

**Before the  
FEDERAL COMMUNICATIONS COMMISSION  
Washington, D.C. 20554**

In the Matter of	)	
	)	
Acurian, Inc. Petition for Declaratory Ruling	)	CG Docket No. _____
Regarding Telephone Communications Seeking	)	
Candidates for Clinical Trials	)	
	)	
Rules and Regulations Implementing the	)	CG Docket No. 02-278
Telephone Consumer Protection Act of 1991	)	

**PETITION FOR DECLARATORY RULING**

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February 5, 2014

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**PETITION FOR DECLARATORY RULING**

Pursuant to Section 1.2 of the Commission’s rules,<sup>1</sup> Acurian, Inc. (“Acurian”) respectfully requests that the Commission issue a declaratory ruling clarifying that a telephone call to a residential landline seeking an individual’s participation in a clinical pharmaceutical trial is exempt from the restrictions on prerecorded calls enacted as part of the Telephone Consumer Protection Act of 1991 (“TCPA”) and codified at 47 U.S.C. § 227(b)(1)(B). Such relief not only would be entirely consistent with existing law, but also would serve the public interest, as it would put an end to a growing number of abusive lawsuits that drive up the cost of clinical trials and frustrate the pharmaceutical testing process mandated by the Food and Drug Administration (“FDA”).

**INTRODUCTION AND SUMMARY**

TCPA class actions are on the rise,<sup>2</sup> driven in no small part by plaintiffs’ class action lawyers searching for new ways to capitalize on perceived ambiguities in the statute and the

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<sup>1</sup> 47 C.F.R. § 1.2; 5 U.S.C. § 554(e).

<sup>2</sup> See *infra* text accompanying notes 19 and 20.

Commission’s implementing rules.<sup>3</sup> One of the targets of these opportunistic lawsuits has been Acurian, a company that identifies and contacts potential candidates for particular clinical drug trials and then refers such individuals to doctors who are participating in such trials. Plaintiffs’ class action lawyers have begun arguing that Acurian’s use of prerecorded messages in telephone calls to potential drug trial candidates violates 47 U.S.C. § 227(b)(1)(B), a provision of the TCPA prohibiting parties from “initiat[ing] any telephone call to any residential telephone line using an artificial or prerecorded voice to deliver a message without the prior express consent of the called party” unless the call “is exempted by rule or order by the Commission under paragraph (2)(B).”

Acurian has long understood that its calls fall squarely within the exemptions adopted by the Commission, which include calls “not made for a commercial purpose”—*e.g.*, “research” or “market survey” calls<sup>4</sup>—as well as calls “made for a commercial purpose” but that do “not introduce or include an advertisement or constitute telemarketing.”<sup>5</sup> Nevertheless, in an ongoing California case where the plaintiff alleges Acurian has violated the TCPA and is pursuing a putative class action seeking \$5 million in damages, the court summarily denied a motion to

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<sup>3</sup> Several courts have recently noted the rising phenomenon of TCPA lawsuit abuse, whereby plaintiffs’ class action lawyers seek to obtain disproportionate attorneys’ fees with little benefit to the class members. *See West Concord 5-10-1.00 Store, Inc. v. Interstate Mat Corp.*, No. 2010-00356, 31 Mass. L. Rep. 58 (Mass. Super. Ct. March 5, 2013) (denying class certification and rejecting use of TCPA “as a device for the solicitation of litigation” and “to generate legal fees where attorneys’ stake in certification far greater than class members”); *Saunders v. NCO Fin. Sys., Inc.*, 910 F. Supp. 2d 464, 465 (E.D.N.Y. 2012) (granting summary judgment in TCPA case and noting “remedial laws can themselves be abused and perverted into money-making vehicles for individuals and lawyers”).

<sup>4</sup> *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, Report and Order, 7 FCC Rcd 8752 ¶ 41 (1992) (“1992 TCPA Order”).

<sup>5</sup> *See* 47 C.F.R. § 64.1200(a)(3)(ii)-(iii).

dismiss filed citing these exemptions. This development now threatens to give rise to copycat lawsuits across the country.

Acurian thus urges the Commission to issue a declaratory ruling clarifying that its exemptions from 47 U.S.C. § 227(b)(1)(B) do indeed cover calls that merely seek an individual's participation in a clinical drug trial. The Commission's prior orders addressing these exemptions strongly support the requested relief. In particular, the calls at issue here are closely analogous to the various examples provided by the Commission of calls "not made for a commercial purpose." Moreover, Acurian's calls plainly do not constitute "advertisements" or "telemarketing" as those terms are defined in the Commission's rules, and the Commission's orders construing these terms leave no doubt that they do not encompass the kinds of calls placed by Acurian.

The requested clarification also would serve the public interest. Such a ruling would help put an end to costly class action litigation that drives up the cost of new drug trials—and, by extension, the prices consumers pay for pharmaceuticals. In addition, such relief would facilitate subject enrollment in clinical trials and thus satisfaction of FDA regulations, which require clinical testing of new drugs before they are deemed safe and effective to market to the public. And finally, the requested clarification would be consistent with, and ensure the regulatory regime's compliance with, the First Amendment. For all these reasons, the Commission should promptly grant the clarification sought in this Petition.

## **BACKGROUND**

Acurian is a leading full-service provider of clinical trial patient recruitment and retention solutions for the life sciences industry. Among other things, Acurian provides a service that matches individuals to pending clinical drug trials. Acurian's matching service plays a key role

in the efforts of pharmaceutical companies to meet obligations under FDA regulations, which require such trials before a new drug is made available to the public.<sup>6</sup> Consistent with FDA guidance, Acurian aims to create suitable, diverse test pools in order to enhance the scientific value of these trials.<sup>7</sup>

In performing this service, Acurian identifies potential candidates for a particular trial, including those who have consented to receiving communications from Acurian regarding clinical trials, and then calls them—often using prerecorded messages to provide introductory information with the opportunity for live follow-up—to inform them of a clinical trial being conducted in their area. If the individual is interested and meets the eligibility requirements for the particular trial, Acurian refers him or her to doctors who are participating in the trial. Where doing so is consistent with the recruitment rules established for the target study, Acurian will complete the call by requesting the individual’s specific consent to be called again about future trials; if he or she declines to grant such consent, Acurian will no longer contact that individual.

These telephone communications do not entail commercial solicitation or marketing of any kind; the sole purpose of these calls is to contact the individual and refer him or her to a local doctor who is participating in a clinical trial in which they are interested. Acurian does not convey any information about the commercial availability of goods or services and does not solicit payment from the individuals it contacts. In fact, many of these individuals end up receiving reimbursements for their costs in participating in the trial (*e.g.*, travel costs) from the

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<sup>6</sup> See, *e.g.*, 21 C.F.R. § 314.50(d)(5) (requiring that all applications to the FDA to market new drugs must include a detailed section “describing the clinical investigations of the drug”).

<sup>7</sup> See FDA, *Inside Clinical Trials: Testing Medical Products in People*, available at <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143531.htm> (“It’s important to test medical products in a wide variety of people because drugs can work differently in people of various ages, races, ethnicity, and gender. The FDA seeks to ensure that people from many different groups are included in clinical trials.”).

pharmaceutical companies that are running the trials. Moreover, unlike marketing activities, which often aim to communicate with as many individuals as possible and usually involve an open-ended invitation to engage in a transaction, Acurian’s matching services are focused and inherently selective. In fact, Acurian often turns down requests to participate in trials when the individual would be a poor match or otherwise would not qualify for the trial.

Notwithstanding the fact that these calls do not have a commercial purpose, and despite their importance to ensuring the development of safe and effective drugs and to complying with FDA regulations, Acurian recently has been subject to various lawsuits alleging that such communications violate the TCPA. One such lawsuit, a putative class action pending in California seeking millions of dollars in damages,<sup>8</sup> relies on a provision of the TCPA codified at 47 U.S.C. § 227(b)(1)(B), stating that it is unlawful “to initiate any telephone call to any residential telephone line using an artificial or prerecorded voice to deliver a message without the prior express consent of the called party, unless the call is initiated for emergency purposes *or is exempted by rule or order by the Commission under paragraph (2)(B).*”<sup>9</sup> Paragraph (2)(B), in turn, authorizes the Commission to exempt “calls that are not made for a commercial purpose” and calls that “do not include the transmission of any unsolicited advertisement.”<sup>10</sup> And indeed, the Commission has adopted rules expressly exempting any calls “not made for a commercial purpose,” as well as calls “made for a commercial purpose” but that do “not introduce or include an advertisement or constitute telemarketing.”<sup>11</sup>

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<sup>8</sup> See *Blotzer v. Acurian, Inc.*, No. 13-cv-3438 (C.D. Cal. filed May 14, 2013).

<sup>9</sup> 47 U.S.C. § 227(b)(1)(B) (emphasis added).

<sup>10</sup> *Id.* § 227(b)(2)(B).

<sup>11</sup> See 47 C.F.R. § 64.1200(a)(3)(ii)-(iii). Under an earlier rule still in effect when the lawsuit was filed, the Commission’s exemption also extended to calls “made for a commercial purpose” but that did not constitute a “telephone solicitation.” See *Rules and*

Acurian filed a motion to dismiss the California suit in July 2013.<sup>12</sup> In addition to explaining that the plaintiff had actually provided express consent,<sup>13</sup> Acurian cited several district court decisions holding that messages that merely request a person’s participation in a research trial—without encouraging the person to engage in any future commercial transaction to purchase goods or services—are not prohibited under the TCPA and the Commission’s rules. For instance, Acurian pointed to a decision from a federal district court in Missouri holding that a message “announcing the existence of a clinical drug trial” and seeking “individuals willing to serve as test subjects” did not constitute an “advertisement” under the TCPA.<sup>14</sup> Acurian also cited a decision from a federal district court in Illinois holding that a message that promoted “a research study” did not constitute an “advertisement.”<sup>15</sup> Like Acurian’s calls, the message at issue in the Illinois case was not an “indiscriminate, open-ended invitation,” but rather made clear that “individuals interested in participating in the research study must be qualified and are pre-screened.”<sup>16</sup>

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*Regulations Implementing the Telephone Consumer Protection Act of 1991*, Report and Order, 18 FCC Rcd 14014 ¶ 141 n.478 (2003) (“*2003 TCPA Order*”).

<sup>12</sup> See *Blotzer v. Acurian, Inc.*, No. 13-cv-3438, Dkt. No. 13 (C.D. Cal. filed Jul. 29, 2013).

<sup>13</sup> See *Blotzer v. Acurian, Inc.*, No. 13-cv-3438, Dkt. No. 24, at 8 (C.D. Cal. filed Oct. 7, 2013).

<sup>14</sup> See *Ameriguard, Inc. v. Univ. of Kan. Med. Ctr. Research Inst., Inc.*, No. 06-0369-CV-W-ODS, 2006 WL 1766812, at \*1 (W.D. Mo. June 23, 2006).

<sup>15</sup> See *Phillips Randolph Enters., LLC v. Adler-Weiner Research Chi., Inc.*, 526 F. Supp. 2d 851, 853 (N.D. Ill. 2007).

<sup>16</sup> *Id.*; see also *Friedman v. Torchmark Corp.*, No. 12-CV-2837, 2013 U.S. Dist. LEXIS 114321 (S.D. Cal. Aug. 13, 2013) (concluding defendant’s calls informing plaintiff of opportunity to sell defendant’s products were not “advertisements” where plaintiff not required to pay for webinar).

Nevertheless, in September 2013, the court summarily denied Acurian’s motion without a written opinion,<sup>17</sup> and soon thereafter scheduled a jury trial on the merits.<sup>18</sup> In addition, various other TCPA lawsuits against Acurian—based on similar legal theories—have sprung up in jurisdictions across the country. So long as plaintiffs can exploit purported ambiguities in the Commission’s rules—and especially if they continue to survive the motion to dismiss stage on these meritless TCPA claims against Acurian—they will be emboldened to demand exorbitant payments as part of any settlement deal. And should a class ever be certified because ambiguities about what constitutes a telemarketing or commercial call prevent early dismissal, Acurian will face the Hobson’s choice that confront most class action defendants—settle the case with big fees for the plaintiffs’ attorneys or roll the dice with a jury and the potential of an enterprise-threatening damages award.<sup>19</sup>

As the Commission is no doubt aware, Acurian is not alone in facing a growing tide of opportunistic TCPA lawsuits. Recent studies have found that the number of TCPA lawsuits brought against companies communicating by telephone, text, and fax has skyrocketed in the past few years.<sup>20</sup> And yet, as one such study by the U.S. Chamber of Commerce points out, even as these lawsuits continue to proliferate, “it is rare these days to see TCPA litigation brought

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<sup>17</sup> See *Blotzer v. Acurian, Inc.*, No. 13-cv-3438, Dkt. No. 22 (C.D. Cal. Sep. 23, 2013).

<sup>18</sup> See *Blotzer v. Acurian, Inc.*, No. 13-cv-3438, Dkt. No. 23 (C.D. Cal. Oct. 4, 2013).

<sup>19</sup> See U.S. Chamber of Commerce, Institute for Legal Reform, *The Juggernaut of TCPA Litigation: Problems with Uncapped Statutory Damages*, at 3-5 (Oct. 2013), available at [http://www.instituteforlegalreform.com/uploads/sites/1/TheJuggernautofTCPALit\\_WEB.PDF](http://www.instituteforlegalreform.com/uploads/sites/1/TheJuggernautofTCPALit_WEB.PDF) (“U.S. Chamber of Commerce Study”).

<sup>20</sup> See, e.g., James G. Snell and Carlos P. Mino, *Telephone Consumer Protection Act Cases Are on the Rise*, Bloomberg Law, available at <http://about.bloomberglaw.com/practitioner-contributions/telephone-consumer-protection-act-cases-are-on-the-rise/> (noting reports that, “as of August 2012, there was a reported 54-percent increase in TCPA filings—many alleged as class actions—over the prior year”).

against its original intended target—abusive telemarketers.”<sup>21</sup> Instead, the targets of these lawsuits increasingly are legitimate businesses like Acurian, engaging in communications that are fully consistent with the letter and spirit of the TCPA, not to mention protected by the First Amendment.

## DISCUSSION

In light of the growing threat of TCPA lawsuits based solely on calls seeking participants for clinical trials—and the danger that more courts might allow such suits to proceed—the Commission should issue a declaratory ruling clarifying that Acurian’s communications are not subject to the restrictions in the TCPA or the regulations adopted thereunder. In particular, the Commission should specify that such communications fall within the exemption to 47 U.S.C. § 227(b)(1)(B) for calls “not made for a commercial purpose.”<sup>22</sup> Alternatively, if the Commission concludes that such communications do have a commercial purpose, the Commission should specify that these communications fall within the exemption for calls that do “not include or introduce an advertisement or constitute telemarketing.”<sup>23</sup> Such relief not only would be entirely consistent with Commission rules and orders construing these terms, but also would serve the public interest, as explained below.

### **I. THE REQUESTED RELIEF IS CONSISTENT WITH COMMISSION RULES AND PRECEDENT**

The Commission’s various orders and rules implementing and interpreting the TCPA strongly suggest that the telephone communications at issue here are exempt from the restrictions in 47 U.S.C. § 227(b)(1)(B), and therefore support the relief sought in this Petition.

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<sup>21</sup> U.S. Chamber of Commerce Study at 1.

<sup>22</sup> *See* 47 C.F.R. § 64.1200(a)(3)(ii).

<sup>23</sup> *See id.* § 64.1200(a)(3)(iii).

**A. The Commission’s Prior Orders Support a Ruling That Calls Seeking Participants for Clinical Trials Are “Not Made for a Commercial Purpose”**

As an initial matter, a ruling clarifying that calls seeking participants for clinical trials are “not made for a commercial purpose,”<sup>24</sup> and thus are exempt from the restrictions in 47 U.S.C. § 227(b)(1)(B), would be in line with longstanding Commission precedent. The Commission’s orders illustrate the distinction between calls “made for a commercial purpose” and calls “not made for a commercial purpose” largely by offering examples. In the *1992 TCPA Order*, the Commission noted that “the exemption for non-commercial calls from the prohibition on prerecorded messages to residences includes calls conducting research, market surveys, political polling or similar activities which do not involve solicitation.”<sup>25</sup> The Commission provided further examples of calls “not made for a commercial purpose” in the *2012 TCPA Order*, including “debt collection calls, airline notification calls, bank account fraud alerts, school and university notifications, research or survey calls, and wireless usage notifications,” so long as such calls do not also include a telemarketing message encouraging the called party to engage in a commercial transaction.<sup>26</sup>

These examples strongly indicate that calls seeking participants for clinical trials are properly considered calls “not made for a commercial purpose.” Like the Commission’s examples, the calls at issue here do not, and are not intended to, encourage the called party to engage in a commercial transaction, and indeed are analogous to the pure “research” calls that

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<sup>24</sup> See 47 C.F.R. § 64.1200(a)(3)(ii) (exempting calls “not made for a commercial purpose”).

<sup>25</sup> *1992 TCPA Order* ¶ 41.

<sup>26</sup> *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, Report and Order, 27 FCC Rcd 1830 ¶ 28 (2012) (“*2012 TCPA Order*”). Moreover, the *2012 TCPA Order* makes clear that this list “is only illustrative and by no means captures all of the calls” that would be exempt as non-commercial. *Id.* ¶ 28 n.76.

the Commission has twice deemed to be exempt.<sup>27</sup> Moreover, the Commission’s examples demonstrate that a call can qualify as one “not made for a commercial purpose” even if it arguably has some connection to commerce down the line. All of the examples above can be traced to some form of commercial activity—in some cases quite directly (*e.g.*, “debt collection calls”). Thus, the fact that Acurian’s calls facilitate enrollment in clinical trials, which in turn aid pharmaceutical companies in obtaining FDA approval for new drugs, which then (if approved) are made available in the stream of commerce, cannot serve as a basis for classifying these calls as having a “commercial purpose.” Indeed, under such an attenuated theory, virtually all calls would be deemed to have a commercial purpose and the Commission’s exceptions would be stripped of any meaning.

**B. The Commission’s Rules and Orders Also Support a Ruling That the Calls at Issue Are Not “Advertisements” or “Telemarketing”**

It is likewise clear that Acurian’s calls are exempt from the restrictions in 47 U.S.C. § 227(b)(1)(B) because they do not constitute “advertisements” or “telemarketing.”<sup>28</sup> The Commission’s rules define “advertisement” as “any material advertising *the commercial availability or quality of any property, goods, or services.*”<sup>29</sup> Similarly, “telemarketing” means “the initiation of a telephone call or message for the purpose of encouraging *the purchase or rental of, or investment in, property, goods, or services.*”<sup>30</sup> Plainly, the calls at issue here do not

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<sup>27</sup> See *id.* ¶ 28; 1992 TCPA Order ¶ 41. While the Commission’s “research” example presumably refers to scenarios where the research is conducted during the call itself (*e.g.*, surveys), the calls at issue here differ only in that they invite the individual to participate in a research study at a later time.

<sup>28</sup> See 47 C.F.R. § 64.1200(a)(3)(iii) (exempting calls that are “made for a commercial purpose” but that do “not include or introduce an advertisement or constitute telemarketing”).

<sup>29</sup> 47 C.F.R. § 64.1200(f)(1) (emphasis added).

<sup>30</sup> *Id.* § 64.1200(f)(12) (emphasis added).

satisfy either of these definitions.<sup>31</sup> Acurian’s messages are targeted solely at identifying individuals that might be eligible to participate in clinical drug trials; they do not make any mention of “property, goods, or services” offered for sale by Acurian or its clients—and they certainly do not “advertise” or “encourage the purchase” of any such property, goods, or services. To the contrary, until a study drug is approved by the FDA, it is illegal to market or sell that drug in the United States,<sup>32</sup> and Acurian’s calls do not involve the solicitation or marketing of anything.

A ruling confirming that such calls are not “advertisements” or “telemarketing” would be consistent with the Commission’s prior orders construing these terms. In both the *2003 TCPA Order* and the *2012 TCPA Order*, the Commission explained that, when deciding whether a particular call meets these definitions, the analysis “should turn . . . on the *purpose* of the message.”<sup>33</sup> Here, the purpose of the call is to match qualified individuals to clinical drug trials, not to advertise or encourage the purchase of any good or service.

The Commission has also clarified—consistent with its focus on the “purpose” of a call—that the term “advertisement” encompasses “offers for free goods or services that are part

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<sup>31</sup> See *Ameriguard, Inc. v. Univ. of Kan. Med. Ctr. Research Inst.*, 2006 U.S. Dist. LEXIS 42552 (W.D. Mo. June 23, 2006), *aff’d*, 222 Fed. Appx. 530 (8th Cir. 2007) (holding defendant’s fax announcing clinical drug trial did not advertise “commercial availability” of goods, services, or property); *Phillips Randolph Enters., LLC v. Adler-Weiner Research Chi., Inc.*, 526 F. Supp. 2d 851, 853 (N.D. Ill. 2007) (same, with respect to “research study”); see also *Friedman v. Torchmark Corp.*, 2013 U.S. Dist. LEXIS 114321 (S.D. Cal. Aug. 13, 2013) (concluding defendant’s calls informing plaintiff of opportunity to sell defendant’s products were not “advertisements” where plaintiff not required to pay for webinar).

<sup>32</sup> See 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.”); see also 21 C.F.R. §§ 314.1 *et seq.* (setting forth application procedures for obtaining FDA approval to market and sell new drugs).

<sup>33</sup> *2003 TCPA Order* ¶ 141 (emphasis added); see also *2012 TCPA Order* ¶ 31.

of an overall marketing campaign to sell property, goods, or services,”<sup>34</sup> as well as “dual purpose” calls that are “informational” but are motivated “by the desire to ultimately sell additional goods or services” to the called party.<sup>35</sup> But the calls at issue here do not fall into either of those categories. Acurian does not couple its offer of compensated (where the individual is reimbursed) or free participation in a trial with *any* other offer or marketing effort to sell *anything*. And Acurian’s calls do not reflect an abstract “desire” to sell goods or services to the called party; the message conveyed on the calls is targeted solely at seeking the called party’s participation in an FDA-mandated clinical trial.

Indeed, the fact that FDA rules require such trials<sup>36</sup> provides an additional basis for finding that Acurian’s calls are not “advertisements” or “telemarketing” under the TCPA. In the *2012 TCPA Order*, the Commission considered the status of “home loan modification and refinance calls” placed by a consumer’s loan service officer “pursuant to the Recovery Act.”<sup>37</sup> The Commission concluded that such calls “are not solicitation calls and do not include or introduce an unsolicited advertisement . . . because the primary motivation of the calling party is to comply with [the Recovery Act’s] outreach requirements.”<sup>38</sup> By the same token, a “primary motivation” behind Acurian’s calls is to match individuals to clinical trials so that pharmaceutical companies may meet the FDA’s pre-marketing testing requirements. Thus, the requested clarification would be entirely consistent with the Commission’s prior determinations

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<sup>34</sup> *2003 TCPA Order* ¶ 140.

<sup>35</sup> *Id.* ¶ 142.

<sup>36</sup> *See* 21 C.F.R. § 314.50(d)(5).

<sup>37</sup> *2012 TCPA Order* ¶ 31.

<sup>38</sup> *Id.*

regarding the meaning of “advertisement” and “telemarketing” under 47 C.F.R. § 64.1200(a)(3)(iii).

## **II. THE REQUESTED RELIEF WOULD SERVE THE PUBLIC INTEREST**

A ruling that such calls are exempt from the restrictions in 47 U.S.C. § 227(b)(1)(B) also would advance the public interest in at least two important respects. First, such a ruling would stamp out the threat of class action litigation based on these communications, thus lowering the cost of new drug trials and ultimately the prices consumers pay for pharmaceuticals. As the Commission is aware, the TCPA authorizes statutory damages of \$500 per violation (escalating to \$1,500 for willful violations).<sup>39</sup> Such damages claims add up quickly in class action lawsuits.

The class action that Acurian currently faces in California involves a damages claim of \$5 million, and plaintiffs’ lawyers, emboldened by the court’s denial of Acurian’s motion to dismiss, may well attempt to file additional lawsuits in other jurisdictions. Accordingly, the cost of litigating these suits and the risk of having to pay such exorbitant damages awards or coercive settlements must be built into the cost of recruiting individuals to participate in a drug trial, and thus into the cost of producing the drug itself. The declaratory ruling sought here would eliminate these substantial litigation costs, leading to more efficient recruitment of participants for clinical trials, more efficient drug development, and ultimately lower healthcare costs for consumers.

Second, such a ruling would facilitate compliance with FDA regulations designed to ensure the safety of drugs marketed to the public. As noted above, the FDA requires extensive clinical trials as a precondition to making new pharmaceuticals available to consumers. Denying the requested relief would severely hinder the process of matching individuals to clinical trials,

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<sup>39</sup> See 47 U.S.C. § 227(b)(3).

and frustrate pharmaceutical companies' efforts to comply with FDA regulations. It is therefore in the public interest for the Commission to clarify that the restrictions in 47 U.S.C. § 227(b)(1)(B) and the Commission's implementing rules do not apply the calls at issue in this Petition.

### **III. THE REQUESTED RELIEF WOULD BE CONSISTENT WITH THE FIRST AMENDMENT**

Finally, the requested clarification would ensure that the Commission's regulatory regime implementing the TCPA comports with the First Amendment. A contrary interpretation of the TCPA and the Commission's rules—one that would subject the calls at issue here to unnecessary restrictions and the threat of potentially crippling liability—would face, and almost certainly would fail, strict scrutiny. As explained above, the purpose of Acurian's calls is to contact and possibly refer individuals to doctors participating in clinical trials, not to convey information about the commercial availability of goods or services or to encourage the called party to engage in a commercial transaction. The Supreme Court has long held that, while intermediate scrutiny applies to restrictions on speech that does “no more than propose a commercial transaction,”<sup>40</sup> strict scrutiny generally applies to restrictions on noncommercial speech.<sup>41</sup>

For the reasons set forth in Section I.A, the fact that Acurian's calls to prospective clinical trial participants are not made for a commercial purpose, but instead are intended to convey information about clinical drug trials and to recruit participants, also signifies that the

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<sup>40</sup> *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983) (quoting *Va. Pharmacy Bd. v. Va. Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)); see also *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 562 (1980) (setting forth framework for analyzing restrictions on “speech proposing a commercial transaction”).

<sup>41</sup> See *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 796 (1988); see also *Mattel, Inc. v. MCA Records*, 296 F.3d 894, 906 (9th Cir. 2002) (“If speech is not ‘purely commercial’—that is, if it does more than propose a commercial transaction—then it is entitled to full First Amendment protection.”).

relevant speech is not considered “commercial” under First Amendment jurisprudence, and any restrictions therefore are subject to strict scrutiny. The Supreme Court also has explained that, even in cases where speech that could be characterized as “commercial” is “inextricably intertwined with otherwise fully protected speech,” the Court will “apply [its] test for fully protected expression.”<sup>42</sup> Thus, even if Acurian were to “propose a commercial transaction” on the call—and it does not—the fact that the call’s primary motivation is to refer individuals to clinical trials would subject any restrictions on such communications to strict scrutiny.

Under strict scrutiny, a ruling subjecting these calls to restrictions under the TCPA and the Commission’s rules would be upheld only “if it were a narrowly tailored means of serving a compelling state interest.”<sup>43</sup> It is highly unlikely that this exacting standard could be met in these circumstances. The government arguably lacks *any* interest (let alone a “compelling” one) in limiting communications that facilitate enrollment in FDA-mandated clinical trials. Moreover, an outright ban on such communications absent prior written consent would be a far cry from “narrowly tailored.”

*A fortiori*, a ruling that subjects the calls at issue in this Petition to a prior express consent requirement would fail under intermediate scrutiny as well. Under *Central Hudson*, a restriction on commercial speech may be upheld only if the government (1) demonstrates “a substantial interest to be achieved by restrictions on commercial speech”; (2) shows that the restriction “directly advance[s] the state interest involved”; and (3) shows that its asserted interest could not “be served as well by a more limited restriction on commercial speech.”<sup>44</sup> As noted above, the

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<sup>42</sup> *Riley*, 487 U.S. at 796.

<sup>43</sup> *Pacific Gas & Electric Co. v. Pub. Util. Comm’n of Cal.*, 475 U.S. 1, 19 (1986).

<sup>44</sup> *Central Hudson*, 447 U.S. at 564.

Commission would be hard-pressed to identify a “substantial” interest in limiting the calls at issue here.

Moreover, such an interest, even if it could be identified and substantiated, could be advanced through much more limited restrictions on Acurian’s speech; for instance, instead of an onerous mechanism requiring prior express written consent (which would needlessly and significantly impede recruitment for participation in FDA-mandated clinical trials), the Commission could establish an opt-out procedure—much like the one currently employed by Acurian.<sup>45</sup> In short, while Acurian submits that Commission precedent confirms that the calls at issue are exempt from the restrictions in 47 U.S.C. § 227(b)(1)(B), the First Amendment interests at stake underscore the need to avoid the imposition of a prior express consent requirement in this context.

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<sup>45</sup> See *supra* at 4.

