ORAL ARGUMENT NOT YET SCHEDULED

United States Court of Appeals
for the District of Columbia Circuit

No. 15-1211,
Consolidated with 15-1218, 15-1244, 15-1290,
15-1304, 15-1306, 15-1311, 15-1313, 15-1314

ACA INTERNATIONAL, *et al.*,

Petitioners,

v.

FEDERAL COMMUNICATIONS COMMISSION;
and UNITED STATES OF AMERICA,

Respondents.

CAVALRY PORTFOLIO SERVICES, LLC; DIVERSIFIED CONSULTANTS, INC.; MRS BPO LLC; MERCANTILE ADJUSTMENT BUREAU, LLC; NATIONAL ASSOCIATION OF FEDERAL CREDIT UNIONS; CONIFER REVENUE CYCLE SOLUTIONS, LLC; COUNCIL OF AMERICAN SURVEY RESEARCH ORGANIZATIONS; MARKETING RESEARCH ASSOCIATION; GERZHOM, INC.,

Intervenors for Petitioner.

On Petitions for Review from an Order
of the Federal Communications Commission

BRIEF AMICUS CURIAE OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC. IN SUPPORT OF PETITIONER RITE AID HDQTRS. CORP

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December 2, 2015

CERTIFICATE OF PARTIES, RULINGS AND RELATED CASES

A. Parties and Amici. Except for the following *amici*, all parties, intervenors and *amici* appearing before the Commission and in this Court are listed in the Joint Brief for Petitioners ACA International *et al.* ("Joint Brief"): Internet Association and the National Rural Electric Cooperative.

B. Rulings Under Review. References to the rulings at issue appear in the Joint Brief.

C. Related Cases. Counsel is unaware of any related cases.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, *amicus curiae* the National Association of Chain Drug Stores, Inc. ("NACDS") submits the following corporate disclosure statement: NACDS is a non-profit, tax exempt trade association incorporated in Virginia. NACDS represents the interests of companies that operate four or more retail community pharmacies throughout the United States. NACDS has no parent corporation, and no publicly held corporation owns 10 percent of more of its stock.

Dated: December 2, 2015 By: /s/ Don L. Bell, II
Don L. Bell, II
Counsel for Amicus Curiae
National Association of
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GLOSSARY

AHRQ	Agency for Healthcare Research and Quality
CMS	Centers for Medicare and Medicaid Services
"Emergency Purposes Exception"	47 U.S.C. § 227(b)(1)(A)(iii)
FCC	Federal Communications Commission
FTC	Federal Trade Commission
GAO	Government Accountability Office
"Healthcare Exemption"	Exemption from TCPA requirements for certain healthcare communications only when satisfying specific requirements pursuant to the Order
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996, Pub.L. 104–191, 110 Stat. 1936
Order	Declaratory Ruling and Order, *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, 30 FCC Rcd. 7961 (2015)
TCPA	Telephone Consumer Protection Act of 1991, Pub. L. No. 102-243, 105 Stat. 2394

CERTIFICATE OF COUNSEL REGARDING
AUTHORITY TO FILE AND SEPARATE BRIEFING

On November 30, 2015, *amicus curiae* National Association of Chain Drug Stores, Inc. (NACDS) filed its Notice of Intent to File an *Amicus Curiae* Brief on Consent in Support of Petitioner Rite Aid Hdqtrs. Corp, stating it would limit its brief to no more than 5,000 words. Pursuant to Circuit Rule 29(d), counsel for *amicus curiae* NACDS* hereby certify that no other non-government *amicus* brief of which they are aware relates to the subjects addressed herein, more specifically, the healthcare implications of the Federal Communication Commission order under review.

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* Pursuant to Fed. R. App. P. 29(c), *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

IDENTITY AND INTEREST OF AMICUS CURIAE

The National Association of Chain Drug Stores, Inc. ("NACDS") submits this brief in support of its member and petitioner Rite Aid Hdqtrs. Corp ("Rite Aid").[1]

NACDS is a 501(c)(6) nonprofit trade association. Its mission includes advancing the interests and objectives of chain community pharmacies, including supporting their role as healthcare providers. NACDS membership consists of chain community pharmacy companies, including traditional drug stores, supermarkets, and mass merchants with pharmacies -- from regional chains with four pharmacies to national companies. NACDS members operate more than 40,000 pharmacies in the United States and employ 179,000 pharmacists. NACDS members fill more than 2.9 billion prescriptions annually and aid patients in taking their medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

As the trade association representing chain community pharmacies nationwide, NACDS has a significant interest in, and offers a unique perspective on, the important healthcare issues raised by Rite Aid. NACDS members have a

[1] To the extent permissible under Court rules, NACDS also concurs in the arguments related to reassigned numbers, automatic telephone dialing systems, and revocation of consent made in the Joint Brief For Petitioners ACA International *et al.* and the supporting brief submitted by *amici curiae* Retail Litigation Center, National Retail Federation and National Restaurant Association.

strong interest in ensuring that they are able to communicate healthcare messages to their patients directly and effectively, without unnecessary regulatory restrictions. NACDS believes that its perspective will assist the Court in resolving this case. *See* Fed. R. App. 29(b).

STATUTES AND REGULATIONS

Most relevant statutes and regulations are contained in the Brief for Petitioner Rite Aid. Where they are not, NACDS has listed them in its Table of Authorities herein.

SUMMARY OF THE ARGUMENT

NACDS supports Rite Aid's Amended Petition For Review, Non-binding Statement of Issues to Be Raised and Brief for Petitioner submitted in opposition to the Federal Communications Commission's ("FCC's") Declaratory Ruling and Order, *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, 30 FCC Rcd. 7961 (2015) ("Order"). As convincingly explained by Rite Aid, the Order's onerous restrictions on "prescription notifications" and other "healthcare" communications by pharmacies to their patients are arbitrary and capricious and contrary to law. *See* Brief for Petitioner Rite Aid ("Rite Aid Brief") at 6-12 (contrasting the promotion of pharmacy communications under HIPAA regulations and in prior FCC decisions with the Order that imposes unnecessary restrictions on pharmacy

communications). As a result, critical healthcare communications are burdened in a manner that conflicts with national healthcare policy.

Healthcare communications such as refill reminders and other prescription notifications that pharmacies send to their patients are critically important to improving patient health and lowering healthcare costs. Studies demonstrate, and government agencies recognize, that patients' failure to take their medications as prescribed harms their health, leading to preventable medical complications and necessitating additional physician interventions and increased hospitalizations. Failure to take medications as prescribed also has been demonstrated to increase overall healthcare costs by billions of dollars every year, due to increased medical problems that require additional medical interventions such as hospitalization. Reminders to patients to retrieve, to replenish and to take their medications as prescribed have been proven to help patients follow their doctors' orders, thereby improving health outcomes and avoiding unnecessary medical costs.

The Order imposes improper restrictions on these helpful pharmacy healthcare communications, contrary to exceptions created by Congress in the Telephone Consumer Protection Act of 1991, 47 U.S.C. § 227 *et seq.*("TCPA"). Rather than uphold onerous restrictions on pharmacies' healthcare messages sent to their patients' wireless phones, the Court should recognize that such calls and texts fall within the "emergency purposes" exception under the TCPA. *See* 47

U.S.C. § 227(b)(1)(A)(iii). This exception recognizes the important purpose of communications impacting consumer "health and safety," and excludes them from the restrictions of the TCPA. The Order neutralizes this exception, imposing several unworkable conditions and requirements before communications by pharmacies affecting their patients' "health and safety" may be made to a wireless phone. Beyond violating the TCPA's emergency purposes exception, the Order unlawfully burdens speech in violation of the First Amendment to the U.S. Constitution.

ARGUMENT

I. Healthcare Communications By Pharmacies To Their Patients' Wireless Phones Are Critical To Improving Patient Health And Lowering Healthcare Costs.

Pharmacies provide their patients with several types of important healthcare communications, which arguably fall within the FCC category of "prescription notifications." *See* Order at ¶ 146. These pharmacy communications remind patients to pick up prescriptions they previously asked their pharmacist to fill, remind patients they are due to refill prescriptions pursuant to their doctors' orders, remind patients that it is time to get their annual flu shots as they have at their pharmacy in the past, inform patients about potential safety issues associated with their medications such as drug recalls, and inform patients about the importance of following appropriate directions for use of their medications. These prescription

notifications rapidly and conveniently alert patients to important and time-sensitive information that is critical to the medically appropriate use of their prescribed medications.

Prescription notifications such as refill reminders and related healthcare communications from pharmacies address a major medical problem: Millions of Americans forget to take their medications as prescribed by their doctors. Studies consistently show that twenty to thirty percent of prescriptions are never filled, and half of medications for chronic disease are not taken as prescribed.[2] This has significant healthcare implications.

Failure to take medications as prescribed, known as medication non-adherence, harms patient health. Non-adherent patients are more likely to experience preventable disease progression, increased hospitalizations, doctor and emergency room visits and other problems arising from poor health.[3] Non-adherence causes an estimated 125,000 deaths a year and up to ten percent of all

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[2] A. Iuga, *et al.*, "Adherence and Health Care Costs," Risk Management and Health Care Policy (2014):7, 35-44, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/pdf/rmhp-7-035.pdf; M. Viswanathan, *et al.*, "Closing the Quality Gap: Revisiting the State of the Science," Medication Adherence Interventions: Comparative Effectiveness, AHRQ Pub. No. 12-E010-EF (Sept. 2012), available at http://www.ncbi.nlm.nih.gov/books/NBK114350/.

[3] A. Iuga, *et al.*, *supra*, at 36.

hospitalizations.[4] Medication adherence is particularly important to a broad range of serious chronic conditions such as heart disease and depression.[5] Non-adherence allows chronic conditions to progress, leading to avoidable complications and reduced well-being. Addressing this problem becomes more pressing as the number of Americans with chronic illnesses increases.[6]

Failure to take medications as prescribed also dramatically increases overall healthcare costs. Medication non-adherence causes up to $290 billion in increased

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[4] M. Viswanathan, *et al.*, "Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review," *Ann Intern Med* (2012);157(11):785-795, (Nov. 20, 2015), http://annals.org/article.aspx?articleid=1357338.

[5] *See, e.g.*, N. Choudhry, *et al.*, "Untangling the Relationship Between Medication Adherence and Post-Myocardial Infarction Outcomes," *Am Heart J* (2014); 167(1):51-58, (Nov. 20, 2015), http://www.ahjonline.com/article/S0002-8703(13)00667-4/fulltext (finding that achieving medication adherence of 80% or higher reduced the risk of hospital readmission after a heart attack); D. Pittman, *et al.*, "Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations," *Am. J. of Cardiology* (June 2011) at 1662, 1665-66, available at http://www.ajconline.org/article/S0002-9149(11)00465-6/pdf (finding that patients with high rates of adherence to statins had significantly lower total healthcare costs and lower risk of cardiovascular disease-related hospitalizations); C. Melfi, *et al.*, "The Effect of Adherence to Antidepressant Treatment Guidelines on Relapse and Recurrence of Depression," *Arch Gen Psychiatry* (1998);55(12):1128-1132, (Nov. 20, 2015), http://archpsyc.jamanetwork.com/article.aspx?articleid=204538 (concluding that adherence to depression treatment guidelines with an antidepressant reduces the probability of relapse or recurrence).

[6] Chronic diseases affect approximately 133 million Americans, and that number is expected to increase to 157 million by 2020. Centers for Disease Control and Prevention, The Power of Prevention (2009), available at www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf.

healthcare costs every year, due to preventable medical complications and resulting physician visits and hospitalizations.[7]

Pharmacy healthcare communications such as refill reminders and other prescription notifications ameliorate the harmful impact of medication non-adherence.[8] Pharmacy medication adherence programs have a demonstrated track record of improving patient health while simultaneously decreasing overall healthcare costs. For example, a 2013 study performed for the federal Centers for Medicare and Medicaid Services ("CMS") found that medication therapy management programs consistently and substantially improved medication adherence for Medicare patients, leading to significant reductions in hospital costs, such as average savings of $400 to $525 in hospitalization costs for each patient with diabetes and congestive heart failure.[9] Additionally, a 2012 study identified the key role that community pharmacies play in improving patient medication

[7] New England Healthcare Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," Research Brief (August 2009), available at http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf .

[8] A. Iuga, *et al.*, *supra*, at 40 (listing reminders and 'automated alerts" as strategies to improve medication adherence).

[9] D. Perlroth, *et al.*, "Medication Therapy Management in Chronically Ill Populations: Final Report Prepared for CMS" (August 2013) at 9, 83, 113, available at https://innovation.cms.gov/files/reports/mtm_final_report.pdf.

adherence, concluding that pharmacy adherence programs contributed to improved behavior with a return on investment of three to one.[10]

The federal government agrees that communicating with patients about the importance of taking their medications as prescribed helps improve patient health and decrease healthcare costs. Congress recognized the importance of medication adherence when it required Medicare drug plans to provide "medication therapy management" services, such as services that "increase[] enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs…." 42 U.S. Code § 1395w–104(c)(2)(B)(ii). The Congressional Budget Office has adjusted its legislative scoring methodology to account for savings that accompany an increase in appropriate use of prescription medicines by Medicare patients.[11]

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[10] T. A. Brennan, *et al.*, "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients," *Health Affairs* 31, no. 1 (2012), at 125, 126 , (Nov. 9, 2015), http://content.healthaffairs.org/content/31/1/120.full; s*ee also* J. Pringle, *et al.*, "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence And Reduced Health Care Costs," *Health Affairs* 33, no. 8 (2014), at 1444, 1449, (Nov. 18, 2015), http://content.healthaffairs.org/content/33/8/1444.full.pdf+html (pharmacy adherence program increased medication adherence by 75%, generating average savings of $341 per patient receiving oral diabetic medication and $241 for patients receiving a statin).

[11] Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, (Nov. 2012), at 1, available at https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-

One of the critical tools that pharmacists use to help increase medication adherence is to quickly and efficiently contact patients on their phones to alert them to information related to their prescriptions.[12] Studies demonstrate that telephonic prescription notifications improve patient health and simultaneously decrease overall healthcare costs, leading to fewer hospitalizations and better health outcomes, and saving lives.[13] After reviewing more than 100 studies, the U.S. Department of Health and Human Services ("HHS") found "encouraging evidence related to the use of health text messaging to improve health promotion,

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MedicalOffsets-11-29-12.pdf (estimating that a 1% increase in the number of prescriptions filled by Medicare beneficiaries causes overall Medicare spending on medical services to fall by roughly one-fifth of 1%).

[12] The vast majority of patients like these types of communications and choose not to opt-out of receiving them. *See, e.g., Kolinek v. Walgreen Co.*, Case No. 13-cv-04806 (N.D. Ill.), Plaintiff's Motion for Preliminary Approval of Class Action Settlement (March 26, 2015) (Dkt. No. 98), at 11 (explaining that even though patients could easily opt out of receiving future pharmacy calls by pressing a single number on the keypad or by other means, overall opt-out rate has been less than 1.5%, and for the most recent year was less than 0.7%).

[13] *See, e.g.*, P. Odegard, *et al.*, "MAP Study: RCT of Medication Adherence Program for Patients with Type 2 Diabetes," *J Am Pharm Assoc* (2003) 2012; 52: 753-762, (Nov. 18, 2015) http://japha.org/article.aspx?articleid=1392753 (brief pharmacy calls to patients who failed to refill their diabetes prescriptions led to statistically significant increase in medication adherence); L. Marzak, *et al.*, "Cognitive Dysfunction and Poor Health Literacy are Common in Veterans Presenting with Acute Coronary Syndrome: Insights from the MEDICATION Study," *Patient Preference And Adherence* (2015) 9: 745–751, (Nov. 24, 2015) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467742/ (Veterans Affairs researchers found refill reminders and other pharmacy calls were significant factor in improving medication adherence among veterans experiencing cognitive disfunction).

disease prevention, and disease management."[14] In 2012, two independent, randomized studies showed that receiving a text message more than doubled the percentage of low income families who sought flu vaccines for their infant children, and doubled-to-tripled the percentage of low income families who sought meningococcal and tetanus-diphtheria-acellular pertussis vaccines for their adolescent children.[15] Now that nearly fifty percent of households no longer have residential landline phones,[16] permitting pharmacists to make prescription notification calls and other healthcare calls to wireless phones is critical to achieving better health outcomes.

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[14] HHS Health Resources and Services Admin., *Using Health Text Messages to Improve Consumer Health, Knowledge, Behaviors and Outcomes: An Environmental Scan* (May 2014) at 27, available at http://www.hrsa.gov/healthit/txt4tots/environmentalscan.pdf; *see also* T. Harrison, "A Randomized Controlled Trial of an Automated Telephone Intervention to Improve Blood Pressure Control," *J. Clinical Hypertension* (Sept. 2013) 650;15(9), available at http://onlinelibrary.wiley.com/doi/10.1111/jch.12162/pdf (evaluating effectiveness of telephonic outreach program to improve blood pressure control among patients with hypertension and concluding healthcare organizations should consider using telephone outreach for quality-improvement interventions).

[15] M. Stockwell, *et al.*, "Text4Health: Impact of Text Message Reminder-recalls for Pediatric and Adolescent Immunizations," *AM. J. Public Health* (Feb. 2012) e15;102(2), (Nov. 20, 2015), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3483980/ (demonstrating through two studies that text messaging for reminder–recalls improved immunization coverage).

[16] *See* CITA – The Wireless Assoc., Annual Wireless Industry Survey (Year-end 2014), (Nov. 20, 2015), http://www.ctia.org/your-wireless-life/how-wireless-works/annual-wireless-industry-survey (showing that 44% of U.S. households were wireless in 2014, a five percent increase from 2013).

Notably, using an automated system to make pharmacy healthcare calls is supported by the federal government's own research. A recent study funded by the HHS Agency for Healthcare Research and Quality ("AHRQ") concluded that prescription refill reminders sent via automated telephone calls "significantly increased adherence" to statins and other cardiovascular disease medications, leading to significantly lower cholesterol levels among at-risk patients.[17] Other studies demonstrate similar success for medication adherence programs that utilize automated telephone calls.[18] In fact, AHRQ has posted on its website a guide promoting the use of automated telephone refill reminders entitled "Automated Telephone Reminders: A Tool to Help Refill Medicines On Time."[19] The AHRQ publication notes that "non-adherence to prescription medications is a documented

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[17] M. Vollmer, *et al.*, "Improving Adherence to Cardiovascular Disease Medications With Information Technology," *Am J Manag Care* (2014);20 (11 Spec No. 17):SP502-SP510, (Nov. 18, 2015), http://www.ajmc.com/journals/issue/2014/2014-11-vol20-SP/Improving-Adherence-to-Cardiovascular-Disease-Medications-With-Information-Technology/.

[18] *See, e.g.*, T. Harrison, *et al.*, "Automated Outreach for Cardiovascular-Related Medication Refill Reminders," *J Clin Hypertens* (2015): 10.1111/jch.12723, available at http://onlinelibrary.wiley.com/doi/10.1111/jch.12723/epdf ; B. Bender, *et al.*, "Pragmatic Trial of Health Care Technologies to Improve Adherence to Pediatric Asthma Treatment," *JAMA Pediatr*. (2015);169[4]:317-323, (Nov. 18, 2015), http://archpedi.jamanetwork.com/article.aspx?articleid=2108035&resultClick=3.

[19] AHRQ Pub. No. 08-M017-EF (2008), (Nov. 18, 2015), http://archive.ahrq.gov/research/findings/factsheets/tools/callscript/pharmacy-call-scripts.html.

public health problem,"[20] and concludes that "telephone reminders to refill or pick up prescriptions improve medication adherence."[21]

II. Pharmacy Healthcare Communications To Patients' Wireless Phones Satisfy the TCPA "Emergency Purposes" Exception.

The TCPA's restrictions on calls to wireless phones do not apply to calls "made for emergency purposes…." 47 U.S.C. § 227(b)(1)(A)(iii) ("Emergency Purposes Exception"). The TCPA's legislative history, the FCC's own rules, and statements of other stakeholder agencies, demonstrate that prescription notifications and related healthcare communications[22] sent by pharmacies to their patients' wireless phones are exactly the type of critical communications covered by the Emergency Purposes Exception.

The FCC has acknowledged that the legislative history of the TCPA shows that Congress intended "emergency purposes" to be interpreted "broadly rather

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[20] *Id.*, *citing, inter alia,* H. McDonald *et al.*, "Interventions to Enhance Patient Adherence to Medication Prescriptions: Scientific Review," *JAMA* (2002);288: 2868-79.

[21] AHRQ Pub. No. 08-M017-EF, *supra*, *citing* D. Kennedy, *et al.*, "Evaluation of Patient Adherence From a Telephone Intervention Program in Community Pharmacy Practice," *Virginia Pharm* (2000);84(Nov):23-27; C. Simkins, *et al.*, "Evaluation of a Computerized Reminder System in the Enhancement of Patient Medication Refill Compliance," *Drug Intell & Clin Pharm* (1986);20(Oct):799-802; *and* F. Ascione, *et al.*, "Evaluation of a Medication Refill Reminder System for a Community Pharmacy," *Pt Educ & Couns* (1985);7(2):157-65.

[22] NACDS adopts Rite Aid's description of such communications as HIPAA-covered healthcare communications, *see* Rite Aid Brief at 3-5, subject to federal privacy laws and applies its arguments herein only to HIPAA-covered healthcare communications, which Rite Aid refers to as "healthcare communications."

than narrowly." *See In the Matter of the Telephone Consumer Protection Act of 1991*, 7 FCC Rcd 2736, ¶17 (1992); *see also Statement of Cong. Edward Markey, Chair, House Telecom. & Fin. Subcommittee*, 137 Cong. Rec. H 11307-01 (Nov. 26, 1991) (discussing broad application of the "emergency purposes" exception). Consistent with that congressional mandate, the FCC's definition of "emergency purposes" includes "health" and "safety" messages, and is not limited to sudden catastrophic events: "The term 'emergency purposes' means calls made necessary in *any situation affecting the health* and safety of consumers." 47 C.F.R. § 64.1200(f)(4) (emphasis added).

However, the FCC has failed to properly apply the broad Emergency Purposes Exception to prescription notifications and other pharmacy healthcare calls and texts to patients' wireless phones**.** Rather, it imposed a burdensome exemption for healthcare communications to wireless phones ("FCC Healthcare Exemption"). For example, the FCC Healthcare Exemption adds an unexplained and undefined "exigency" requirement. *See* Rite Aid Brief at 11 (explaining how HIPAA-covered communications are not subject to an exigent requirement). The FCC Healthcare Exemption also imposed a no cost requirement, which bars healthcare calls and texts that count against the call recipient's cell phone plan minutes. Order at ¶ 148. Additionally, the FCC Healthcare Exemption restricts the content, length, frequency and number of healthcare communications to

patients' wireless phones, even though these restrictions can impede the ability of a pharmacy to provide sufficient healthcare information to patients. *Id.* at ¶ 147.

When the FCC imposed these burdens as part of the FCC Healthcare Exemption, however, the FCC failed to consider the existing Emergency Purposes Exception for communications related to health and safety, which has already been established by the TCPA and the FCC's own implementing regulations. This inexplicable failure is arbitrary and capricious because, as a result, healthcare communications from pharmacies to patients' wireless phones are made subject to the burdensome FCC Healthcare Exemption even though they fall squarely within the FCC's own definition of "emergency purposes" which *excludes* pharmacy healthcare calls and texts from TCPA requirements.

The FCC has neutralized the Emergency Purposes Exception with this new burdensome FCC Healthcare Exemption, putting at risk the public health that the Emergency Purposes Exception was meant to protect. We ask the Court to recognize that prescription notifications and other healthcare communications by pharmacies to their patients' wireless phones affect the health of patients[23] and qualify as a necessary communication for "emergency purposes" under the TCPA, without the burdensome requirements imposed by the FCC Healthcare Exemption.

[23] *See* discussion, *supra*, at Argument Section I (reviewing multiple studies and reports by the government and others which show that patient health is improved by these communications).

Applying the Emergency Purposes Exception to refill reminders and other pharmacy healthcare communications to patients would be consistent with government-wide treatment of healthcare communications. HHS, the Federal Trade Commission ("FTC"), and even the FCC[24] have determined that refill reminders and similar prescription notification calls are beneficial health-related messages that deserve special legal status. HHS, for example, ruled that "to ensure essential healthcare communications are not impeded," HIPAA's prohibition on using patient health information for "marketing" purposes without the patient's consent specifically excludes communications made "[t]o provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual . . ."[25] As a result, HHS allows pharmacies to make refill reminders and other healthcare calls to their patients without the patient's prior authorization.

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[24] The FCC has recognized the benefit and need for special legal status for healthcare communications, when made via landlines. *See* Rite Aid Brief at 9; *c.f.* discussion, *supra*, at 9 (discussing Congressional support for these communications in the Medicare program).

[25] *See* HHS Office of Civil Rights, "The HIPAA Privacy Rule and Refill Reminders and Other Communications about a Drug or Biologic Currently Being Prescribed for the Individual," (Nov. 24, 2015), http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketingrefillreminder.html; *see also* 45 C.F.R. § 164.501 (definition of "marketing" under HIPAA "does not include a communication made … [t]o provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual…").

The FTC similarly exempted these pharmacy healthcare calls from the prior written consent requirement for recorded telemarketing calls, noting that these calls generate "demonstrable improvements in patient outcomes." 73 Fed. Reg. 51164, 51191 (Aug. 29, 2008) (codified at 16 C.F.R. §§ 310.1, *et seq.*). The FTC recognized that

> "[w]hile proactive patients who are attentive to their healthcare may be likely to provide a written agreement to authorize prerecorded messages from their healthcare providers, such reminder and other communications are most needed by the patients who are least attentive to their healthcare—those who 'frequently procrastinate or make ill-informed decisions'—and therefore are least likely to get around to responding to requests for authorization to receive such calls." *Id.*

As such, the FTC concluded that "[r]equiring the prior written agreement of patients to receive prerecorded calls subject to HIPAA quite obviously could burden or jeopardize the improved medical outcomes that such calls have made possible by enabling healthcare providers to achieve higher rates of patient compliance with treatment regimens at low cost." *Id.* (discussing GAO studies showing that "low rates of patient compliance contributed to significantly higher than necessary national healthcare costs because they resulted in increased hospitalizations, morbidity and mortality rates."). For the reasons stated above, we ask the Court to find that pharmacy healthcare communications are necessary for patient health and covered by the Emergency Purposes Exception, and to vacate the Order.

III. The Order Violates the First Amendment

Under the First Amendment, "Congress shall make no law … abridging the freedom of speech . . . ." U.S. Const. Amend. I. "Abridging the freedom of speech" includes not only banning but also burdening speech because "the "distinction between laws burdening and laws banning speech is but a matter of degree." *U.S. v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 812 (2000). The level of scrutiny applied to government regulation of speech depends on the type of speech restricted and the nature of the government restriction. *See, e.g.*, *State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (describing the intermediate scrutiny standard used to evaluate restrictions on commercial speech).

A law that bans or burdens speech irrespective of its content, such as a law that restricts, time, place or manner of speech, is reviewed under intermediate scrutiny. *See Moser v. FCC*, 46 F.3d 970, 973 (9th Cir. 1995). To survive this review, a law must be "justified without reference to the content of the regulated speech," "narrowly tailored to serve a significant governmental interest," and "leave open ample alternative channels for communication of the information." *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (citations omitted).

At a minimum, the FCC Healthcare Exemption requirements burdening healthcare communications from pharmacies to patients' wireless phones are subject to intermediate scrutiny. Under that standard, the Order fails to meet the

"narrowly tailored" requirement. The FCC may argue that the governmental interest the TCPA is meant to protect are privacy, preventing abusive telemarketer calls, and in connection with wireless phones, costs to the consumers for such calls. *See* Rite Aid Brief at 3-4 (describing the intent of TCPA to restrict telemarketer calls); Order at ¶¶ 144, 146, 148 (addressing the desire to protect patient privacy and guard against consumer costs for wireless calls). [26] Even assuming these were the interests that Congress sought to address in the TCPA, the FCC overreaches, colliding head on with another Congressionally-recognized significant government interest: promotion of healthcare communications.

The FCC, HHS and FTC have repeatedly recognized the substantial interest in allowing patients to receive unburdened healthcare communications from their providers.[27] The FCC recognizes this substantial interest in its own implementation of the Emergency Purposes Exception. Under that exception, the FCC excludes from TCPA requirements *any* communications if they are necessary to the recipient's health or safety. By doing so, the FCC concedes that calls related to patient health and safety should be completely unburdened by TCPA requirements, regardless of other government interests protected by TCPA.

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[26] *But see* Joint Petitioner Brief at 1, 14-15, 27 (describing, instead, the intent of the TCPA to restrict the use of prerecorded calls and certain autodialing systems).

[27] *See discussion, supra*, at Argument Section II (*citing* HHS and FTC rules regarding the treatment of healthcare communications).

Because the new FCC Healthcare Exemption restricts pharmacy healthcare communications to wireless phones[28] that the TCPA specifically declines to restrict under its Emergency Purposes Exception, the FCC Healthcare Exemption is not "narrowly tailored" to withstand First Amendment scrutiny. *See McCullen v. Coakley*, 573 U.S. __, 1345 S. Ct. 2518, 2534-37 (2014) (striking down a content neutral ordinance as too burdensome and not narrowly tailored for the purposes of achieving the government's interest).

Consequently, the FCC Healthcare Exemption for healthcare communications to patient wireless phones, such as pharmacy refill reminders, should be struck down as unlawful under the First Amendment, and instead the Court should apply the TCPA's Emergency Purposes Exception to refill reminders and other pharmacy healthcare communications.

[28] In light of the ubiquitous presence of wireless phones, and their ever growing replacement of landlines, it is difficult to justify discriminating against wireless phone users when deciding who should be the recipient of important, timely, unburdened healthcare communications. It should matter, for the purposes of satisfying the substantial government burden, that the number of consumers who rely exclusively on wireless phones to communicate with their pharmacies and healthcare providers (and indeed with anyone) has grown rapidly and will continue to grow. *See* fn. 16, *supra*, reflecting annual increase in wireless-only households.

CONCLUSION

For the reasons stated above, the Order should be vacated, and healthcare communications by pharmacies to their patients should be recognized as "necessary" and "affecting the health and safety of consumers" placing them within the Emergency Purposes Exemption.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I certify the following:

This brief complies with the type-volume limitations of Fed. R. App. P. 29(d) because it contains 4,567 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of December, 2015, a true and correct copy of the foregoing Brief of Amicus Curiae the National Association of Chain Drug Stores, Inc. in Support of Petitioner Rite Aid Hdqtrs. Corp was filed with the Clerk of the United States Court of Appeals for the D.C. Circuit via the Court's CM/ECF system. Except as noted below, counsel for the parties are registered CM/ECF users and will be served by the appellate CM/ECF system. The following counsel for the parties that are not registered CM/ECF users will be served via first class mail, postage pre-paid:

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