

No. 04-2550

UNITED STATES COURT OF APPEALS
THIRD CIRCUIT

Citizens for Health, American Psychoanalytic Association, American Association for Health Freedom, New Hampshire Citizens for Health Freedom, American Mental Health Alliance, American Association of Practicing Psychiatrists, Health Administration Responsibility Project, Congress of California Seniors, National Coalition of Mental Health, Professionals and Consumers, California Consumer Health Care Council, American Association of Practice Psychiatrists, Sally Scofield, Eugene B. Meyer, Daniel S. Schragger, Morton Zivan, Michaele Dunlap, Tedd Koren, Jane Doe, Janice Chester, Deborah Peel
Plaintiffs - Appellants

v.

Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services
Defendant - Appellee

On Appeal from United States District Court
Eastern District of Pennsylvania

BRIEF OF AMICUS CURIAE
TEXAS CIVIL RIGHTS PROJECT

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This Brief is filed in support of Citizens for Health, *et. al.*, the Plaintiff-Appellant, and urges reversal of the lower court.

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IDENTITY OF THE AMICUS

The Texas Civil Rights Project (“TCRP”) is a non-profit public interest law organization that promotes racial, economic, and social justice, as well as civil liberty under the Bill of Rights of the Texas and United States Constitutions. TCRP, with a membership base of approximately 1200 Texans, works toward these goals primarily through education and litigation involving civil rights violations. Having handled more than 550 cases, TCRP maintains a vigorous litigation and education campaign on behalf of all Texans. TCRP regularly represents members of the State’s disability community, disability rights and mental health organizations, and women and school children who face invidious discrimination, domestic violence and/or sexual assault, all of which invoke the strongest of privacy concerns. TCRP also handles a significant First Amendment docket, and commonly represents individuals in litigation involving privacy rights.

TCRP submits this brief because of the importance of the privacy issues raised in this case, and because of the harm that will befall the very individuals that TCRP undertakes to serve if private industry’s capture of the United States’ Department of Health and Human Services (“HHS”), as demonstrated by the promulgation of the Amended Privacy Rule demonstrates, goes unchecked.

Moreover, as a civil rights organization, TCRP is highly interested in providing this Court with its analysis of the state action issue, upon which the lower court apparently rested its ruling.

TCRP has filed a Motion for Leave to File an Amicus Brief, seeking authority to file this brief.

SUMMARY OF THE ARGUMENT

The federal government, through the Secretary of the United States Department of Health and Human Services, has recently reversed course on the issue of medical privacy. Although the federal government had just enacted a rule requiring health providers to obtain patient consent prior to disclosing medical information to third parties, it suddenly rescinded the right to consent, and developed an elaborate system by which long standing privacy rights will be unilaterally rescinded (the “Amended Privacy Rule”). Under the Amended Privacy Rule, the most private medical information of every American health care consumer stands to be published to countless business and insurance industries, despite any efforts taken to protect the information from use and disclosure.

Plaintiff-Appellants sued to enjoin the Amended Privacy Rule, but the lower court, relying solely on the *DeShaney* line of cases, determined that there was not sufficient state action to trigger constitutional protections. Under well established constitutional standards, however, the resulting loss of privacy is sufficiently

attributable to the federal government. As such, the Amended Privacy Rule must withstand the strictest of constitutional scrutiny if it is to remain in effect, and the lower court erred by concluding otherwise. TCRP, therefore submits this brief to express support for the Plaintiff-Appellants, and to urge reversal of the lower court's judgment.

ARGUMENT

I. THE HISTORY OF HIPAA AND THE AMENDED PRIVACY RULE.

The Health Insurance Portability and Accountability Act ("HIPAA") was signed into law by the President in 1996. Pub. L. 104-191, 110 Stat. 1936. As the District Court correctly surmised, HIPAA was designed to make the health care industry more efficient "by replacing the many non-standard formats used nationally with a single set of electronic standards." *Citizens for Health, et. al. v. Thompson*, 2004 WL 765356 at *1 (E.D. Pa. 2004) ("District Court Opinion").

Among other things, Title II of HIPAA directed the Secretary of the Department of Health and Human Services ("the Secretary") to develop standards for the electronic storage and exchange of medical information in connection with the provision and payment of health services. *See* HIPAA § 262(a); 42 U.S.C. § 1320d-2. It also directed the Secretary to adopt standards for the privacy of medical information. *Id.* These standards were to include the privacy rights of individual patients, the procedures for exercising and protecting privacy rights, and the use and disclosure of medical

information. *See* § HIPAA 264(b).

Pursuant to these directives, in late 1999, the Secretary commenced the rulemaking process, and ultimately promulgated regulatory standards to protect the privacy of identifiable health information as required under § 264(c) of HIPAA. *See* 64 Fed. Reg. at 59,927; 59, 924. As Citizens for Health note, the Original Rule’s purpose was “to protect and enhance the rights of consumers, improve the quality of health care by restoring trust in the health delivery system, and create a national framework for health privacy building on the efforts of states and others.” *See* Brief of Appellants at 4, *citing* 65 Fed. Reg. at 82. The Original Rule was published near the end of the prior Administration. 65 Fed. Reg. 82,462 (December 28, 2000). Under the Original Rule, consent had to be obtained by a health provider before using or disclosing an individual’s identifiable health information for certain “routine” purposes (i.e. treatment, payment or health care operations). 45 C.F.R. § 164.506.

In March of 2002, the new Administration proposed the Amended Privacy Rule, fundamentally changing the regulatory scheme that had existed under the Original Privacy Rule, and deliberately creating the means by which any “covered entities” would disclose private medical information without consent.¹ The Amended Privacy Rule was

¹ Under the Amended Privacy Rule, “Covered Entity” is defined broadly to include any health plan, health care clearinghouse and any provider, whether the entity is private or governmental. 45 C.F.R. § 160.102. The Amended Privacy Rule also applies to “business associates” who might handle health information on behalf of covered entities including lawyers, consultants and

formally adopted on August 14, 2002. 67 Fed. Reg. at 53,182.

The Amended Privacy Rule creates a new federal regulatory method by which all “covered entities” and their “business associates” will, and are currently using and disclosing individuals’ identifiable health information for routine purposes without their permission, and even over their objection. 67 Fed. Reg. at 53,211. The Secretary also made clear that he expects covered entities to utilize the new governmental process to disclose personally identifiable health information created prior to the Amended Privacy Rule’s April 14, 2003 compliance date. *See id.*

The Appellants have produced undisputed summary judgment evidence that there are currently over 600,000 “covered entities,” and millions of “business associates” who have been granted express federal power to intrude on the medical privacy expectations of every health care consumer. *See Appellants Brief at 7.*

II. THE DISTRICT COURT ERRED IN CONCLUDING THAT BECAUSE THE AMENDED RULE IS PERMISSIVE, IT DOES NOT VIOLATE CONSTITUTIONAL RIGHTS.

Despite the overwhelming role the Secretary played in the intentional creation of the very means by which significant amounts of personally identifiable medical information will be used and disclosed without consent, the District Court, relying solely on the *DeShaney v. Winnebago County Soc. Servs. Dept’t.*, 489 U.S. 189, 195 (1989) line of cases, found that “[b]ecause the Amended Privacy Rule does not compel anyone to

financial advisors. 45 C.F.R. § 160.103.

use or disclose the plaintiffs' health information for routine purposes without the plaintiffs' consent . . . the Amended Privacy Rule does not violate the plaintiffs' constitutional rights.² *See* District Court Opinion at *15-16.

The District Court reasoned that the Amended Privacy Rule is not compulsory, and therefore, does not sufficiently "affirmatively" interfere with any constitutional right. *See id.* The Court adopted the government's position that it cannot be held accountable for either the remarkable disclosure of private information that results from its Amended Privacy Rule or the harm that necessarily flows from this unprecedented disclosure because the government regulation does not compel any person or entity to use or disclose private medical information. But the government told only half of the story.

Appellants challenge both the District Court's factual findings concerning state action, and its articulation of the applicable legal standards governing such determinations. The summary judgment evidence stands uncontested that the foreseeable, and indeed, intended effect of the Amended Privacy Rule, which enables covered entities to use and disclose protected health care information without consent, is that covered entities will do so. By rescinding the consent requirement, the Secretary

² Although the District Court is correct that *DeShaney* and its progeny stand for the proposition that the Constitution generally operates as a limitation on the government's authority, and does not mandate the government to affirmatively protect individuals from one another, the District Court ignored a number of other lines of cases, which consistently hold that where, as here, the government undertakes to regulate a field, or to purposely empower individual actors to do those things it cannot do itself, there is often a finding of state action.

intentionally provided the very means by which the health care industry, and its “business associates,” both private and public, will undoubtedly standardize itself in a manner in which consent is not sought or obtained prior to the use or disclosure of private medical information.³ As the District Court itself found, the very purpose of HIPAA was to “replac[e] the many non-standard formats used nationally with a single set of . . . standards.” District Court Opinion at *1. Despite the Secretary’s claim that state law is not automatically preempted by HIPAA, this assertion rings hollow in light of the stated governmental goal of standardization, and the summary judgment evidence concerning the coercive nature of HIPAA.

The Supreme Court has long recognized that although not compulsory, statutes nevertheless run afoul of the Constitution when they encourage or enable private conduct that the government itself lacks power to engage in, or when they provide the means by which private parties may engage in otherwise unconstitutional conduct. *See McCabe v. Atchison, Topeka, & Santa Fe Railway Co.*, 235 U.S. 151 (1914) (state statute could not permit railway to provide accommodations for Caucasian patrons, but not African American patrons); *Gilmore v. City of Montgomery, Alabama*, 417 U.S. 556 (1974) (precluding city from allowing private groups from using and controlling city facilities,

³ The government also conveniently ignores that the Amended Privacy Rule fails to distinguish between private and public covered entities. There is no question that to the extent the Amended Privacy Rule applies to public covered entities, the Rule is unconstitutional unless the government satisfies the stringent

since those private groups could deny access to the facility on the basis of race); *see also Nixon v. Condon*, 286 U.S. 73 (1932) (striking down state statute which permitted political parties [which the Court assumed to be private “voluntary associations”] to deny party membership on the basis of race).

In *Nixon*, the Supreme Court found that a state statute granting political parties, which the Court assumed to be private associations, authority to set their own membership requirements constituted state action, and ran afoul of the Constitution. *Nixon*, 286 U.S. at 88-89. The Court in *Nixon* rested its decision not on the nature of political parties under state law, but rather, on the state’s enactment of the law that “permitted” parties to exclude members on the basis of race. *Id.* at 82-84.

The *Nixon* Court noted that the power at issue, the power to exclude, was “statutory, not inherent,” and that had “the state not conferred it, there would be hardly color of right to give a basis for its exercise.” *Id.* at 85. The Court concluded that the challenged conduct was sufficiently attributable to the government, not the private political party, and therefore unconstitutional because “the statute lodged the power in a committee, which excluded the petitioner and others of his race, not by virtue of any authority delegated by the party, but by virtue of an authority originating or supposed to originate in the mandate of law.” *Id.* at 84.

The *Nixon* Court was clearly troubled that the party had not merely acted on its

requirements of the compelling governmental interest test.

own accord, but had instead acted with power “the statute had . . . attempted to clothe them with . . .” *Id.* at 86.

Similarly, in *Reitman v. Mulkey*, the Supreme Court struck down a provision of the California Constitution that purported to give all persons the right to refuse to sell, lease or rent his property to another, in his sole discretion. 387 U.S. 369, 381 (1967). In invalidating that provision of the state constitution, the Court noted that contrary to the assertions of the state, any resulting discrimination would not be “purely private discrimination,” but would instead impermissibly involve the power of the state. *Id.* at 375, citing *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 726 (1961) (striking down state law which “authorized” racial discrimination in private businesses). In reaching its holding, the Court cited *McCabe*, 235 U.S. at 151 for the proposition that a statute authorizing carriers to provide cars for whites but not blacks would be sufficient state action (and unconstitutional) even though the statute was a permissive state statute that gave authorization to violate the Constitution. See *Reitman*, 387 U.S. at 379.

Moreover, in *Reitman*, the Court found it important that the state had passed several laws, prior to the constitutional amendment, that had made racial discrimination in the sale or renting of real estate illegal. See *id.* at 376-77. The Court emphasized that the California constitutional amendment effectively repealed those previous laws and put the government’s stamp of approval on private parties’ ability to discriminate in the sale

of renting of real estate:

Private discriminations in housing were now not only free from [previous anti-discrimination statutes] but they also enjoyed a far different status than was true before the passage of those statutes. The right to discriminate, including the right to discriminate on racial grounds, was now embodied in the State's basic charter, immune from legislative, executive, or judicial regulation at any level of the state government. Those practicing racial discriminations need no longer rely solely on their personal choice. They could now invoke express constitutional authority, free from censure or interference of any kind from official sources.

Id. at 377.

Such a scheme, although undeniably authorizing only “private” conduct, still implicated the government, and therefore, ran afoul of the Constitution.

The Supreme Court has embraced similar logic outside of the context of Fourteenth Amendment jurisprudence. In *Public Utilities Commission of the District of Columbia v. Pollak*, 343 U.S. 451, 462-63 (1952), the Court found “sufficient Federal Government action to make the First and Fifth Amendments applicable thereto” as a result of the government's regulatory authority. In that case, a privately owned transportation company in Washington, D.C. received and played certain radio programs through loudspeakers in its passenger vehicles, and there was a constitutional challenge based on the content of those radio programs. *See id.* at 453. The Court determined that

the conduct at issue did raise a constitutional issue, and the Court based its conclusion on the fact that the transportation company operated under the regulatory supervision of the Public Utilities Commission of Washington, D.C., a governmental agency authorized by Congress. *See id.* at 462. The Court went on to state:

We rely particularly upon the fact that that agency, pursuant to protests against the radio program, ordered an investigation of it and, after formal public hearings, ordered its investigation dismissed on the ground that the public safety, comfort and convenience were not impaired thereby.

Id.

Finally, the Supreme Court has intuitively used a similar method to analyze state action for purposes of determining whether a state has impermissibly established or endorsed a religion. *See e.g. Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971). Under this line of cases, the Court has repeatedly found that “permissive” statutes may invoke sufficient state action to trigger constitutional scrutiny. For example, in *Wallace v. Jaffree*, 472 U.S. 38 (1985), the Supreme Court affirmed a court of appeals judgment that an Alabama statute allowing a moment of silence for meditation or voluntary prayer in schools was unconstitutional, despite the fact that it was not compulsory. The Court affirmed the appeals court’s statement that Alabama’s statute was an attempt to “encourage a religious activity...even though [the statute was] permissive in form.” *Id.* at 47. *See also Engel v. Vitale*, 370 U.S. 421 (1962).

The conduct at issue in the case at bar bears a remarkable similarity, in the constitutional sense, to the conduct at issue in *Nixon*, *Reitman*, *Pollak* and *Wallace*. As in *Pollak*, the government agency in the present case conducted investigations (of the rulemaking variety) and public hearings (due to the same) and rendered the government's position on the issue. As in *Pollak*, the government has harmed the Plaintiffs-Appellants by its public regulation of what certain entities (in this case, medical providers) may or may not do, since HHS's regulations have a causal link with the impact on the plaintiff's right to medical privacy. Like in *Reitman*, the government action in this case has “embodied,” in specific HHS regulations, the right for third parties to violate the constitution and the government provides express “authority” for those violations.

The bottom line is that, in the present case, the Plaintiffs-Appellants cannot protect their constitutional right to medical privacy under the current HHS Amended Privacy Rule. And that is really the ultimate criterion. As the Supreme Court recently stated, the state action doctrine is designed “to assure that constitutional standards are invoked ‘when it can be said that the State is responsible for the specific conduct of which the plaintiff complains.’” *Brentwood Academy v. Tennessee Secondary School Athletic Association*, 531 U.S. 288, 295 (2001). Whether the state is responsible for the specific conduct is a matter of normative judgment, and the criteria lack rigid simplicity. @ *Id.*

III. THE HIPAA AMENDED PRIVACY RULE UNCONSTITUTIONALLY INTERFERES WITH INDIVIDUALS' ABILITY TO SAFEGUARD PRIVATE MEDICAL INFORMATION FROM DISCLOSURE.

The District Court, relying solely on the *DeShaney* line of cases, erroneously determined that there was not sufficient state action to evaluate the constitutionality of the underlying disclosure scheme the government created via the Amended Privacy Rule. *See* District Court Opinion at *15-16. Because, as described above, state action may arise in situations that fall short of direct, compulsory regulation, the District Court should have considered whether the Amended Privacy Rule comports with traditional constitutional standards. Specifically, the District Court should have considered whether the Plaintiffs-Appellants have a privacy interest in identifiable medical information, and whether the government had a compelling governmental interest in nonconsensual disclosure sufficient to override the individual privacy interest.

A. Disclosural Privacy With Respect To Medical Information Is A Constitutionally Protected Right.

All citizens enjoy certain constitutional protections that form the very bedrock upon which our government is founded, and federal courts have long recognized their duty to zealously . . . protect individuals from abridgments of their rights to liberty and privacy...@ *See United States v. Berry*, 670 F.2d 583, 590 (5th Cir. 1982). Among the most important of these protections are the substantive Due Process clauses of the Fifth and Fourteenth Amendments which, *inter alia*, protect individuals from unwarranted

government intrusions into certain private realms. *See Lawrence v. Texas*, 123 S.Ct. 2472, 2475 (June 26, 2003).

There are two distinct forms of privacy which enjoy heightened protection under the United States Constitution. First, there is the constitutional right of privacy to make certain personal decisions without government interference, which the Supreme Court just affirmed again last term. *See Lawrence*, 123 S.Ct at 2476. Second, individuals enjoy the right to protect certain personal information, including medical information, from disclosure. *See Whalen v. Roe*, 429 U.S. 589, 599 (1977).

In *Whalen*, the United States Supreme Court made clear that the government cannot impair individuals' ability to protect private information from disclosure. *See id.* at 599. Interestingly, *Whalen* dealt specifically with individuals' right to protect their private medical information, and determined that this is a constitutionally protected fundamental right. *See id.*; *see id.* at 880 (Brennan, J., *concurring*). As a result, the government lacks power to engage in conduct that jeopardizes individuals' ability to protect private medical information from disclosure unless it clearly demonstrates that it has a compelling governmental interest for engaging in the conduct, and proves that its interests cannot be achieved by some less intrusive, or narrower means. *See id.* at 880.

The government program at issue in *Whalen* required physicians prescribing certain drugs to file a copy of the prescription with the state so that the information could be recorded in a centralized computer file in order to help control the distribution of

dangerous drugs. *See id.* at 593-94. Although the Court held that there was no constitutional violation under the facts of *Whalen*, that case did not involve public disclosure of medical information and, instead, the Court was persuaded that the significant security precautions and limitations of access to the information prevented a significantly grievous threat to the plaintiff's privacy rights. *See id.* at 594-95, 601.

However, the Court noted the limitations of its holding by stating as follows:

We therefore need not, and do not, decide any question which might be presented by the unwarranted disclosure of accumulated private data whether intentional or unintentional or by a system that did not contain comparable security provisions. We simply hold that this record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment.

Id. at 605. Therefore, *Whalen* clearly contemplated a situation, such as the one in this case, where disclosure of private medical information would jeopardize the Fifth and/or Fourteenth Amendment privacy rights of individuals.

The “unwarranted disclosure of accumulated private data,” referred to in the above quote from *Whalen*, is exactly the situation before the Court in the present case. As a result, the District Court should have applied the compelling interest test to the government's regulatory actions that have resulted in the loss of the ability of individuals to safeguard their confidential information provided in the course of medical treatment.

B. The Government Has Taken An Active Role To Regulate The Disclosure Of Individuals= Highly Confidential and Personal Medical Information.

The federal government has chosen to interject itself directly into the field of medical informational privacy by regulating the manner in which medical providers may disclose individuals= highly confidential information given in the course of health care. Specifically, as previously discussed, on April 14, 2001, the Secretary put into effect the Original Rule that governed such disclosure and that provided the following privacy standard: “[with certain exceptions] a covered health care provider must obtain the individual=s consent, in accordance with this section, prior to using or disclosing protected health care information to carry out treatment, payment, or health care operations.” 45 CFR 164.506(a); 66 Fed. Reg. at 12,434/1. This Original Rule contained limited exceptions to the privacy standard. *See, e.g.*, 45 CFR 164.506(a)(2)(i) and (ii) (exceptions for those with “indirect treatment relationship with the individual” and those providing services to inmates of prisons); 45 CFR 164.506(a)(3)(i)(A), (B), and (C) (exceptions for emergency treatment situations); 45 CFR 164.510(b)(1)(i) and (ii) (exceptions for disclosure to friends or relatives in certain circumstances).

On August 14, 2002, HHS abruptly reversed course and issued the Amended Privacy Rule that amended its previously enacted privacy standard. 67 Fed. Reg. 53, 187. The Amended Privacy Rule applies to roughly 600,000 “covered entities” and all of their “business associates,” and expressly provides regulatory permission for them to use

and disclose otherwise private medical information of their patients, even if the patients expressly object to their personal medical information being disclosed. *See* 67 Fed. Reg. at 53,211. This Amended Privacy Rule does not provide for notice to the individual of the actual use and disclosure of his or her personal health information for routine purposes, nor does it provide an opportunity for individuals to object to the repeated disclosure of their personal health information.

C. The Government Has Violated The Constitutional Right Of Disclosural Privacy.

The government=s about-face on the issue of medical privacy is particularly disturbing because, as already discussed above, it concerns the fundamental constitutional right of individuals to protect their private medical information. *See Whalen*, 429 U.S. at 599 (noting that privacy is a fundamental right encompassing a right to privacy in personal information). By enacting a regulation that removes the previous government-provided right of consent for medical information disclosure and by now providing for the effective free-flow of such information, the government has violated the constitutional guarantee of disclosural privacy for medical information.

It is important to note that the government has not simply assumed a position of neutrality and allowed private parties (namely patients and their medical providers) to order their affairs concerning use of medical information as they see fit. Rather, the government has chosen to actively interject itself into the relationship between patients

and covered entities by creating an elaborate regulatory scheme regarding disclosure and confidentiality, and by setting into play the very mechanism by which most Americans will forfeit all ability to control the use and disclosure of their private medical information. The government has redefined the duties of medical provider and patient in a manner that confers authority on medical providers to use and disclose the patient=s private medical information without that patient=s consent.

HHS is responsible for the actions that plaintiffs complain of in the present case, regardless of whether the government can characterize the Amended Privacy Rule as a “permissive state statute” that only gives “authorization” to deny individuals their right to privacy in personal information, in violation of the Constitution. *See Reitman*, 387 U.S. at 378. As the government has candidly admitted, privacy is a fundamental right that encompasses a right to privacy in personal information. Therefore, the Amended Privacy Rule should be invalidated unless HHS demonstrates a compelling governmental interest for engaging in the conduct, and proves that its interests cannot be achieved by some less intrusive, or narrower means.

D. The Government Has Not Articulated A Compelling Interest To Justify Its Actions, Nor Can It.

The government has not attempted to offer a compelling governmental interest in support of the Amended Privacy Rule. While the government contends that HHS was attempting to promote administrative simplification in the medical industry through its

regulatory enactment, this does not rise to the level of a “compelling governmental interest” that overrides individuals= constitutional right to medical privacy.

Moreover, it is highly unlikely that the government could offer any other interest that would qualify as “compelling” since the same HHS administration adopted a contrary privacy policy, in the Original Rule, less than two years prior to the enactment of the Amended Privacy Rule. Certainly, the government would have been able to identify any such “compelling” interest before it enacted the Original Rule, if one had existed.

IV. CONCLUSION.

For the foregoing reasons, the Texas Civil Rights Project believes that the government violated individuals= constitutional right to medical privacy by enacting its Amended Privacy Rule. As a result, the Amended Privacy Rule adversely impacts nearly all individuals who seek health care in this country, particularly including those individuals that TCRP frequently undertakes to represent.

Dated: September __, 2004

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Civil Procedure 32(a)(7)(C), the undersigned certifies that this brief complies with the type-volume limitations of Rule 29 and 32(a)(7)(B).

1. Exclusive of the exempted portions in Rule 32(a)(7)(B), the brief contains no more than 7,000 words.
2. The Brief has been prepared in proportionally spaced typeface, using Word XP in 14 point Times New Roman font.

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