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Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Re: Petition Requesting That the FTC Maintain Its Current Enforcement Policy Permitting the Use of Prerecorded Messages (When There is An Established Business Relationship) For the Narrow Subset of Health-Related Calls Made By Entities Regulated Under HIPAA

Dear Mr. Clark:

On behalf of our client, Silverlink Communications Inc. ("Silverlink"), and Eliza Corporation ("Eliza"), we respectfully submit this Petition pursuant to 16 C.F.R. § 1.25 to urge the Federal Trade Commission ("FTC" or "Commission") to maintain the *status quo* and continue to forbear from bringing any enforcement actions against the narrow-class of automated health-related calls made by entities subject to regulation under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). As explained herein, these types of HIPAA-regulated calls to healthcare consumers bear no relationship to the types of prerecorded messages disseminated by the telemarketing industry (as opposed to the healthcare industry).

Silverlink and Eliza are leading providers of automated voice solutions for the healthcare industry. Their services enable health enterprises, including health plans, pharmacy benefit managers ("PBMs"), specialty pharmacies, and disease management companies to deliver personalized, interactive, and HIPAA-compliant phone messages to millions of healthcare consumers – including elderly and chronically ill consumers who rely upon such messages for their health care needs.

Silverlink and Eliza's prerecorded, privacy-protected messages delivered to individual healthcare consumers have been highly successful in driving positive health outcomes and generally lowering health care costs. The types of calls made by Silverlink, Eliza, and other parties as well as calls placed by PBMs, health plans, and other HIPAA-regulated entities, include but are not limited to: health screening reminders including mammogram reminders and colonoscopy reminders, prescription drug refill reminders, brand to generic drug conversions, flu shot

reminders, child immunization reminders, benefit plan selection reminders, and disease management plan reminders.

These prerecorded messages are valued by consumers, are expressly permitted under HIPAA, and have been expressly permitted by the FTC pursuant to the enforcement policy announced by the FTC in its November 17, 2004 *Federal Register* notice; this notice provided that the FTC would forbear from bringing any enforcement actions under the Telemarketing Sales Rule ("TSR") against those entities who use prerecorded messages to contact consumers who have an "established business relationship" with the seller.[1]

This petition is necessary because these health-related calls are currently in jeopardy based upon the FTC's October 4, 2006 *Federal Register* notice announcing that the FTC will abandon its current enforcement policy and begin enforcing against such calls beginning January 2, 2007.[2] Although there is an open comment period, which closes on December 18, 2006, we are concerned that nine business days is simply not a sufficient amount of time for the FTC to review comments and alter its current plan to initiate enforcement starting January 2, 2007. A change in the FTC's current enforcement policy would have a dramatic impact on the transmission of important health-related information. Based on a review of Silverlink's call data, and the scope and size of the healthcare industry, the proposed FTC action would directly impact anywhere from 10 to 20 million consumers who annually receive these kinds of health-related calls, and it may be assumed that these consumers rely on these calls to refill their necessary prescriptions and medical supplies.

We are therefore submitting this petition in advance of the December 18, 2006 comment deadline to afford the FTC additional time to consider and rule upon our request. We will be separately submitting comments on behalf of our client prior to December 18, and those comments may include additional data in support of our position.

Although this rulemaking effort has been ongoing since 2004, we believe businesses and consumers have not been adequately informed that these types of health-related calls, made by HIPAA-regulated entities, are in jeopardy of being prohibited by the FTC. A careful review of the administrative record demonstrates significant industry and consumer confusion – acknowledged repeatedly by the FTC – regarding the distinction between "informational calls" (not covered by the TSR) and calls to solicit the purchase of goods or services (covered by the TSR). Based upon the significant confusion regarding the scope of the TSR (particularly with

[1] 69 Fed. Reg. 67287 (November 17, 2004).

[2] 71 Fed. Reg. 58716 (October 4, 2006).

regard to health-related calls), and based upon the absence of any substantive comments directly on point, there is simply no evidence in the administrative record that consumers oppose the narrow class of health-related calls subject to this petition. Moreover, the recent 40 day comment period extension granted by the FTC does not cure the absence of adequate notice as consumers are still not sufficiently aware that mammogram reminders, prescription drug refills, colonoscopy reminders, and similar health-related calls are at risk of being terminated starting January 2, 2007.[3]

Finally, because consumers rely upon these health-related calls, we believe it would not be in the interest of the FTC, businesses, or health-care consumers, for the FTC to prohibit these calls starting January 2, 2007 – and subsequently (after a careful review of submitted comments) decide to permit such calls at a later date. Interruption of health-care services and reminders serves no one's interests, and for this reason we respectfully request that the FTC immediately extend the enforcement forbearance policy for the narrow class of health-related calls made by HIPAA-regulated entities.[4]

I. Background on the Proposed Rule

The TSR has been remarkably successful in providing consumers with added privacy protections and defenses against unscrupulous telemarketers. Notably, Section 310.4(b)(1)(iv) of the TSR prohibits telemarketers from abandoning calls.[5] An outbound telephone call is "abandoned" under this section if a person answers it and the telemarketer does not connect the call to a sales representative within two seconds of the person's completed greeting. The TSR applies only to

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[3] Silverlink and Eliza recently conducted an informal survey of a number of their HIPAA-regulated customers. The vast majority of the officials they contacted were unaware of the FTC's announced revocation of its forbearance policy, and did not know that their automated health-related calls would be negatively impacted on January 2, 2007.

[4] At a minimum, the FTC should extend its forbearance policy for these health-related calls on an interim basis, and open a new rulemaking proceeding explaining that these types of calls would be in jeopardy, and soliciting comments expressly addressing health-related calls. If this approach is adopted, in this new rulemaking we believe the FTC should explain the difference between health-related calls that are "informational" and those that are considered "telemarketing," and request comments addressing, among other things: (1) whether consumers distinguish health-related calls from telemarketing calls; (2) whether such calls have a positive impact on health outcomes; (3) whether such calls decrease health-care costs; (4) whether HIPAA regulations provide adequate safeguards; and (5) whether the FTC's regulation of these health-related calls would conflict with HIPAA requirements. We believe it would be inappropriate for the FTC to alter its current policy of forbearance for the narrow class of health-related calls if the above issues have not been carefully examined. We further believe that proceeding without a full understanding of these issues may result in negative health-related consequences that the Commission may not have intended when it proposed this rulemaking.

[5] 16 CFR § 310.4(b)(1)(iv).

"telemarketing" which is defined in pertinent part as a plan, program, or campaign that is conducted to induce the purchase of goods or services or a charitable contribution.[6] The TSR does not apply to informational calls unless the calls combine an informational message with a sales invitation or promotional pitch.

On November 17, 2004, the FTC announced in a *Federal Register* notice that it will forbear from bringing any enforcement action for violation of the TSR's call abandonment prohibition, 16 CFR § 310.4(b)(1)(iv), against a seller or telemarketer that placed telephone calls that deliver prerecorded telephone messages to consumers with whom the seller has an "established business relationship."[7]

On October 4, 2006, however, the FTC issued a proposed rule announcing the revocation of its policy of forbearance from bringing enforcement actions against sellers and telemarketers who make prerecorded telemarketing calls, effective January 2, 2007.[8] On November 3, 2006, the FTC extended the comment period on this proposed rule by 40 days to December 18, 2006 - but expressly stated the Commission would nonetheless begin to enforce against companies using prerecorded messages on January 2, 2007 – nine business days after the end of the comment period.[9]

II. Background on the HIPAA Privacy Rule

The HIPAA Privacy Rule is intended to protect the privacy of all individually identifiable health information in the hands of covered entities. The HIPAA Privacy Rule limits marketing activities in the health care arena, and requires a "covered entity"[10] or a covered entity's "business associate"[11] to obtain patient authorization before engaging in any "marketing" activities.[12]

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[6] 16 CFR § 310.2(cc).

[7] 69 Fed. Reg. at 67287. An "established business relationship" means a relationship between a seller and a consumer based on: (1) the consumer's purchase, rental, or lease of the seller's goods or services or a financial transaction between the consumer and seller, within the 18 months immediately preceding the date of a telemarketing call; or (2) the consumer's inquiry or application regarding a product or service offered by the seller, within the 3 months immediately preceding the date of a telemarketing call. 16 CFR § 310.2(n).

[8] 71 Fed. Reg. at 58716.

[9] 71 Fed. Reg. 65762 (November 9, 2006).

[10] A "covered entity" is defined to mean: "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." 45 CFR § 160.103.

The HIPAA Privacy Rule, however, excludes and intentionally allows communications about patient treatment and certain health care operations activities in the definition of "marketing."[13] Such communications and activities may include, for example, automated calls for health screening reminders (including mammogram reminders and colonoscopy reminders), prescription

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[11] A "business associate" is defined to mean:

(1) Except as provided in paragraph (2) of this definition . . . with respect to a covered entity, a person who: (i) On behalf of such covered entity or of an organized health care arrangement . . . performs, or assists in the performance of: (A) A function or activity involving the use or disclosure of individually identifiable health information . . . ; or (B) Any other function or activity regulated by this subchapter; or (ii) Provides . . . management, administrative, accreditation, or financial services to or for such covered entity or arrangement, . . . where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity. 45 C.F.R. § 160.103

[12] 45 C.F.R. § 164.508(a).

[13] Marketing is defined to mean, in pertinent part:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:
    (i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.
    (ii) For treatment of the individual; or
    (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.
(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service. 45 C.F.R. § 164.501 (emphasis added).

drug refill reminders, brand to generic drug conversions, flu shot reminders, child immunization reminders, managed care enrollment calls, and retail-to-mail pharmacy conversions. Such services are included in most standard plans of care across the nation and sometimes involve a nominal co-pay. In most cases, most of the cost is borne by the healthplan, not the consumer, and may often reduce consumer expense (e.g., by utilizing lower cost generic drugs). The Department of Health and Human Services ("HHS") initially, and unintentionally, prohibited such communication in the proposed HIPAA Privacy Rule, but given the overwhelming backlash from the health care industry, and HHS' realization that such a prohibition would significantly impede the quality of health care, HHS decided to affirmatively allow these particular types of communications without obtaining authorization from the individual.

Covered entities and their business associates may engage in such exempt communications without first obtaining patient authorization. A covered entity and a covered entity's business associate are defined under HIPAA to include certain health plans, health providers, prescription benefit managers, pharmacies, and companies with contractual relationships with such entities.

Accordingly, the FTC's decision to enforce against such calls as of January 2, 2007, may directly conflict with the careful policy developed under HIPAA by Congress and HHS.

III. Health-Related Calls Provided by HIPAA-Regulated Entities Provide Health Benefits and are Widely Accepted By Consumers

Health-related prerecorded calls from HIPAA-regulated entities are highly beneficial to public health and widely accepted by their recipients.[14] Published research indicates that health-related calls delivered by HIPAA-regulated entities are an effective means of driving behaviors that improve health outcomes and reduce health-care costs. For example, an October, 2003 GAO Report cited an Eliza outreach program as an example of the appropriate and beneficial use of technology.[15] Notably, the report highlighted that as a result of these calls, diabetic retinal exams

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[14] It is a well-recognized fact, supported by common sense, that opt-in approaches are far less effective than opt-out approaches in the health-care context. Extensive health care consumer data show that consumers who actively opt-in to receive healthcare services are typically healthy, pro-active people. The type of people who actually need (and would benefit greatly from) health-related calls and reminders are therefore the least likely to opt-in. At a minimum, however, to the extent the FTC believes that opt-in is the appropriate approach, it should extend the forbearance policy and publish a new rulemaking to obtain consumer comments on the continued receipt of these calls.

[15] GAO Report, "*Information Technology: Benefits Realized for Selected Health Care Functions*," GAO-04-224 (October, 2003).

increased from 71% to 93%, and the rate of adolescents receiving a full schedule of vaccinations increased from 29% to 43%.[16]

Moreover, industry data demonstrates that consumers are not opposed to receiving automated health-related telemarketing calls. Eliza and Silverlink's HIPAA-regulated customers have reported that they receive very few complaints about automated calls. For example, a Pharmacy Benefit Management company reported that of the 140,000 refill reminder calls it made in the period from March, 2004 to September, 2004, the company received only 50 "opt-out" requests which represents a trace .035 percent of the called population. Similarly, another Silverlink HIPAA-regulated customer reported that of the more than 100,000 Medicaid members it has placed an automated call to in 2006, only 25 have elected to opt out of receiving future automated calls from the company.

Additionally, a Silverlink health plan placed over 29,000 automated flu shot reminders to seniors in October, 2006. In addition to being very effective in encouraging recipients to obtain the flu shot, the health plan reported that 3 percent of recipients (roughly 1,000 people) subsequently made an unsolicited call into the health plan to express gratitude for having received the call.

Trends in managed care are making consumers increasingly responsible for managing and funding their own healthcare. As consumers are required to accept more choice, responsibility and risk, they need and want better access to the information necessary to make the best decisions for themselves and their families. Automated calls are the best way for healthcare fiduciaries to interact with consumers at home to educate, collect information, and drive behavior. Healthcare fiduciaries using automated calls consistently achieve a success rate that is dramatically superior to other alternatives such as mail, email, or web portals.[17]

IV. There Is Inadequate Public Notice and an Insufficient Administrative Record to Support a Change in Policy

Not only are health-related automated calls valued by consumers, permitted under HIPAA, and beneficial to the public health, but there is also no basis in the administrative record to support a change in the FTC's current enforcement policy. In fact, the preamble to the FTC's proposed rule reveals significant confusion among those commenting as to whether certain practices come

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[16] *Id.* at 107.

[17] Automated calls increase effective consumer contact at a fraction of the cost of live calls. Using automated calls is becoming a healthcare reality since staff limitations preclude making live calls to large numbers of patients to drive healthy behaviors such as mass immunizations, mammograms, etc.

within the TSR and the prohibition on prerecorded calls. The FTC has acknowledged in the preamble to the proposed rule that both companies and consumers do not fully understand the distinction between informational calls and calls intended to induce the purchase of goods and services.

For example, the FTC acknowledged that:

- "Many of the comments, both from the telemarketing industry and consumers, exhibited a fundamental misconception of the TSR's scope."[18]

- "Like many industry comments, most of the consumer comments that seemed to support the proposal to allow prerecorded messages in telemarketing calls to established customers exhibited a basic misunderstanding of the TSR's applicability."[19]

- "The Commission's Rules of Practice afford . . . telemarketers the right to seek any advisory opinions they may need to clarify the types of prerecorded informational messages that are not covered by the TSR, and thus are not prohibited."[20]

- "[T]he majority of . . . [the] relatively few supportive consumer comments indicated that they did not want the Commission to prohibit prerecorded informational messages such as reminder messages -- although such messages have never been covered, much less barred, by the TSR. These consumers expressed appreciation for prerecorded informational messages about delivery dates for previously purchased goods or services, medical prescription order notifications, flight cancellation alerts, and overdue bill and appointment reminders."[21]

- "Several industry comments posited that consumers are interested in receiving prerecorded messages. Although some of the examples cited to support this contention were prerecorded messages governed by the TSR (such as letting customers know of special promotional events or upcoming sales), many of the examples, if not most, were informational messages that are not covered by the TSR at all. For example, SBC cited a

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[18] 71 Fed. Reg. at 58719.

[19] 71 Fed. Reg. at 58720.

[20] 71 Fed. Reg. at 58725-58726.

[21] 71 Fed. Reg. at 58720 (emphasis added).

survey of 1217 of its DSL Internet access customers on the use of prerecorded informational messages to remind them of their service installation dates, in which 55.1 percent said they would like to receive such messages in the future. As previously noted, such informational messages are neither governed nor prohibited by the TSR, because they are not 'telemarketing' as defined by the Telemarketing Act or the Rule."[22]

- "Of the 77 positive consumer comments, more than half – 47 – sought only to preserve prerecorded informational messages that are not prohibited by the TSR. These 47 consumers opposed any limitation on prerecorded 'reminder' messages, with some 36 of them seeking to avoid any need to sign a consent form to receive such messages, apparently in the mistaken belief that this would be necessary if the proposed amendment were not adopted."[23]

This confusion suggests that commentators were not fairly apprised of the scope of the proposed rule, and may have commented differently had they known valuable automated health-related telemarketing calls would be in jeopardy. This is particularly significant since the FTC is required under the Administrative Procedure Act ("APA") to provide adequate notice on the scope of the proposed rule.

More specifically, the APA requires that notice of a proposed rule be published in the *Federal Register* and include "either the terms and substance of the proposed rule or a description of the subjects and issues involved," and that interested persons be given an opportunity to comment on the rule.[24] Notice and opportunity to comment serve to educate the agency, provide fair treatment to persons affected by the rule, and assist in judicial review.[25] Notice is sufficient if it "fairly appraise[s] the interested parties of the subjects and issues before the Agency," and thereby "affords interested persons a reasonable and meaningful opportunity to participate in the rulemaking process."[26] Courts have recognized that it can be appropriate to look to comments

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[22] 71 Fed. Reg. at 58719.

[23] 71 Fed. Reg. at 58720, footnote 53.

[24] 5 USC § 553(b)(3), (c).

[25] *See e.g., Small Refiner Lead Phase-Down Task Force v EPA*, 705 F.2d 506, 547 (D.C. Cir 1983); *Standard Oil Co. V. DOE*, 596 F.2d 1029, 1057-58 (TECA 1978).

[26] *See e.g., American Iron and Steel Institute v EPA*, 568 F.2d 284, 291 (3rd Cir. 1977); *American Water Works Ass'n v EPA*, 40 F.3d 1266, 1274 (D.C.Cir. 1994).

for evidence of adequate notice,[27] and that comments indicating "confusion" about a proposed rule "suggest that adequate notice was not provided."[28]

Given the extensive confusion in the administrative record, we believe the FTC should immediately extend its forbearance policy for health-related calls made by HIPAA-regulated entities.

V. The FTC's Rationale For Prohibiting Prerecorded Telemarketing Calls Does Not Apply to Health-Related Calls Made By HIPAA-Regulated Entities

Not only is there extensive confusion in the record about the scope of the proposed rule, but the rationale applied by the FTC in determining that prerecorded telemarketing calls should be prohibited does not apply to health-related calls made by HIPAA-regulated entities. The FTC concluded that it should prohibit prerecorded telemarketing calls because it determined that the administrative record showed: (1) consumers have an aversion to prerecorded calls even when the calls are made to established customers; (2) the harm to consumer privacy is not outweighed by the value of the prerecorded calls; and (3) there is nothing unique about the relationship between sellers and their customers that gives sellers sufficient incentive to self-regulate and avoid prerecorded telemarketing campaigns that their customers would consider abusive.[29]

Unlike telemarketing calls, Eliza, Silverlink and other vendors' experience in placing health-related calls has shown that recipients appreciate receiving health-related prerecorded calls and want to continue receiving them. Moreover, health-related prerecorded calls are directly beneficial to consumer health and welfare, and therefore have great value to healthcare consumers. Finally, the relationship between customers and HIPAA-regulated entities is unique in that it involves highly beneficial health-related information, the entities placing the calls are subject to HIPAA's Privacy Rule and marketing limitations, and the consumers receiving the calls have a preexisting health-related relationship with the entities placing the calls.

VI. The FTC Has Insufficient Time to Review Comments on the Proposed Rule

We believe it would be inappropriate for the FTC to implement a significant change in an enforcement policy that directly impacts consumer health without carefully considering and

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[27] *Horsehead Resource Devel. v Browner*, 16 F.3d 1246, 1268 (D.C.Cir. 1994).

[28] *Rafael Convalescent Hospital v Shalala*, 1998 WL 196469 (N.D.Cal.).

[29] 71 Fed. Reg. at 58723.

reviewing comments submitted by interested parties. A two-week period, from December 18, 2006 to January 2, 2007, is simply not sufficient for the FTC to carefully consider comments and make a well-informed decision, particularly due to the intervening holiday season that leaves only nine business days for the FTC to review comments.

As previously noted, although the FTC has already provided the public with a 40-day extension to comment on the proposed rule, this extension is inadequate due to the substantial confusion in the record on the scope of the proposed rule. Both consumers and businesses do not fully understand the difference between "informational" calls that are not subject to the telemarketing sales rule, and "marketing" calls that are subject to the telemarketing sales rule. It is apparent from the administrative record that many commenters did not fully comprehend that HIPAA-regulated health-related calls would be included in the FTC's abandonment of its existing enforcement policy.

VII. Conclusion

In light of the above, we petition the FTC to maintain the *status quo* and continue to forbear from bringing any enforcement actions against the narrow-class of health-related calls delivered by entities subject to regulation under HIPAA. We further request that the FTC announce the extension of this forbearance policy well in advance of the anticipated January 2, 2007 enforcement date.

Respectfully Submitted,

Paul D. Rubin

cc: Mr. Allen Hile, Federal Trade Commission
Mr. Craig Tregillus, Federal Trade Commission