April, 2011, and Professor Richards is not receiving any treatment for her cancer at this time.

Respectfully Submitted,

Janet Richards
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PETITIONER

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CERTIFICATE OF SERVICE

I, Michael Richards, do hereby certify that a true and exact copy of this petition for declaratory order has been sent via U.S. Mail, Federal Express, and e-mail, postage pre-paid, to Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, Cordell Hull Building, 425 5th Avenue N., Nashville, Tennessee 37243, this the 6th day of June, 2011.

Michael Richards

MEMORANDUM

TO: Mark Cherpack
Mary Kennedy
Tony Greer

FROM: Mike Richards
Jamie Whitney

DATE: June 21, 2011

RE: Janet Richards' Request for Off-Label Coverage of Hycamtin and Votrient

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We understand the Tennessee Department of Finance and Administration (TDFA) has some concern regarding whether the group insurance program for state employees falls within the mandate of T.C.A. § 56-7-2352 regarding coverage of off-label drugs. Based on the legislative history of the statute, attached hereto in relevant part, we believe the state employee plan is clearly covered by the statute.

The off-label coverage statute was passed in 1997 by an overwhelming majority in both houses of the Tennessee legislature. The bill originated in the Senate under the sponsorship of Senator Cooper. See Exhibit A, Senate Session Tape # s—32, 4/2/1997, 3:00 p.m., Log Page #2, Recorder KL. The House unanimously enacted the bill as passed by the Senate. Exhibit B, House Session Tape # H-61, 5/7/1997, 2:05 pm, Log Page #1, Recorder Guillaum.

As initially drafted, the bill carried a fiscal note predicated in part on its expected impact on TennCare coverage. See Exhibit C at pp. 2—3, Senate Commerce Committee Tape #1 (at 1524), 3/25/1997, 1:38 p.m., Log Page #2, Recorder Yates. However, the legislature determined that it was not necessary to include TennCare in the reach of the statute, in large part because TennCare is already required to provide off-label coverage of prescription drugs under the rules governing Medicaid. *Id.*

The purpose of the Tennessee off-label statute is actually to bring state-regulated insurance programs in line with the rules governing off-label coverage under federal law. *Id.* at 1. Since TennCare is already governed by these federal rules, there is no need for it to be included in the Tennessee statute. *Id.* at 3. As Representative Jackson explained in the floor debate in the House Commerce Committee,

> There's an amendment which does remove, effectively removes TennCare from the effect of this bill and the reason that I'm willing to do that is TennCare is already paying for off-label drug use, so what this bill will do is provide for the rest of Tennessee what TennCare and Medicare is already providing to the other population of the state of Tennessee.

Exhibit D at 2, House Commerce Committee Tape #1 (at 260), 4/8/1997, 9:02 a.m., Log Page #1, Recorder Guillaum

In contrast, the state employee benefit plan is not subject to federal rules regarding off-label coverage, either under Medicaid or ERISA. Thus, the effect of applying the Section (a)(9) exemption for "a governmentally funded health care program, if the program requires the provision of medically necessary services" to the state employee benefit plan would be to make the state employee benefit plan the only insurance program in the state of Tennessee that is ***not*** required to provide off-label coverage of prescription drugs when the proposed treatment is supported in the medical literature.

Nothing in the plain language of the statute or its legislative history supports this anomalous result. On the contrary, the statute itself states that "equity among employers who obtain insurance coverage for their employees and fair competition among insurance companies require that insurance companies assure citizens reimbursement for drugs in the same way and in the way citizens expect." T.C.A. § 56-7-2352(a)(5). It would be strange to argue that all employers *except* the state are subject to this rule of equity.

The language of the exception at issue, T.C.A. § 56-7-2352(a)(9), lends little support to this unfair and unintended result. Section (a)(9) does not exempt all insurance plans receiving any state funding. Rather, it exempts only a narrow category of state funded insurance plans: those plans that are "governmentally funded health care programs, if the program requires the provision of medically necessary services." *Id.* This language describes TennCare—a completely state-funded medical welfare program whose provision of minimum levels of health care is required by federal law. This language does not fairly encompass the state employee benefit plan, which is a state-subsidized, premium-driven general employee benefit program whose coverage levels are entirely within the discretion of the state insurance committee from year to year.

Given the statute's stated purpose of promoting equitable coverage across the board, it is difficult to argue that the state employee benefit plan is the beneficiary of a tacit amendment excluding it and only it from any obligation to fund off-label coverage. This argument becomes even more unsupportable in light of the recorded floor debates in the Senate Commerce Committee, the House Commerce Committee, the Senate, and the House all stating that the purpose of the language now codified at section (a)(9) is to exempt TennCare, specifically, from the reach of the statute.

We believe it is in the interest of the parties to mediate this dispute. Professor Richards is more than willing to withdraw her petition under T.C.A. § 56-7-2352 if the state employee benefits plan will reconsider her medical records and make a finding that, based on Professor Richards' unique medical history and the advice of her long-time treating physician, the prescription of Votrient and Pazopanib is medically necessary and therefore covered in her specific case.

WMR/JRW

EXHIBIT A

Senate Session Tape # s-32

4-2-1997 Recorder KL

3:00 pm Log Page #2

Clerk: Senate Bill number 834 by Senator Cooper [audio interference] insurance coverage for drugs.

Lt. Gov. John S. Wilder: Senator Cooper

Senator Cooper: Mr. Speaker, members of the senate, right now certain insurance companies do not authorize reimbursement of FDA approved off label drugs for life-threatening diseases such as cancer and what this bill does is eliminate that problem and I move passage in order to call up the amendments.

Wilder: So moved and seconded. Amendment number one.

Clerk: Amendment number one by Senator Rochelle filed timely.

Wilder: Senator Rochelle withdraws amendment number one without objection. There is no objection. Amendment number two.

Clerk: Amendment number two, Commerce Committee Amendment.

Wilder: Senator Cooper

Cooper: Well I'm confused now. How many amendments have you got up there?

Clerk: Four.

Cooper: Huh?

Clerk: Four.

Cooper: Okay, I thought the first amendment exempted, Senator Rochelle, TennCare that we discussed in the Commerce Committee.

Wilder: Senator Rochelle

Rochelle: No, that's number two.

Wilder: Senator Cooper

Cooper: Amendment number two exempts TennCare from the provisions of this act and I move adoption.

Wilder: So moved. Seconded. Those in favor. Senator Womack.

Womack: Why should we exempt TennCare? What is in the best interest of people everywhere else that isn't in their good interest in TennCare?

Wilder: Senator Cooper.

Cooper: Well, Senator Womack needless to say I had a problem with the administration on this bill and some of the insurance companies. I don't disagree with what you're saying. At the same time HCFA already uses off label drugs itself. In order for me to pass this bill, I made a commitment to the administration that I would exempt TennCare for whatever reason. That's the truth.

Wilder: Number two. Those favoring two, say Aye. Opposed, no. You adopt. Number three.

. . ..

EXHIBIT B

House Session Tape # H-61

5-7-1997 Recorder Guillaum

2:05 pm Log Page #1

Clerk: House bill 772 by Representative Jackson and others. An act to amend TCA Title 56 relative to insurance coverage for drugs including life threatening illnesses such as cancer, aids, and coronary heart disease. The senate bill is on the desk.

Speaker Naifeh: Representative, Chairman Jones, for what purpose.

Jones: Mr. Chairman, two things. Mr. Speaker, two things. I'd like to recognize a constituent of mine from North Memphis, that brought our precious cargo down, Ms. Anita Owens, who's up in the balcony. If you'd make her welcome. And also Mr. Speaker see if we can come from under the rules.

Naifeh: I've been requested by the bipartisan leadership that we stay under the rules. Representative Jackson.

Jackson: I think Mr. Speaker, members of the house, I would move to substitute and conform to the senate bill.

Naifeh: Without objection. You're recognized.

Jackson: Thank you Mr. Speaker and members of the house. This is what I consider to be a very, very important bill in the fight against aids and cancer and other life-threatening diseases. What this bill will do will require that there be insurance coverage for off label drug use. This is a very, very important piece of legislation. It will be of tremendous benefit to research facilities such as St. Jude's Children's Research Hospital and others throughout the state of Tennessee. Mr. Speaker, I take great pride in being a sponsor of this legislation and it's my sense of the membership, having talked with many, that they, too, appreciate this legislation and if it's not out of order, I would respectfully request, if there's not objection, that those who vote in the affirmative on this bill be listed as co-prime sponsor.

Naifeh: There's a sign-up sheet that will be available on the desk by Representative Jackson as he is. . . In discussion again with the leadership, Representative McDaniel, Representative Hargrove, and Representative Stamps and Representative Brinks and Speaker Pro Tem DeBerry, we felt that when we do that on a bill that it may put someone in a situation where they may want to vote for a bill but they may not want to be the sponsor of it. We do it on resolutions and this came up early in the session and we are just requesting that we do that on

resolutions but we'll have a sign-up sheet right up here for anyone who wants to sign on to this bill. Thank you for your indulgence. Representative Jackson.

Jackson: Thank you Mr. Speaker, members of the house. Again, 772 I think is certainly a non-controversial piece of legislation that most of your constituents will like, if not all, and to allow time for members to think about that as to whether they wish to co-sponsor that legislation, I would respectfully request that senate bill 834 be moved one space.

Naifeh: Without objection. Call up the next bill.

[discussion of HB768]

Clerk: Mr. Speaker the house is back on page 3, page 3, the last item, the house is ready for further consideration of senate bill 834 by Representative Jackson.

Naifeh: Representative Jackson.

Jackson: Thank you Mr. Speaker. I would move, renew my motion on passage of senate bill 834.

Naifeh: Gentleman renews his motion, properly seconded. Mr. Clerk, call up the first amendment.

Clerk: House Commerce Committee amendment number one. It is spread on the members' desk and is the same as senate amendment number two.

Naifeh: Chairman Reinhart.

Reinhart: Move to withdraw.

Naifeh: Without objection. Withdrawn.

Clerk: House Commerce Committee amendment number two. It is spread on the members' desk and is the same as senate amendment number three.

Naifeh: Chairman Reinhart.

Reinhart: Move to withdraw.

Naifeh: Without objection. Withdrawn.

Clerk: No further amendments.

Naifeh: Representative Jackson.

Jackson: Renew my motion, Mr. Speaker.

Naifeh: Gentleman renews his motion. Seconded. Discussion. Is there objection to the question? Seeing none, all those in favor vote aye when the bell rings, those opposed will vote no. Let every member cast their vote. Every member voted. Representative Jackson votes aye. Any member wish to change their vote? Mr. Clerk, take the vote.

Clerk: Ayes, 97, nos, none.

Naifeh: Senate bill 834 having received a constitutional majority, I hereby declare it passed.

EXHIBIT C

Senate Tape # 1 (at 1524)

Commerce Committee

3-25-1997 Recorder Yates

1:38 pm Log Page #2

Cooper: Senator Koella recognizes me on Senate bill 834. Members of the committee, what this does is try to establish a procedure relative to the, to insurance coverage on life threatening diseases and what I'd request is for us to stand in recess for five minutes to listen to Dr. Charles Pendley and without objection, we're in recess and Dr. Pendley if you'd come forward and explain the bill and the reasons why we need to consider this bill. So ladies and gentlemen, if you'd listen to Dr. Pendley.

Dr.Pendley: Thank you for having me. Basically, this piece of legislation is designed to include the non Medicare, Medicaid population under the rules and regulations that control the off label, the approval of off label use of pharmaceuticals in those patients. You probably are aware that there's an on label indication that a pharmaceutical agent may receive when it's approved by the Food and Drug Administration. Once a drug is approved by the FDA, many times additional uses are discovered through continuing clinical research and those uses are brought into general practice, those are considered off label uses. The pharmaceutical industry does not usually go back to the FDA and seek FDA labeling approval for those uses because of the extreme expense that's involved and the time that's involved. And for many years this practice has continued and it's the standard of care. The problem is today, that in an attempt to ratchet down the cost of health care, some third party payers and MCO's have used off label, the off label indication, or the off label parlance to deny coverage for a particular chemotherapeutic agent in the treatment of a cancer in which there's available science that says it's sound practice and it's the standard of care. And as I've said, the HCFA rules control this, the HCFA rules make it mandatory to cover these uses, and what we're hoping to do is to make a uniform policy across the board, whether it be a Medicare recipient or a privately insured patient.

Cooper: So essentially we're dealing with, doctor, with life threatening diseases such as cancer and . .

Dr. Pendley: Yes, cancer, and the bill concerns itself primarily with cancer, aids, and cardiac disease.

Cooper: Right. Has anybody got any questions for this gentleman?

Dr. Pendley: I might add one thing. It slipped my mind and it's that this bill also will help children who are being treated for cancer. Most of these drugs, the research is done on adult populations, so when FDA approves these drugs, they're not giving tacit, or explicit approval for use in the pediatric population. Obviously, there's a large population in our state at St. Jude's and at Vanderbilt's Children Hospital in which the treatments are almost entirely off label and this will really help their cause considerably.

Cooper: Any questions? Sir, we appreciate your being here and we appreciate your having the bill before us. We're back in order. There's a motion and second on the bill. Any discussion on the bill? I need to say this for the record, the administration is concerned about the caption of the bill, which I can understand. It opens, I think, the entire title 56 and, for the record, I would like to state that no other issues, other amendments that could be put on the senate floor regarding the patient advocacy bill, favored nations, since I'm the sponsor of the bill, those types of amendments will not be placed on this bill. So I think the administration wanted that statement made for the record. Amendment number one takes TennCare, right now there's a fiscal note on the bill, in fact, I've got two fiscal notes. The first fiscal note addresses the fact that TennCare right now is included in the bill and amendment number one essentially takes out TennCare. Is that correct? So, amendment number one's been moved and seconded. Any discussion on amendment number one? If not, all those in favor of amendment number one say aye, all those opposed say no. Amendment number one is adopted. I think I've covered everything. So we're back on the bill as amended. Senator Rochelle.

Rochelle: Did you get a fiscal note with the amendment as to what it was? Otherwise, I think we're going to have to send it to finance.

Cooper: Well, that's what I was getting to with you, Senator Rochelle. I've got a revised fiscal note now and it says it still exceeds $100,000 and that's due to, it says it could have an impact or can have an impact on the health insurance industry and as required by 3-2-111. So we've taken care of the TennCare situation, so my question to you is going to be, do we need to send it to Finance Ways and Means now, has it got to go behind the budget, and I'm just, I'm not knowledgeable where these go now.

Rochelle: You got a revised fiscal note?

Cooper: Yes sir, and the only part. . . Could you pass this down to Senator Rochelle? I need a rules expert here. There's a section of the code, apparently, that says anything that has to do with impact on the health insurance industry, now remember TennCare, we've taken out TennCare. That section of the code is 3-2-111, and we've got a fiscal note that doesn't impact state government but it impacts, could impact the health care industry, so I don't know.

Rochelle: I think the rules only apply to state government and local governments, increases or decreases, revenues, expenditures, whatever, so this just says health insurance industry, so I don't, I wouldn't think it had to go to Finance.

Cooper: I think after we. . . wait a minute. Yeah, I need another amendment, Senator Rochelle. There in the bill itself, there was a seven board panel, member board set up and what amendment number two does is just changes all that just to the commissioner of health. It takes out that part of cost that could be to state government. So amendment number two has been moved and seconded. Any discussion on number two? If not, all those in favor of amendment number two say aye. All those opposed say no. So amendment number two is adopted. So we're back to the question of 3-2-111, Senator Rochelle, if everybody's in agreement, is saying, that Senator Koella, or the chairman, is saying that it does not have to go to Finance Ways and Means. Unless there's objection, the motion will be made to move it to the calendar committee. Senator Dixon.

Dixon: I want to be clear before we do the final vote. You give me the impression now that TennCare is okay with the bill now. I want to make sure that TennCare has no objections.

Cooper: TennCare is taken out by amendment number one. I'm getting a headshake in the affirmative.

Dixon: So patients of TennCare will not be allowed to use this drug on an off label situation. Is that correct?

Cooper: Let's stand in recess for just one minute. Doctor, you want to come back forward? To the podium, yes sir.

Dr. Pendley: As it stands currently, HFCA rules and regulations govern the Medicare population. These policies are in place in the HFCA rules and I'm not a legal expert, but my understanding is that because HFCA has mandated that Medicaid follow their lead on these things, then the TennCare thing is already in place. Essentially, they are required to follow these same rules because they come under some governance of the HFCA administration now. But in reality this is not an issue with TennCare right now. The off label coverage exists with TennCare patients as it exists for Medicare patients.

Dixon: Well maybe Mrs. Ginger would probably be more appropriate to answer the question. My . . . Ginger, what's your last name? But my concern . . .

Cooper: Please come to the podium and state your name and position.

Pera: I'm Ginger Pera. I'm legislative liaison for the Bureau of TennCare. It is my understanding that TennCare enrollees are currently covered through our medically necessary provisions. That is, if the drugs are medically necessary they can be used.

Dixon: And yet it has no fiscal impact.

Pera: That would mean. . . We're currently covered by medically necessary so it would not change our fiscal.

Cooper: I think what, and I'm not interrupting Senator Dixon, but I think the procedure is if a doctor right now finds or a provider finds that one of these, some of this medicine might be helpful then they contact TennCare and TennCare has to approve it right now. That's what's going on right now. Is that correct?

Pera: That's correct. And we have a grievance process to grieve that decision.

Cooper: And we're not changing any of that.

Dixon: So you don't expect any higher utilization? But, as I understand it, basically, FDA may have approved or may approve a drug that can be used to cure some illness at some point in time then also TennCare would have access to it.

Pera: It could appear on our formulary.

Dixon: Okay, the only thing I just can't understand, and maybe later you can explain, is how that doesn't have a fiscal impact.

Cooper: Senator Rochelle.

Rochelle: I'd like to hear from Dr. Dr. Giles with Blue Cross. I want to ask a question of him if I could.

Cooper: Dr. Dr. Giles is recognized. State your name and your position.

Dr. Dr. Giles: I'm Dr. Robert Dr. Giles, Jr. I'm the corporate pharmacist for BlueCross and Blue Shield of Tennessee.

Rochelle: Dr. Dr. Giles, as I understand it, this doesn't mandate that those drugs be allowed. It creates a presumption that if they're recognized in some publications out there as valid for use for some illness other than that for which it was FDA approved. It creates a presumption that the insurance company or the insurer, HMO, whoever, would pay for it. You could still object. The insurer could still object and it'd go to the commissioner of commerce, I guess, and he would decide who was right. But it really switches the burden, does it not, from the doctor who's doing the prescribing to the insurer, as to whether this type of use would be allowed for the drug.

Dr. Giles: All right.

Rochelle: Tell me about it.

Dr. Giles: Okay, Senator. We currently, and I speak only for Blue Cross and not the insurance industry as a whole in Tennessee, but currently we follow similar guidelines as outlined in OBRA 90, that is, that the drug has to be approved by the FDA and appear in three national compendium. It also, we request that it appear in some broad based studies in peer reviewed journals. And under this, this eliminates the possibility of it being just done experimental or that perhaps a physician orders the drug just on a whim. And it does, we are following those basic guidelines both for the TennCare business as well as for our commercial business as well. And I think right now the system works very well without either being mandated or by having the commissioner of insurance involved with this at this time.

Rochelle: All right. I'm dealing in two areas. One is the burden of showing who has to show something. The bill right now lists where it's got to be published and such as that. This is only for uses that were not approved by FDA but there's some recognition in the medical community, research community that this is valid for another purpose. Does the bill, is it strong enough as to where it should be published, the particular things, publications it should be published in and such?

Dr. Giles: I think the three compendia that are listed in the bill are nationally recognized compendia, which give a fairly unbiased approach to the drug and that basically legitimizes the drug and tells us that that has, that is a drug that has been FDA approved in most cases, some are pending. And so it does tell us all about the drug. It gives some legitimacy to that drug and that's the first part.

Rochelle: So, whether you agree with the premise or not, the language of the bill as to where it should be published and all that, that's satisfactory.

Dr. Giles: That's correct, sir.

Rochelle: Okay, the second area is, you've got a commercial business that you do with state, with local governments.

Dr. Giles: That's correct.

Rochelle: The fiscal note, why, I don't know. I've never seen this one before, where they say it exceeds a hundred thousand to the health insured's industry. I don't know how much by. I don't know by what amount it exceeds a hundred thousand. The impression that I have is that it does, it shifts some of the bureaucratic things, the obligation to get together and keep up with the data from the doctor or provider to the insurer. Who might be better able to do it. Tell me, do you foresee any more than a negligible increase at the local governments as a result of the bill?

Dr. Giles: No sir, I anticipate that there will be some significant increase, simply because of the expense of a lot of these cancer drugs. It's nothing to have five or ten thousand dollars worth of drugs for one patient in a course of treatment. And certainly on our commercial side of the business, which covers a large number of metropolitan governments in this state, and I do anticipate it will be a significant increase.

Rochelle: Well right now, if it's been published in any of those other things, Blue Cross, for y'all's part, you'd approve its use.

Dr. Giles: If it shows up in the compendia and if it has been proven to be effective in peer reviewed national journals.

Rochelle: Does the bill not include the peer reviewed national journals?

Dr. Giles: It does. Yes sir.

Rochelle: Okay, so right now, for your company and every company would be different, but for your company, there wouldn't be any, I don't see, would there be a difference? Because you're approving it now for those expensive cancer patients, if it meets these requirements.

Dr. Giles: If it meets the criteria.

Rochelle: All right, then what the bill says is that if it meets that same criteria, I think, then you must approve it, or the presumption is, is that you have to.

Dr. Giles: Well, there's a third element is there's also roles for the commissioner of insurance to also approve and that's an element we don't have right now, so it's certainly possible that the drug could not appear in one of the broad based journals or whatever and the commissioner of insurance could then mandate the coverage and that's what I have a little trouble with.

Rochelle: Well, I don't think anybody's suggesting we should have the commissioner mandate coverage unless it meets those other requirements.

Dr. Giles: The way the bill was written, he would have an advisory board which would look at those drugs which do not meet that, those first two criteria.

Rochelle: Well, I think they eliminated the advisory board didn't you Senator Cooper because of the cost?

Cooper: If that amendment passes.

Rochelle: I don't believe it's anybody's intent to tell the commissioner of commerce that he can approve any of these, whataya call em, off label drugs unless they've met those requirements that are professional type requirements. I don't believe Senator Cooper desires that, do you Senator Cooper?

Cooper: No sir.

Rochelle: All right. If we change that portion where you knocked out the commissioner of insurance and you just kept those same specs that you're using now, would you still foresee any appreciable increase in your company, as to your company?

Dr. Giles: I doubt for my company we would see an appreciable increase.

Rochelle: How about other companies of which you have knowledge?

Dr. Giles: I would say there would be a possibility with other companies who perhaps don't cover off label drugs at this time to do that. But they do come under the OBRA 90 law, so I'm just not aware of any other companies that don't cover these.

Rochelle: Okay, can I ask the doctor, then, if we're finished here, can I ask the doctor on the

Cooper: Sure, Senator Rochelle. If there's no objection, we'll hear from Dr. Pendley again.

Rochelle: Doctor, of course my question is, it's been interpreted by some that the bill could provide for the commerce commissioner to approve something that has not been through these professional publications and testing and such. Was that your intent?

Dr. Pendley: No. The intent was basically to ensure that claims are not denied purely on the basis of the off label use of a pharmaceutical agent being the main crux of the claim's approval or denial. I think the difference that we may have in our interpretation of this, and I'm hoping that I'm clear on this, is that as it exists today, the final word on whether a claim is actually approved or denied, outside the setting of a lawsuit or some other endeavor, the final word today is with the medical director of the particular third party payer. And what this bill hoped to do was to take that, or to perhaps put that in another context, so that other experts in the field would have an opportunity to impact the decision making when we're talking about.. .

Rochelle: Okay, but my question is, is that it is not your desire for a drug to be used for off label illnesses by the commissioner, not to be approved by the commissioner unless it meets those requirements.

Dr. Pendley: Absolutely. We're not talking about out of mainstream medicine here. We're talking about peer reviewed literature. We're talking about standard published reference materials. We're talking about mainstream medicine.

Rochelle: All right. That's all the questions I've got, Mr. Chairman.

Cooper: I think, okay we're back in order. Senator Rochelle.

Rochelle: I don't know the bill well enough to come up with the exacting language but I would think, and the sponsor may want to do it, is to state that we're not authorizing, the bill is not authorizing the commissioner to approve off label uses or drugs for off label uses unless that has been published in these periodicals, and done the field testing, the things set out in the bill, the professional qualifications set out in the bill. Maybe Sally has something for me on that. [discussion away from mike] Well, evidently, the problem is created when you take out that review panel

[meeting continued on a second tape]

Senate Tape # 2 (at 0 -152)

Commerce Committee

3-25-1997 Recorder Yates

2:36 pm Log Page #1

Rochelle: Well, evidently, the problem is created when you take out that review panel that you had. That's was the language, evidently, where that issue was resolved and since you took that language out it opens it back up again as to whether they have, whether it's possible for the commissioner to approve something that has not gone though that process required by the bill. I don't know how to fix it, but I'd suggest you want to.

Cooper: Okay, if I could, Senator Rochelle, if it's agreeable to the members of the committee to move it out of this committee and let me get with Sally between now and before it goes to the floor and come up with some language to address the issue and I'll bring it to you and let you look at that language before the bill's presented on the senate floor. Is that agreeable? Okay. Any objection? Further discussion on the bill? If not, madam secretary call the roll.

Roll call

Cooper: Nine ayes. The bill will be referred to the calendar committee.

EXHIBIT D

House Tape # 1 (at 260, or 12 minutes)

Commerce Committee

4-8-1997 Recorder Guillaum

9:02 am Log Page #1

Chairman: Mr. Jackson, you're recognized on . . .

Jackson: Thank you, Mr. Chairman, members of the committee. . .

Chairman: 772. May I interrupt just before you get started.

Jackson: Yes sir.

Chairman: There is a flag on this bill.

Jackson: Yes sir.

Chairman: But the flag can be removed if you tell you're not going to try to expand the coverage of TennCare above what this does.

Jackson: Yes sir, Mr. Chairman. There's an amendment which does remove, effectively removes TennCare from the effect of this bill and the reason that I'm willing to do that is TennCare is already paying for off-label drug use, so what this bill will do is provide for the rest of Tennessee what TennCare and Medicare is already providing to the other population of the state of Tennessee.

Chairman: All right, so you don't intend to broaden Medicaid, TennCare with this amendment?

Jackson: No, Mr. Chairman.

Chairman: Okay. All right, you're recognized.

Jackson: Thank you Mr. Chairman. House bill 772 is really a very, very important bill. This deals with FDA approved drugs that through the usage of medicine and through experiences of physicians we discover that there are other uses for FDA approved drugs other than what the drug was originally certified for. This is particularly done in a lot of the research treatments like cancer. This is a bill that directly addresses some of the needs of St. Jude's Children Research Hospital here in the state of Tennessee. It's an important bill that will allow physicians, research centers, and hospitals to use FDA approved drugs for off-label purposes. That's what the bill does and I'd appreciate a motion.

Chairman: We have a motion. Second. We need to adopt the amendment. Have a motion on the amendment. We have a motion by the insurance companies to adopt the amendment. Do we have a second? Discussion. All in favor will say aye on the amendment, opposed, no. The ayes have it. We're back on the bill as amended.

B

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6th Circ.'s Narrow Path For Plaintiffs Under Twombly

Law360, New York (August 10, 2011) -- In 2007, the United States Supreme Court decided Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed. 2nd 929. The court analyzed Federal Rule of Civil Procedure 8(a)(2) in conjunction with Federal Rule of Civil Procedure 12(b)(6) to decide whether or not a complaint for violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, should survive a motion to dismiss.

The complaint at issue described parallel conduct of competitors but failed to allege an agreement between competitors. The court held that, notwithstanding Rule 8's simple "notice pleading" requirement, a complaint must allege sufficient facts, taken as true for Rule 12(b)(6) purposes, to state "plausible grounds" to determine that an agreement exists to violate Section 1 of the Sherman Act.

Twombly represents a significant departure from the long-standing rule set out in Conley v. Gibson, 355 U.S. 41, 78 S.Ct. 99, 2 L.Ed. 80 (1957), that a complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt that the plaintiff can prove "no set of facts" in support of his claim which would entitle him to relief.

In 2009, the United States Supreme Court further developed the new 12(b)(6) standard in Ashcroft v. Iqbal, 129 S.Ct. 1937, 173 L.Ed. 2nd 868 (2009). The Iqbal decision clarified that the Twombly standard is not limited to the antitrust context but is applicable to all federal civil complaints. Id. at 555—56.

Additionally, Iqbal greatly magnified Twombly by holding the underlying rule that a court must accept a complaint's allegations as true is inapplicable to "threadbare recitals of a cause of action's elements, supported by mere conclusory statements." Id. at 555. Importantly, the court further held that where a complaint is deficient under Federal Rule of Civil Procedure 8, the plaintiff is not entitled to take discovery when faced with a Rule 12(b)(6) motion to dismiss.

Together, Iqbal and Twombly have created as many questions as they have answered. In the four years since Twombly changed the 12(b)(6) landscape, courts in the Sixth Circuit and throughout the country have struggled to determine exactly how specific and how credible the factual allegations of a complaint must be in order to establish "plausibility" without vitiating the notice pleading standard of Rule 8.

The Sixth Circuit Court of Appeals recently decided two antitrust cases, one a Robinson-Patman Act price-discrimination case, and the other a Section 1 Sherman Act case, applying Twombly and its progeny. Together, these recent cases shed light on what is necessary to tip a complaint over the line from "conclusory" to "plausible" in the Sixth Circuit.

In New Albany Tractor Inc. v. Louisville Tractor Inc., (6th Cir., June 21, 2011), the Sixth Circuit affirmed the dismissal of a complaint pursuant to Rule 12(b)(6) for violation of the Robinson-Patman Act applying and construing both Twombly and Iqbal. The plaintiff is a retailer of mowing equipment in the Louisville, Ky., geographic market who sued the manufacturer and the exclusive distributor, who was also a competing retailer, for the product in the Louisville area.

The plaintiff's theory of violation of the Robinson-Patman Act was that the exclusive distributorship arrangement was a "dummy" or "strawman" arrangement created to insulate the manufacturer from Robinson-Patman liability, and that the manufacturer, in fact, controlled the pricing by the

exclusive distributor, thus satisfying the requirement that the discriminatory sales by the manufacturer be to two different purchasers, the plaintiff and the competing exclusive distributor/retailer.

The district court concluded that the complaint did not allege sufficient facts as to pricing to indicate that the manufacturer "set or controlled the [distributor's] resale price." The court discussed the "plausibility" pleading standard imposed by Twombly that requires a plaintiff to plead enough factual detail to state a claim that is plausible on its face in order to defeat a motion to dismiss, and which prohibits the court from accepting conclusory legal allegations which do not include specific facts necessary to establish a cause of action.

The court acknowledged that evidence of discriminatory pricing, which would be required under the Robinson-Patman Act, would be solely within the knowledge of the parties to the exclusive distributorship arrangement. Nevertheless, applying Iqbal, the court affirmed the trial court's holding that the plaintiff must allege specific facts of price discrimination even if those facts are only within the "head or hands" of the defendants, and is foreclosed from using discovery to obtain these facts after filing in this suit based upon the holding in Iqbal that the plaintiff was "not entitled to discovery."

The court analyzed the indirect purchaser document under the Robinson-Patman Act, and held that the allegation in the complaint (i.e., that the manufacturer refused to allow purchasers in the exclusive sales area to purchase from any distributor other than the exclusive distributor for the territory) was insufficient, since it failed to show control by the manufacturer over the distributor and exclusive distributorships alone do not violate the Robinson-Patman Act or any other antitrust provision. Thus, the complaint was deficient on both the factual allegations regarding specific discriminatory pricing and control by the manufacturer of the distributor's selling price of the product to downstream customers, including the plaintiff.

In Watson Carpet & Floor Covering Inc. v. Mohawk Industries Inc., (6th Cir., June 22, 2011), the Sixth Circuit Court of Appeals reached the opposite result from that which it held in New Albany Tractor and reversed the dismissal of a Sherman Act complaint for failure to state a claim for relief.

The plaintiff, a seller of carpets to home builders, sued the defendant supplier alleging that it and another supplier dominated 95 percent of the geographic market. The complaint alleged that the defendant supplier, wielding substantial market power, refused to sell to the plaintiff, and that other defendants/competitors maliciously made false accusations about the plaintiff to the plaintiff's existing and potential customers.

The suit is procedurally complicated by the fact that the plaintiff had sued the supplier and other defendants in a state court lawsuit and had settled with the defendants other than the supplier. The present suit was based upon a subsequent refusal to deal after the settlement.

The plaintiff obtained a judgment in the state court action against the nonsettling defendant supplier, which was then vacated by the Court of Appeals. The plaintiff filed suit in the district court alleging violations of Section 1 of the Sherman Act based upon refusals to sell in 2005 and 2006 prior to the settlement, and in 2007 subsequent to the settlement.

The complaint alleged that the defendants engaged in a conspiracy to drive the plaintiff out of business and it contained specific factual allegations about defamatory statements allegedly made by defendants to customers and potential customers in furtherance of the conspiracy. It also contained allegations that one of the conspirator-competitors instructed its sales people to "low ball" price quotes to keep the plaintiff from obtaining the business.

The court granted one of the defendants' motions to dismiss or for a judgment on the pleadings as to the pre-settlement refusals to sell, but held that the refusal to sell subsequent to the settlement was not barred by the four-year statute of limitations, but it granted the motion to dismiss on the grounds that the plaintiff had failed to provide specific facts supporting its conclusory allegation that the defendants took actionable steps in furtherance of the pre-settlement conspiracy.

The Sixth Circuit reversed the dismissal for failure to state a claim and concluded that the complaint alleged that the pre- and post-settlement refusals to sell by the supplier plausibly stemmed from the original conspiracy. The court cited criminal cases holding that once a conspiracy has been established, it is presumed to continue until there is an affirmative showing that it has been abandoned, and concluded that this doctrine was equally sensible in the civil context.

The district court had concluded that the plaintiff's allegations of refusal to sell pursuant to a conspiracy were inadequate because the history of acrimonious state court litigation offered a nonviolative alternative explanation for the defendant's refusal to sell. The Sixth Circuit, however, quoting from Twombly, held that the pleadings must be plausible, not probable. The court reviewed a series of cases establishing that it is not uncommon, and therefore not implausible, for antitrust conspiracies to last for many years.

Read together, New Albany Tractor and Watson Carpet suggest that in order to survive a motion to dismiss post-Iqbal, a plaintiff must gather specific facts in support of his claim for relief but need not necessarily gather facts sufficient to rule out or rebut defenses to his claim. The deciding factor was that in the first case, New Albany Tractor, the complaint was factually deficient on the requisite elements of a Robinson-Patman Act violation and discovery was forbidden by Iqbal.

In the second case, the complaint stated specific factual allegations that the refusal to sell was in furtherance of a conspiracy in violation of Section 1 of the Sherman Act. Despite the defendants' proffered lawful explanation for their conduct, the plaintiff's specific allegations stated a "plausible" claim for relief and therefore survived the new, heightened standard under Rule 12(b)(6).

--By Michael Richards, Baker Donelson Bearman Caldwell & Berkowitz PC

Michael Richards is a shareholder in the Memphis, Tenn., office of Baker Donelson.

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IN THE SUPREME COURT OF TENNESSEE

STEVEN AMODEO, D.C., MICHAEL BAST, D.C., GLENN R. BURFORD, D.C., WILLIAM J. CROMER, D.C. DWAYNE CURLE, D.C., CRAIG GANGWISH, D.C., TOM GILL, D.C., DAVID C. HALL, II, D.C., MICHAEL C. HOLLIMAN, D.C., BEN KEMKER, D.C., AND ROCK WOOSTER, D.C., Individually and as Class Representatives,	)	
Plaintiffs/Appellants,	)	
vs.	)	No.: W2007-02610-SC-R11-CV
CONSERVCARE, LLC, RICHARD L. COLE, D.C., DON E. COLE, D.C., TERRY J. HANSON, D.C.*, HEALTH CHOICE, LLC*, ABC THIRD PARTY ADMINISTRATOR(S) and JOHN DOE INSURANCE CARRIER(S),	)	
Defendants/*Appellees.	)	

ANSWER OF DEFENDANT/APPELLEE HEALTH CHOICE, LLC TO PLAINTIFFS/APPELLANTS' RULE 11 APPLICATION

MICHAEL RICHARDS, ESQ.
(Tennessee Bar No. 7973)

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STATEMENT OF ISSUES PRESENTED FOR REVIEW

I. WHETHER THE APPELLATE COURT CORRECTLY AFFIRMED THE TRIAL COURT'S GRANT OF SUMMARY JUDGMENT BASED UPON THE APPLICABLE STATUTES OF LIMITATIONS.

II. WHETHER PLAINTIFFS/APPELLANTS' EXCLUSION FROM DEFENDANT/APPELLEE HEALTH CHOICE, LLC'S MANAGED CARE PLAN WAS LAWFUL AND EXPRESSLY AUTHORIZED BY TENN. CODE ANN. § 56-32-229(A).

III. WHETHER THE COURT OF APPEALS PROPERLY HELD THAT THE TENNESSEE TRADE PRACTICES ACT (T.C.A. § 47-25-101 AND 102) DOES NOT APPLY TO CHIROPRACTORS WHO DIAGNOSE AND TREAT BY MANIPULATION MISALIGNMENTS OF THE SPINE ON THE BASIS THAT THESE SERVICES ARE NOT "GOODS AND ARTICLES" TO WHICH THE TENNESSEE TRADE PRACTICES ACT IS APPLICABLE.

STATEMENT OF THE CASE

Defendant/Appellee Health Choice, LLC ("Health Choice") is a non-profit entity owned equally by Methodist Health Systems and Metro Care Physicians, Inc., a Methodist Hospital based group of physicians (Vol. 12, R14-15). Health Choice is a third-party administrator of managed healthcare plans and contracts with employers, insurance companies, other third-party providers, and other health networks to provide health care treatment by providers affiliated with Methodist Health Systems (Vol. 12, R17-20).

Credentialing of medical doctors for the physician panel members of the managed care plan offered by Health Choice is performed by Metro Care Physicians, Inc. Health Choice did not fully understand chiropractic treatment or credentialing of chiropractors and decided to delegate this function to Defendant ConservCare ("ConservCare"), a chiropractic managed care organization, in an effort to save costs, standardize care, and facilitate credentialing (Vol. 12, R76-78; 83-88).

On August 3, 1998, Health Choice advised the chiropractic members of its plan, including several of the Plaintiffs, that credentialing of chiropractors for the plan had been contracted with ConservCare, for cost and efficiency reasons. The change was to be effective August 31, 1998 (Vol. 1, R104). This deadline was extended to January 1, 1999 (Vol. 1, R105).

Plaintiffs in their complaint and in their statement of the case quote in part from T.C.A. § 56-32-229(a), a statute applicable to managed care organizations such as Health Choice, which prohibits discrimination as to any provider within a class of providers (R.22, complaint, ¶ 42; Appellants' statement of case, p. 2). Plaintiffs' fail to include the entire text of that statute. The omitted portion is critical and provides as follows:

> This section shall not be construed as prohibiting managed health insurance issuers from including providers or classes of providers only to the extent necessary to meet the needs of the managed health insurance issuer's plan and its enrollees, or from limiting referrals or establishing any other measure designed to maintain quality and control costs consistent with the responsibilities of the plan. This chapter shall not be construed as creating coverage for any service that is not otherwise covered under the terms of the managed health insurance issuer's plan.

The above language of the statute expressly authorizes managed care plans to limit the number of providers in a particular class, such as chiropractors, to the number needed to meet the needs of the plan and its enrollees and permits the managed care plan to establish other measures to maintain quality and control costs.

On September 24, 1998, Dr. Gill responded to Health Choice by letter stating, in part, "that a group of chiropractors have employed an attorney to file suit against ConservCare and to prepare legislation to correct the problem created by this little selfish group's effort to gain control of the all of the insurance business with this city" (Vol. 18, exhibit 5, p. 2; Vol. 14, pp. 126-130).

On March 3, 2003, more than four years after these actions, fifteen chiropractors[1] doing business in Shelby County, Tennessee sued ConservCare, three of its officers, and Health Choice. In paragraph 33 of the complaint (Vol. 1, R15), Plaintiffs allege that Health Choice's decision to contract with ConservCare for credentialing the chiropractic component of its managed care panel providers resulted in the exclusion of the Plaintiffs from the panel (Vol. 1, R22) in violation of the above statute (Vol., R20, ¶ 42), the Tennessee Trade Practices Act § 47-25-101 and 102 (Vol. 1, R16-17 ¶ 35), and the Tennessee Consumer Protection Act, T.C.A. § 47-18-105 et seq., (Vol. 1, R14 ¶ 32).[2] The complaint alleges causes of actions for a litany of tort claims (Vol. 1, R15-16, ¶ 33 (a-n) and 34), but does not expressly include a claim for common law civil conspiracy against Health Choice. Plaintiffs' conspiracy claims relating to Health Choice are limited to conspiracy to alleged violations of the federal and state antitrust statutes (Vol., R.15-18, ¶¶ 34-37).

The only date referenced in the complaint is that in 1997 a group of chiropractors formed ConservCare (Vol. 1, R11, ¶ 25). Health Choice moved for

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[1] Four of the Plaintiffs chose to be voluntarily dismissed from the lawsuit (Vol. 1, R57, 59, 61, and 96). The complaint also sought class action certification which Plaintiffs never pursued (Vol. 1, R.6-8).

[2] The complaint also alleges violation of a federal antitrust statute, Section 1 of the Sherman Act, 15 U.S.C. § 1 (Vol. 1, R17, R17-18, ¶ 37). Defendants removed this action to federal court which has exclusive jurisdiction over the statute (Vol. 1, R23). The matter was remanded to state court after counsel for Plaintiffs represented to United States Judge Daniel Breen that the federal claims would be dropped.

summary judgment based upon the applicable statutes of limitations (Vol. 1, R98). The basis for this motion was that more than four years had elapsed since the January 1, 1999, effective date of Plaintiffs' exclusion from the managed care chiropractic panel and the filing of the complaint on March 3, 2003. As of September 24, 1998, Plaintiffs had retained an attorney to file suit to challenge this arrangement with ConservCare (Vol. 2, R310, Vol. 18, Ex. 5, p. 2).

Health Choice moved to dismiss the claims under the Tennessee Trade Practices Act based upon controlling judicial precedent holding that the plain language of that statute refers to "articles" and "goods" and is inapplicable to services (Vol. 1, R106-122).

These motions were argued before the Honorable Jerry Stokes in Division VI of the Circuit Court of Tennessee for the Thirtieth Judicial District at Memphis on November 29, 2006 (Vol. 5 of record pp. 1-41). At the conclusion of the arguments, Judge Stokes indicated that he felt that Plaintiffs' counsel was "pushing a big rock up hill" (Vol. 5 of record, p. 34), but allowed Plaintiffs additional time to take discovery.

Eight discovery depositions of the parties were taken during a period of several months exhausting over 2000 pages of transcript (Vols. 7-14 of record) and containing eighty-two exhibits (record, Vols. 15-18).

At the conclusion of this discovery, on March 30, 2007 the trial judge heard additional oral arguments on the pending motions (Vol. 6 of record) and granted both motions (Vol. 4, R505A). This judgment became final on October 23, 2007 (Vol. 4, R505A). Plaintiffs filed this notice of appeal on November 19, 2007 (Vol. 4, R510).

Health Choice respectfully submits that the following facts are relevant to the issues presented for review:

STATEMENT OF FACTS

On March 3, 2003, fifteen Shelby County chiropractors brought suit in the circuit court in Memphis against ConservCare, a newly formed chiropractic managed care organization, three of its officers, and Health Choice, a third party administrator of managed care plans affiliated with Methodist Health Systems (Vol. 1, R1-5; R8-14). The complaint alleged a variety of common law torts and violations of the Tennessee Consumer Protection Act and Tennessee Trade Practices Act (Vol. 1, R1-22).

The complaint alleges that the Defendants, including Health Choice, conspired to exclude Plaintiffs from inclusion in the managed care plan administered by Health Choice in violation of the Tennessee federal and state antitrust statutes, the Tennessee Consumer Protection Act, T.C.A. § 47-18-105 et seq., (Vol. 1, R14 ¶ 32), and a Tennessee statute relating to managed care plans, (Vol., R20, ¶ 42) The complaint does not specify a date or dates when these actions occurred (Vol. 1, R1-22).

Not all of the Plaintiffs had been a member of the plan or plans administered by Health Choice and that the alleged exclusion occurred in 1998 (Vol. 3, R.318-19; 429-30, 337-38).

On August 3, 1998, the chief executive officer of Health Choice, William R. Breen, wrote a letter to Dr. Gill and members of the plan, including several of the

Plaintiffs, that credentialing of chiropractors for the plan had been contracted with ConservCare for costs and efficiency reasons. The change was to be effective August 31, 1998 (Vol. 1, R104). This deadline was extended until January 1, 1999 (Vol. 1, R105). On September 24, 1998, Dr. Gill responded to Mr. Breen by letter stating, in part, "that a group of chiropractors have employed an attorney to file suit against ConservCare and to prepare legislation to correct the problem created by this little selfish group's efforts to gain control of all the insurance business with this city" (Vol. 2, R310; Vol. 18, exhibit 5, p. 2; Vol. 14, pp. 126-130).

Health Choice is owned 50% by Methodist Health Services, Inc. and 50% by Metro Physicians Health Care, an independent physicians organization comprised of medical doctors to practice throughout the Methodist hospital system (Vol. 12, pp. 14-15). Health Choice felt inadequate to credential chiropractors because Health Choice, through its members, had insufficient knowledge of chiropractic treatment. ConservCare is a managed care organization formed by chiropractors for the purpose of credentialing chiropractors and performing utilization reviews and standardizing treatment that would be of benefit to Health Choice and other managed care plans and its patient enrollees from a cost and efficiency standpoint (Vol. 12, pp. 76-78, 83-88).

A number of Plaintiffs filed affidavits in which they enumerated certain articles or goods that they utilized in their diagnosis and treatment of chiropractic

patients such as splints, x-rays, and elevated heels (Vol. 1, R316-339). The defendant chiropractors Cole and Hanson testified while their goods such as x-rays or heel lifts might be utilized in the diagnosis and treatment of chiropractic patients they were adjunctive or supportive to the treatment by manipulation of the spine (Vol. 13, pp. 258-260).

Plaintiffs also argued that access to patients through managed care plans is a "product" (Vol. 9, pp. 34-35;Vol. 13, pp. 170-171).

Counsel for Appellants devotes over thirty pages of Appellants' Statement of Facts to documents relating to events occurring after Plaintiffs' exclusion from the panel. Counsel for Health Choice respectfully submits that the analysis of competitive market conditions, whether or not Health Choice was profitable, the wisdom or foolishness in Health Choice's decision to contract with ConservCare for credentialing of the chiropractic panel, "messengering" health care negotiations, the alleged conflicts of interest on the part of the Coles, and efforts to obtain additional contracts with insurance companies, employers, and other heath care networks are irrelevant because Plaintiffs' exclusion from or denial of admission to Health Choice chiropractic panel was lawful. Many of these instances of post-exclusion activities are based upon inadmissible hearsay.

The decision to exclude plaintiffs from Health Choice's managed care panel of chiropractors was not done for an unlawful purpose or through an unlawful

means and is not actionable because it is expressly authorized by T.C.A. § 56-32-229(a) (full text) which authorized inclusion of providers or classes of providers in a plan only to the extent necessary to meet the needs of the plan and its enrollees and authorized taking other measures to maintain quality and control costs.

SUMMARY OF ARGUMENT

No unlawful civil conspiracy occurred. The full text of T.C.A. § 56-32-229(a) expressly provides that a managed care organization may determine the number of a class of providers that it deems necessary to be included in the plan, necessarily resulting in the lawful exclusion of other providers in that class.

The trial court correctly held that Plaintiffs causes of action are barred by the applicable statute of limitations. The complaint was filed on March 3, 2003 (Vol. 1, R1-32). Health Choice gave notice of its decision to contract credentialing of chiropractors for its managed care panel to ConservCare by letter dated August 3, 1998. The termination was to be effective August 31, 1998 and was later extended to January 1, 1999 (Vol. 1, R105). On September 24, 1998 Dr. Gill wrote a letter to William Breen, chief executive officer of Health Choice indicating that a number of chiropractors have hired a lawyer for a purpose of bringing suit (Vol. 18, exhibit 5, p. 2, Vol. 14, pp. 126-130). The suit was not brought until over four years later (Vol. 1, R1-22).

Plaintiffs' argument that Health Choice participated in a continuing conspiracy fails for several additional reasons.

As of the date of termination, those Plaintiffs that were members of the panel knew that they had been excluded from the panel. Those Plaintiffs who had not previously been members of the panel suffered no harm because they did not

belong to the panel in the first place. In any event, if any tort occurred, the cause of action arose at the time of the exclusion. Any subsequent damages flowed from this single exclusion.

The alleged conspiracy to exclude Plaintiffs occurred no later than January 1, 1999. There is no evidence that suggests that Health Choice met annually to conspire with ConservCare to re-affirm its earlier exclusion of panel members.

Plaintiffs allege that Health Choice engaged in a civil conspiracy in violation of the Tennessee Trade Practices Act. Under the expressed terms of the Tennessee Trade Practices Act and the uniform case law construing the statute, the act is inapplicable to the provision of services including chiropractic services. Because this decision did not violate the Tennessee Trade Practices Act, the means employed were not unlawful.

Plaintiffs seek to "backdoor" the statute by arguing that chiropractors sell products and that access to patients is a product. Chiropractors are engaged in the diagnosis and treatment of misalignments of the spine. Patients do not go to chiropractors to buy x-rays or cervical splints or elevated heels. Patients seek chiropractors for their diagnosis and treatment of misalignments of the spine. Any "goods" or "articles" such as splints, neck braces, or x-rays are incidental to the services chiropractors perform. Access to patients is not a "product".

Because chiropractic services are outside the scope of the Tennessee Trade Practices Act, no violation of the Tennessee Consumer Protection Act occurred as a matter of law. Bennett v. Visa USA, Inc., 198 S.W. 3d 747, (Tenn. Ct. App., E.S., 2006) and the authorities cited therein. Further, the one year statute of limitations and the four year statute of repose of the Tennessee Consumer Protection Act, T.C.A. § 47-18-110 bars any claim for violation of the Tennessee Consumer Protection Act.

ARGUMENT

I. WHETHER PLAINTIFFS' EXCLUSION FROM DEFENDANT HEALTH CHOICE'S MANAGED CARE PLAN WAS LAWFUL AND EXPRESSLY AUTHORIZED BY T.C.A. § 56-32-229(a).

No civil conspiracy occurred. T.C.A. § 56-32-229(a) (full text) expressly authorizes inclusion of providers or classes of providers in a panel only to the extent necessary to meet the needs of the plan and its enrollees authorizes establishing any other measures designed to maintain quality or control costs consistent with responsibilities of the plan.

Based upon the authorities set forth in the argument relating to issues II, III, and IV, infra, the actions of Health Choice in delegating credentialing to ConservCare which resulted in the exclusion of or non-admission of Plaintiffs to the managed care plan do not violate the Tennessee Trade Practices Act, T.C.A. § 47-25-101 and 102 or the Tennessee Consumer Protection Act, T.C.A. § 47-18-101 et seq.

In Beaudreau v. Larry Hill Pontiac/Oldsmobile GMC, Inc., 160 S.W.3d 874 (Tenn. Ct. App., M.S., 2004), plaintiff contended that the practice of a car dealership receiving a percentage of the financing it arranges for customers known as the "dealer reserve" violated the Tennessee Consumer Protection Act and Tennessee Trade Practices Act and constituted a civil conspiracy. The Court of Appeals held that this practice did not constitute an unfair or deceptive practice

under the Tennessee Consumer Protection Act and therefore could not constitute a civil conspiracy. The court held:

> Because we hold that the practice of dealer reserve does not have "an unlawful purpose" or constitute the accomplishment of a lawful purpose "by unlawful means"-an essential element of a civil conspiracy claim-we find this issue to be without merit. Id. at 881.

Because the exclusion of Plaintiffs from Health Choice's managed care panel is lawful and authorized by statute, the elements of civil conspiracy are not present.

II. WHETHER THE TRIAL COURT PROPERLY GRANTED SUMMARY JUDGMENT IN FAVOR OF DEFENDANT HEALTH CHOICE BASED UPON THE APPLICABLE STATUTES OF LIMITATIONS BY FINDING THAT PLAINTIFFS' EXCLUSION FROM THE CHIROPRACTIC PANEL OCCURRED MORE THAN FOUR YEARS PRIOR TO FILING SUIT BY APPELLANTS.

On August 3, 1998, Plaintiffs received notice of Health Choice's decision to have ConservCare credential chiropractors, to be effective August 31, 1998 (Vol. 1, R104). This deadline was later extended to January 1, 1999 (Vol. 1, R105).

As early as September 24, 1998, Plaintiffs had retained an attorney to file suit for a redress of this arrangement with ConservCare (Vol. 18, ex. 5, p. 2; Vol. 14, pp. 126-130, Vol. 1, R247-248 and 310). Suit was not filed until more than four years after Plaintiffs had been excluded from the managed care plan of Health Choice (Vol. 1, R1-5, R8-14).

Disregarding the plain language of the full text of T.C.A. § 56-32-229(a), and assuming that a common law civil conspiracy had been plead as to Health Choice, no continuing conspiracy existed.

The decision to delegate credentialing was made in 1998. The exclusion was effective January 1, 1999. There is no evidence in the record either Health Choice or ConservCare met periodically to continue to exclude these Plaintiffs. The post-exclusion events argued by Plaintiffs do not establish a continuing

conspiracy between Health Choice and ConservCare, particularly since no illegal civil conspiracy existed in the first place.

Counsel for Plaintiffs argues that because three of its members were never members of the Health Choice panel of chiropractors, because they did not receive notice, the statute of limitations could not begin to run against them. If they were never members of the panel, no tort was committed and they suffered no harm. The mere fact that a medical provider applies for membership in a PPO and a managed care organization and is not approved does not constitute a tort T.C.A. § 56-32-229 (a) (full text).

Counsel for Plaintiffs relied in the trial court and in his appellate brief on the unreported case Swafford v. MIPA, 1998 WL 281935 (Tenn. App. 1998) (Appendix to brief of appellant), for the proposition that the statute of limitations commences to run from the last overt act not from the first. That case involved when the statute of limitations runs in a libel case. The Plaintiff physician sued a managed care organization for libel because it had reported his termination for substandard care to a data bank. The trial court dismissed the cause of action based upon the one year statute of limitations applying to libel because the report to the data bank was filed more than one year prior to the filing of the law suit. The Court of Appeals reviewed the single publication rule in defamation actions traditionally applicable to print publications. Judge Lillard rejected the application

to single publication rule to the facts of that case. The court held that under the facts of that case the limitations period for each claim commenced on the date when the potential user retrieved the defamatory information from the data bank.

The trial court properly held that the applicable statutes of limitations barred Plaintiffs tort and statutory claims and granted Plaintiffs' motion to dismiss.

III. WHETHER THE TRIAL COURT PROPERLY DISMISSED PLAINTIFFS' CLAIMS PURSUANT TO THE TENNESSEE TRADE PRACTICES ACT, T.C.A. § 47-25-101, BECAUSE THE ACT APPLIES ONLY TO "ARTICLES" OR "PRODUCTS" AND DOES NOT APPLY TO SERVICES.

T.C.A. § 47-25-101 provides:

> **47-25-101. Trusts, etc., lessening competition or controlling prices unlawful and void.** – All arrangements, contracts, agreements, trusts, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in the importation or sale of articles imported into this state, or in the manufacture or sale of articles of domestic growth or of domestic raw material, and all arrangements, contracts, agreements, trusts, or combinations between persons or corporations designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article, are declared to be against public policy, unlawful, and void.
>
> (emphasis supplied)

In McAdoo Contractor's Inc. v. Harris, 439 S.W.2d 594 (Tenn., 1969) the Tennessee Supreme Court unanimously held that the Tennessee Trade Practices Act by in its express terms applies only to goods and articles and not to contracts or services.

This controlling precedent has been followed in every other appellate decision upon this issue.

The most recent decision is Bennett v. Visa USA, Inc., 198 S.W. 3d 747, (Tenn. Ct. App. E.S. 2006), supra p. 12, in which a class of plaintiffs who utilized debit cards to purchase goods and services from merchants brought suit claiming

that the card issuer's requirement that the merchants also carry debit cards was an illegal tying arrangement that caused plaintiffs as a class to pay higher prices and violated the Tennessee Trade Practices Act, T.C.A. § 47-25-101 et seq. The trial court dismissed these claims based on the fact that the Tennessee Trade Practices Act did not apply to "a product or an article".

In Joanne Foreman, Inc., et al. v. National Counsel of Compensation Insurance, Inc., et al., 13 S.W.3d 365 (Tenn. Ct. App., M.S., 1999), the Court of Appeals was faced with determining whether or not the Tennessee Trade Practices Act applies to workman's compensation insurance which is an intangible contract right or service. The court reviewed the holding of the Tennessee Supreme Court in McAdoo, supra, p. 8, and concluded that the Tennessee Trade Practices did not apply.

The court discussed the fact that several separate bills had been introduced into the legislature since the decision in McAdoo seeking to expand the scope of the act beyond goods or articles and none were enacted. The court observed:

> The legislature is presumed to know the interpretation which courts make of its enactments; the fact that the legislature has not expressed disapproval of a judicial construction of a statute is persuasive evidence of legislative adoption of the judicial construction, especially where the law is amended in other particulars, or where the statute is reenacted without change in the part construed. (citing Hamby v. McDaniel) 559 S.W.2d 774, 776 (Tenn., 1977) *Id.* at 373.

Plaintiffs' attempt to do indirectly what they cannot do directly by arguing that they provide cervical collars, splints, or x-rays in connection with diagnosis and treatment of chiropractic patients and that access to patients through managed care plans constitute products. Plaintiffs are putting form over substance since these goods are clearly ancillary to chiropractic diagnosis and treatment of misaligned spines. Plaintiffs do not allege that there was an effort to fix prices for cervical collars, splints, or x-rays. Patients are not products.

In Beaudreau, 160 S.W.3d 882, supra at pp. 13-14, plaintiffs argued that the dealer reserve was a product, rather than a service. The Court of Appeals rejected that argument relying upon Joanne Foreman, Inc., 13 S.W.3d at 370, supra, at p. 19, (holding insurance premiums are not "articles" or "products") and McAdoo Contractors, Inc., 439 S.W.2d 597 supra, at p. 18.

In Bennett, 160 SW3d at 752-753, supra, at pp. 12; 18-19, plaintiff argued that the tying arrangement (holding a building construction contract was not an "article") relating to credit card processing services affected the price of goods and therefore was included under the Tennessee Trade Practices Act. The Court of Appeals quoted from Hanes v. City of Pigeon Forge, 883 S.W.2d 619 622 (Tenn. Ct. App. E.S., 1994) for the proposition that one cannot do indirectly what cannot be done directly. For the same reasons, plaintiffs' arguments that splints and x-rays ancillary to chiropractic diagnosis and treatment and access to patients

through managed care plans are products under the Tennessee Trade Practices Act are attempts to do indirectly what cannot be done directly.

IV. WHETHER THE TRIAL COURT PROPERLY DISMISSED ON PLAINTIFFS' CLAIMS THAT THE TENNESSEE CONSUMER PROTECTION ACT, T.C.A. § 47-18-101 et seq.

Plaintiffs' contention that the trial court improperly dismissed alleged causes of action for violation of the Tennessee Consumer Protection Act, T.C.A. § 47-18-101 et seq. is unsupportable. First, that statute has an express statute of limitations set forth in T.C.A. § 47-18-110 barring actions that are brought more than one year after the consumer transactions are more than four years after discovery. This suit was brought more than four years after Plaintiff's exclusion from the manage care organization's chiropractic panel.

Second, in the Bennett case, 198 S.W.3d at 753-55; supra at pp. 12; 18-19; 20, the court rejected plaintiff's arguments that defendant's tying arrangement tying debit cards to issuance of credit cards constituted an unfair or deceptive practice under the Tennessee Consumer Protection Act. The court held that anti-competitive conduct which falls outside of the scope of the TTPA, such as the provision of chiropractic services in the instant case, cannot be used to form a basis for violation of the Tennessee Consumer Protection Act.

CONCLUSION

Health Choice's decision to delegate the credentialing of chiropractors for membership in its managed care panel to ConservCare for cost and efficiency reasons is expressly authorized by T.C.A. § 56-32-229(a). No civil conspiracy existed ongoing or otherwise. Plaintiffs' suit was filed more than four years after this exclusion occurred and is barred by the applicable statutes of limitations. Because chiropractors render services by diagnosing and manipulating misalignments of the spine, the Tennessee Trade Practices Act is inapplicable. Because these services are outside the scope of the Tennessee Trade Practices Act, they cannot, as a matter of law, constitute an unfair or deceptive practice in violation of the Tennessee Consumer Protection Act.

The decision of the trial court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have caused to be delivered via U.S. Mail, postage prepaid, a true and correct copy of the foregoing document to the following counsel of record this the ____ day of _____, 2008.

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