**IN THE DISTRICT COURT OF APPEAL**
**FIRST DISTRICT, STATE OF FLORIDA**

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v.

Case No. 1D15-0109
L.T. Case No. 2012-CA-002677

JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, and her children, ANGEL ALSTON and JAZMIN HOUSTON, minors, and ERVIN ALSTON; KRISTIN FERNANDEZ, D.O.; YUVAL Z. NAOT, M.D.; SAFEER A. ASHRAF, M.D.; INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC; ANDREW NAMEN, M.D.; GREGORY J. SENGSTOCK, M.D.; JOHN D. PENNINGTON, M.D.; and EUGENE R. BEBEAU, M.D.; and ROBERT E. ROSEMUND, M.D.,

Respondents.

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# *AMICUS CURIAE* BRIEF OF THE JOINT COMMISSION IN SUPPORT OF PETITIONER

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## STATEMENT OF INTEREST

*Amicus Curiae*, The Joint Commission on the Accreditation of Healthcare Organizations ("The Joint Commission") files this *Amicus Curiae* Brief in support of Petitioner, Southern Baptist Hospital of Florida, Inc. The Joint Commission is a not-for-profit, 26 U.S.C. § 501(c)(3) tax exempt corporation, which evaluates, accredits, and certifies nearly 20,500 health care organizations and programs in the United States, including the Petitioner's programs. Founded in 1951, it is the nation's oldest and largest standards-setting and accrediting body in the healthcare field.

The purpose of accreditation is "[t]o continuously improve health care for the public…by evaluating health care organizations [such as the Petitioner's hospital] and inspiring them to excel in providing safe and effective care of the highest quality and value." The Joint Comm'n., Mission Stmt. (Aug. 15, 2009) (available at www.jointcommission.org/assets/1/18/Mission_Statement_8_09.pdf.). The standards adopted by The Joint Commission are implemented voluntarily by their participating organizations. They are aspirational and intended to set a threshold for patient safety but not to limit new and innovative approaches like those made possible by the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, *et. seq*. ("Patient Safety Act").

The Joint Commission is governed by a 32 member Board of Commissioners that includes physicians, nurses, healthcare administrators, quality experts, business leaders, and a consumer patient safety advocate, among others. Corporate members include: The American College of Physicians; The American College of Surgeons; The American Dental Association; The American Hospital Association; and The American Medical Association.

The Joint Commission goes beyond accreditation to help organizations improve healthcare. It is also a healthcare quality and patient safety improvement organization, along with its affiliates, Joint Commission Resources and the Center for Transforming Healthcare. The ultimate purpose of The Joint Commission's accreditation process is to enhance quality of care and patient safety, and it provides numerous resources to help accredited organizations meet accreditation requirements. Joint Commission Resources provides consultation and education to healthcare organizations on quality and patient safety issues. The Center for Transforming Healthcare's mission is to transform healthcare into a "high reliability" industry by developing highly effective durable solutions to healthcare's most critical safety and quality problems and by disseminating solutions widely and facilitating their adoption.

Upon becoming accredited by The Joint Commission, many healthcare organizations, including the vast majority of hospitals in the United States, are

deemed to meet the Medicare and Medicaid regulations, making them eligible to participate in these programs without the need for a separate government quality inspection. *See* 45 C.F.R. § 488.8. Because the aspirational standards of The Joint Commission have been so effective at promoting quality health care, the vast majority of states recognize The Joint Commission accreditation for licensure purposes, including the State of Florida, which accepts The Joint Commission accreditation as evidence that a hospital meets the licensing requirements for hospitals [Rule 59A-3.253, F.A.C.]; ambulatory health care organizations [§ 400.9935, Fla. Stat.]; nursing care centers [§ 430.80, Fla. Stat.]; behavioral health programs [§ 394.90, Fla. Stat.]; and others.

The Joint Commission's mission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. It has long been concerned with the need to improve the level of safe and effective patient care in the United States, and has been at the forefront of driving needed patient safety initiatives. *See* Kelly Devers, et al., *What is Driving Hospitals' Patient-Safety Efforts?* Health Affairs, Vol. 23, No. 2 (Mar./Apr. 2004). However, The Joint Commission is well aware that its activities alone cannot fully support healthcare organizations to deliver safe and effective care of the highest quality and value without the involvement of other

stakeholders—which is why it is so vitally important that one of those stakeholders, patient safety organizations ("PSOs"), successfully perform what Congress intended PSO's to accomplish.

Despite The Joint Commission's focus on promoting quality improvement and patient safety, The Joint Commission's accreditation activity precludes it from becoming a certified patient safety organization under the Patient Safety Act.[1] Certain entities may not seek listing as a PSO, including "[a]n entity that accredits or licenses health care providers." 42 C.F.R. § 3.102(a)(2)(ii)(A). Therefore, The Joint Commission has no direct corporate interest in this matter. The Joint Commission's only interests in submitting this brief are to assist this Court, promote PSOs, and support the confidentiality and privilege of "patient safety work product," to further patient safety enhancing efforts, and hasten the introduction of evidenced-based solutions for some of the more vexing and recurring adverse patient safety events.

Based on The Joint Commission's accreditation experience, it knows that safety improvement efforts should be confidential and privileged to encourage open, candid, and honest evaluations to the benefit of patients. Unfortunately, the lack of adequate confidentiality and privilege protection has been an enormous

[1] Under the Patient Safety Act, The Joint Commission's affiliates can obtain certification as "component patient safety organizations" so long as certain firewall protections are established between accreditation and PSO activities. The Joint Commission has no component PSO at this time.

barrier to progress in patient safety. The Joint Commission has a compelling interest in this case because, long before the Patient Safety Act was passed, The Joint Commission sought federal legislation to create safe harbors for information collected or developed for the purpose of reducing risks associated with delivering patient care and health care services. As explained in this brief, the confidentiality of information provided under the Patient Safety Act is imperative to developing prompt processes for reducing those risks.

The Joint Commission is not filing this amicus brief to discuss the specific medical facts of the case or the standard of care for this liability dispute—and its participation should not be taken as expressing any view on the merits of the underlying claims or defenses. The Joint Commission seeks only to provide context for the Petitioner's position and to inform the Court about national matters of extreme importance to patient safety and quality improvement in health care.

## SUMMARY OF THE ARGUMENT

Before the Patient Safety Act, The Joint Commission worked for years with Congress to provide federal safe harbors for patient safety activities reported to accrediting bodies. The Joint Commission is in a unique position of understanding the important need—on a national level—to maintain the privilege and confidentiality of the information at issue. The answer is simple. Information provided through the patient safety evaluation system ("PSE System") under the

Patient Safety Act is protected—regardless of state laws to the contrary. Information that is not in the PSE System is not protected. The latter information, such as the factual bases for the issues in a particular case, is available for a states' review and may be reported in an incident report. But federal law protects against disclosure of submissions provided to the PSE System, which includes much more than pure facts.

Information provided under the Patient Safety Act is critical to promoting quality patient care, which is why The Joint Commission sought and received a permitted disclosure of patient safety work product by a provider to the provider's accrediting body. The interaction between patients, providers (such as hospitals and doctors), state and federal governments, and The Joint Commission's accreditation program itself would be severely thwarted if that information were deemed unprotected from discovery. In formulating the Patient Safety Act, Congress understood the difference between the hard, cold facts of a particular incident or occurrence, which are discoverable, and the facts and analyses that are developed for patient safety activities in accordance with the Patient Safety Act, such as root cause analyses. Obviously, patients' rights are paramount—which is why a patient's medical records, billing, discharge information, or other original patient information is specifically excluded from the definition of patient safety work product. The Joint Commission also understands and supports the states' need

for factual information to carry out independent licensure actions. But organizations supply more than the facts of an incident when they conduct patient safety activities; and if that data is within a PSE System, it is protected from discovery under federal law.

At issue are systems and processes that are constantly in need of change as new problems arise. To open up to litigation all of a provider's efforts to make the system better and prevent patient harm thwarts Congressional intent and The Joint Commission's mission. Allowing for confidentiality of information provided under the Patient Safety Act is critical so that problems in the system can be quickly addressed and changed when necessary to prevent reoccurrence. Allowing discovery of this information would not only be in derogation of federal law; it would also be harmful both nationally and to Florida's citizens, all of whom have an interest in promoting and obtaining quality healthcare and patient safety.

## ARGUMENT

### I. THE JOINT COMMISSION HAS UNIQUE INSIGHT INTO THE PATIENT SAFETY ACT GIVEN ITS EXTENSIVE INVOLVEMENT IN ITS DEVELOPMENT—AND THE ACT IS CRITICAL TO PATIENT SAFETY PROTECTION.

"Patient safety" is the prevention of errors and adverse effects to patients that are associated with health care. *See* World Health Organization, Health Topics, *Patient Safety*, www.who.int/topics/patient_safety/en/ (last visited Feb. 4, 2015). In health care, mistakes are often the result of systems and processes that

invite human error or, more importantly, that do not prevent humans from causing inadvertent harm. Health care processes must establish defensive barriers to prevent patient injury, wrapping risk points with protections that prevent errors from reaching the patient. When The Joint Commission began its quest in 1997, calling for Congressional action on this issue, the term "patient safety" was not yet widely used in healthcare. At that time, few in the healthcare field appreciated the fact that many of the reasons for the occurrence of adverse patient safety events were due to the failure of organizations and practitioners to systematically identify, analyze, and take appropriate action against preventable risks. Serious adverse events, or risks thereof, were not routinely reported, nor shared among providers, for fear of reprisal, shame, or litigation.

To improve systems and processes for the enhancement of safety, hospitals and other health care providers need to learn from patient safety experts inside and outside their organizations. Thus, the purpose of the Patient Safety Act's privilege for "patient safety work product" is to encourage reporting to outside experts in patient safety so organizations can obtain expert analysis and feedback on individual and collegial processes and systems for additional analysis and critique, and rapid advancement in patient safety and health care quality.

Understanding the etiology of serious adverse events and the existence of risks is essential to mitigating harm. The Joint Commission thus embarked on a

dialogue with Congress for the purposes of obtaining legislation to encourage health care organizations to uncover their own risks, report adverse events, and share this information with their accrediting body to find ways to reduce the likelihood of inevitable human error from reaching patients. The Joint Commission intended that such information be used to help individual organizations address their specific issues, to inform and reform its accreditation standards, and to share causal information among all healthcare organizations about risks and solutions in a de-identified manner.

Although the House of Representatives twice passed a provision that would have provided safe harbor protection for sensitive information shared with accrediting bodies, the legislation never passed both chambers. Instead, through the actions of a larger coalition of over 100 professional and patient advocacy groups, including The Joint Commission, the concepts were later broadened and incorporated into the Patient Safety Act. Indeed, as noted in Petitioner's certiorari petition, The Joint Commission's then President, Dennis O'Leary, testified at the hearings regarding this legislation, asking Congress to extend protection to the root cause analyses that providers perform and The Joint Commission collects. [Pet. Br. at 38] The impetus behind the broad array of stakeholders was a strong belief that, without a learning environment within which to surface information free from concerns over confidentiality and privilege, there would continue to be hesitancy

for providers to thoroughly analyze serious events, perform prospective risk analyses to identify potential vulnerabilities, collect information related to systems and process failures, or otherwise delve deeply into sensitive information that could be used against an organization or individual practitioner in court.

The Joint Commission thus played a key role and strongly supported the Patient Safety Act from its inception, including its establishment of privilege protection for patient safety work product as that term is defined in the Act. Joint Commission representatives were at the critical stakeholder meetings, participated in drafting language proposals, and responded to legislative language as it evolved. Joint Commission staff continue to be very knowledgeable about the purpose and meaning of this legislation. For these reasons, The Joint Commission believes its understanding of the Patient Safety Act, as outlined in this brief, will assist this Court's understanding of the Patient Safety Act, and help the Court to interpret its provisions as intended by Congress.

## II. JOINT COMMISSION ACCREDITATION STANDARDS DO NOT PREEMPT THE CONFIDENTIALITY AND PRIVILEGE OF PATIENT SAFETY WORK PRODUCT.

When a document satisfies the definition of Patient Safety Work Product, it should not be stripped of its federal protection just because there is a state statute, rule, accreditation, or licensing provision underlying or prompting its creation or maintenance. Such an interpretation would only discourage further efforts to

refine and revise such standards and undermine the safety of patients and the advancement of patient safety efforts. The trial court's order directing discovery of such information eviscerates the federal statutes' intended force and defeats Congress's core purpose of improving the quality of health care nationally.

The Patient Safety Act provides very broad confidentiality and privilege protections to certain data that has been properly collected in a special collection system called the "patient safety evaluation system," as defined by the Act. When that data has been properly collected in a patient safety evaluation system, it is known as "patient safety work product," and it is entitled to confidentiality and privilege, without exception, when it is to be submitted, or it has been submitted, to a patient safety organization.

Like PSOs, The Joint Commission is an expert patient safety resource, helping hospitals and other healthcare organizations develop systems and processes to enhance the safety of care, treatment, and services to patients. Historically, The Joint Commission's standards, and other requirements, were directly related to creating systems that promote patient safety. In 1995, The Joint Commission introduced its Sentinel Event Policy, which requires hospitals to conduct a "root cause analysis" after a sentinel event,[2] to help prevent the recurrence of unexpected

[2] A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

outcomes in care. The Joint Comm'n, *Comprehensive Accreditation Man. for Hosps.*, SE at 1-18 (Jan. 2015). A root cause analysis is a process for identifying basic or causal factors underlying variation in performance, including the occurrence of a sentinel event. Indeed, the Patient Safety Act's very definition of patient safety work product includes the term "root cause analyses," because this type of analysis is just the kind of patient safety activity protected by the Patient Safety Act. 42 U.S.C. § 299b-21(7). The term "root cause analyses" is thought to have originated in the aerospace industry in the 1950's, but has since been adopted by other industries, including the healthcare field. *See, e.g.*, Jens Rasmussen, Annelise M. Pejtersen, L.P. Goodstein, *Cognitive Systems Engineering* (1994).

The preparation of a root cause analysis, after the occurrence of an adverse patient safety event, became more prevalent in the healthcare industry only after The Joint Commission introduced its Sentinel Event Policy in 1995. Each accredited organization is strongly encouraged, but not required, to report sentinel events to The Joint Commission. *Comprehensive Accreditation Man. for Hosp.*, SE at 6. Joint Commission accredited organizations are expected to identify and respond appropriately to all sentinel events occurring in the organization. An appropriate response includes a timely, thorough, and credible root cause analysis, the development of an action plan to reduce risk, implementation of the action plan, and the monitoring of its effectiveness. *Id.* at 8.

A root cause analysis begins with data collection and reconstruction of a patient safety event through record review and participant interviews. A root cause analysis focuses primarily on systems and processes, not on individual performance. The ultimate goal of is to prevent future harm by eliminating the latent problems that often underlie adverse events. The following example explains how root cause analyses work to improve patient safety:

> [A] patient [] underwent a cardiac procedure intended for another, similarly named patient. A traditional analysis might have focused on assigning individual blame, perhaps to the nurse who sent the patient for the procedure despite the lack of a consent form. However, the subsequent [root cause analysis] revealed 17 distinct errors ranging from organizational factors (the cardiology department used a homegrown, error-prone scheduling system that identified patients by name rather than by medical record number) to work environment factors (a neurosurgery resident who suspected the mistake did not challenge the cardiologists because the procedure was at a technically delicate juncture). This led the hospital to implement a series of systematic changes to reduce the likelihood of a similar error in the future.

U.S. Dep't of Health and Human Servs., Agency for Healthcare Research and Quality, Patient Safety Primers, *Root Cause Analyses*, psnet.ahrq.gov/primer.aspx?primerID=10 (last visited Feb. 4, 2015).

This example illustrates the patient safety activity Congress sought to encourage in the Patient Safety Act. By providing broad confidentiality and privilege protections to a root cause analyses, the Patient Safety Act can hasten the speed of improvements in healthcare. By providing this analysis to its PSO, a

provider can help disseminate to other health care providers the need to implement systematic process changes to avoid similar errors.

By the definition of patient safety work product alone, it is clear Congress knew that The Joint Commission's accreditation requirement for a root cause analysis would be created and maintained by hospitals in patient safety evaluation system as patient safety work product. There was never any intent to exclude The Joint Commission-required root cause analyses from the patient safety activities protected by the Patient Safety Act.

The mission of The Joint Commission is only further enhanced by the adoption of a national patient safety system. Like PSOs, The Joint Commission can provide expert analysis and feedback when it reviews an organization's root cause analyses. But, The Joint Commission knew when the Patient Safety Act was still a working draft, that if a root cause analysis was created and maintained as patient safety work product, the strong confidentiality and privilege protections of the Patient Safety Act would prevent The Joint Commission from reviewing a hospital's root cause analysis. Therefore, The Joint Commission sought, and obtained from Congress, a permitted disclosure of confidential and privileged patient safety work product by health care organizations to accrediting bodies. The broad coalition of stakeholders supported this permitted disclosure because they appreciated The Joint Commission's use of that information in a non-regulatory

capacity; that is, for the promotion of broad based learning and a diminution of adverse patient safety events.

Section 922(c)(2)(E) of the Patient Safety Act, states:

> (2) Exceptions from confidentiality. Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:
>
> . . . .
>
> (E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

The title of this subsection, "*Exceptions* from Confidentiality," may be somewhat of a misnomer because patient safety work product maintains its confidentiality, and its privilege, even when it is disclosed in any one of the ten ways permitted by this subsection. *See* 42 U.S.C. § 299b-22(d)(1). The exception permits a disclosure of the information to The Joint Commission so that the organization performance can be assessed, and The Joint Commission can assist the entity in question. Voluntary disclosures to The Joint Commission of root cause analyses, created as patient safety work product, are still confidential and privileged under the Patient Safety Act for all other purposes—without exception. Thus, when a hospital chooses to prepare a root cause analysis in its patient safety evaluation system for submission to a PSO, The Joint Commission considers the root cause analysis to be patient safety work product and protected under the Patient Safety Act.

Without the permitted disclosure noted above, a hospital could be fined by the Office of Civil Rights for violating the confidentiality provisions of the Patient Safety Act if it submitted a root cause analysis, created as patient safety work product, to The Joint Commission, even though that root cause analysis was conducted in the same way recommended for accreditation by The Joint Commission. The Patient Safety Act protects voluntary disclosures of patient safety work product to The Joint Commission and to other accrediting bodies precisely to encourage the adoption of powerful analytic techniques like the root cause analysis. Thus, organizations do not violate the confidentiality provisions, nor strip information of the privilege, when they voluntarily share root cause analyses with their accrediting bodies. 42 U.S.C. § 299b-22(c)(2)(E).

Moreover, without this permitted disclosure provision in the Act, if a hospital informed The Joint Commission that its root cause analysis had been created, and was maintained, in the organization's patient safety evaluation system for reporting to a patient safety organization, The Joint Commission could not view the root cause analysis, nor cite the organization for non-compliance with the Sentinel Event Policy. The organization had created the root cause analysis in compliance with the Sentinel Event Policy, and it did so in its patient safety evaluation system for submission to a patient safety organization. The fact that this patient safety work product contained information about a Joint Commission-

required root cause analysis would change nothing about its status as patient safety work product, nor would it strip the confidentiality or the privilege protections afforded that root cause analysis by the Patient Safety Act. The same treatment for privilege would apply to information and documents created and maintained for other obligations, when they are properly created as patient safety work product.

Florida has recognized, similar to here, that opinions and deliberations arising from a health care provider's internal risk management program can remain confidential even if the resulting investigative report itself is not. For instance, in *Bayfront Medical Center, Inc. v. Florida Agency for Healthcare Administration,* 741 So. 2d 1226 (Fla. 2d DCA 1999), the court rejected the argument that one subsection of Florida's peer review statute overrode another. In doing so, the court emphasized the distinction between risk management and professional competency in finding some documents remained confidential—the purpose being to protect the integrity of the "peer review" process. Following *Bayfront,* the Florida Supreme Court in *Brandon Regional Hospital v. Murray,* 957 So. 2d 590 (Fla. 2007), reaffirmed the distinction at issue there, going even further by finding that the documents sought by the state agency in *Bayfront* could not be disclosed in civil litigation.

As in *Bayfront,* this Court should recognize the distinctions between the patient safety work privileged information provided under the Patient Safety Act

that are confidential and other information that is not. Each serve completely different purposes, and the confidentiality afforded patient safety work product is essential to the integrity of the Patient Safety Act's purposes.

The distinctions here are analogous to the distinctions between attorney fact work product (which is generally not protected) versus attorney opinion work product (which is generally protected). *See, e.g., Fla. Eye Clinic, P.A. v. Gmach,* 14 So. 3d 1044, 1049 (Fla. 5th DCA 2009) (citing *Upjohn Co. v. United States,* 449 U.S. 383, 399-401 (1981) (distinguishing fact work product pertaining to a client's case and prepared and gathered in connection therewith, from opinion work product consisting of an attorney's mental impressions, conclusions, opinions or theories concerning a client's case)). In preparing root cause analyses, as with attorney opinion work product, there is a solicitation and collection of opinions and efforts to find systemic errors and, under the Patient Safety Act, these must be protected from discovery and litigation.

## III. THE PATIENT SAFETY ACT ALLOWS PATIENT SAFETY WORK PRODUCT TO CONTAIN INFORMATION REQUIRED FOR OTHER OBLIGATIONS AND PROVIDES A MECHANISM FOR MEETING THOSE OBLIGATIONS.

The Joint Commission was keenly aware of the careful balance Congress sought to strike between protecting patient safety work product and meeting state licensure and other obligations. The Patient Safety Act does not supplant or interfere with state required incident reports, but it distinguishes these obligations

from each other and declares they are separate and apart. Once information is collected and maintained within a PSE System, it is considered patient safety work product. The information may be extracted from the PSE System by the provider before the information is reported to the PSO, but once it is reported to the PSO, the patient safety work product cannot be used to meet other obligations. In the words of the Department of Health and Human Services:

> Providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. **All of this information, collected in one patient safety evaluation system, is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state.** Once removed from the patient safety evaluation system, this information is no longer patient safety work product.

73 Fed. Reg. 70742 (Nov. 21, 2008) (emphasis added).

Thus, the confidentiality and privilege of patient safety work product is not changed when a hospital fails to separately collect the information to comply with external obligations, such as root cause analyses for accreditation and incident reports for state regulations. The Joint Commission's understanding in this case is that the hospital has already produced the responsive documents it reported to the State and two occurrence reports related to Marie Charles, neither of which had been submitted to its PSO. [*See, e.g.*, Pet. App. at 23.] To produce the additional requested information, the hospital would have to create separate reports

concerning the same events, reviving concerns that providers would have to maintain duplicate systems to separate information, which might discourage participation in the Patient Safety Act's reporting system due to costs and burdens.

## CONCLUSION

The Joint Commission's support of a broad privilege for patient safety work product is intended solely to improve healthcare and patient safety across the country. Its support reflects Congressional intent as to its goals for the Patient Safety Act. Based on The Joint Commission's extensive knowledge of the field, if the trial court's orders stand, the Patient Safety Act's goal of improvements in patient safety will be severely compromised. This Court should exercise its certiorari jurisdiction to quash the trial court's order under review.

Respectfully submitted,

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I HEREBY CERTIFY that a true and correct copy of the foregoing has been electronically uploaded to the First District Court of Appeal's eDCA and further certify that a true and correct copy of the foregoing was furnished by E-Mail to counsel for the parties listed below on February 4, 2015.

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I HEREBY CERTIFY that the font used in this brief is the Times New Roman 14-point font and that the brief complies with the font requirements of Rule 9.210(a)(2).

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