

June 28, 2002

**Via E-Mail and Hand Delivery**

Mr. Donald S. Clark  
Secretary  
Office of the Secretary  
Room 159  
Federal Trade Commission  
600 Pennsylvania Ave., NW  
Washington, D.C. 20580

**Re: Telemarketing Rulemaking -- User Fee Comment  
[FTC File No. R411001]**

Dear Secretary Clark:

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

The National Association of Chain Drug Stores, Inc. ("NACDS") hereby submits comments on the Notice of Proposed Rulemaking regarding the Telemarketer User Fee for the Do-Not-Call registry ("the Registry").<sup>1</sup> *See* 67 Fed. Reg. 37362 (May 29, 2002).

NACDS members are nearly 200 chain community pharmacy companies. Chain community pharmacy is the largest component of pharmacy practice, with over 100,000 pharmacists working in more than 34,000 retail community pharmacies. Chain operated community retail pharmacies fill over 70% of the 3 billion prescriptions dispensed annually in the United States, with annual sales totaling over \$450 billion. NACDS membership also includes over 1,200 suppliers of goods and services to chain community pharmacies, as well as 130 international members from 34 countries. NACDS was founded in 1933 and is based in Alexandria, Virginia.

**I. PATIENT-BASED HEALTH IMPROVEMENT PROGRAM  
COMMUNICATIONS SHOULD NOT BE SUBJECT TO THE  
TELEMARKETING SALES RULE ("TSR")**

NACDS respectfully requests that pharmacies engaged in communications pursuant to their patient-based health improvement programs not be considered to be telemarketers subject to the FTC's rules on telemarketing sales. Indeed, to conclude otherwise creates a real and substantial health risk.

---

<sup>1</sup> These comments are in addition to those supplemental comments NACDS jointly submitted with the National Retail Federation on this same day. *See* Supplemental Comments of the National Retail Federation, Telemarketing Rulemaking - Supplemental Comment, FTC File No. R411001 (Proposed Amendments to the Telemarketing Sales Rule).

### **A. Telephone Calls from Pharmacies to Patients Pursuant to Patient-based Health Improvement Programs**

As a matter of practice, many pharmacies use patient-based health improvement programs to save patients' lives and money. Pursuant to these programs, pharmacies inform patients about prescription refills, less expensive generic drugs, therapy education programs, and other treatment options. These pharmacy/patient communications sometimes are conducted via telephone calls from the pharmacy to the patient. Such communications are generally welcomed by patients. Notably, only three percent (3%) of patients who are automatically enrolled in these programs do not want to receive the information provided by the pharmacy through them. *See* 1997 Study by Elensys, a Massachusetts-based firm that helped healthcare providers design and implement these programs.

Pharmacy patient-based health improvement programs are "conducted to induce" patients to properly take their medications as prescribed by their doctors and to obtain the greatest health benefit from their prescription drugs. 16 C.F.R. § 310.2(u) (describing telemarketing, conversely, as "conducted to induce the purchase of goods or services"). As such, telephone calls from pharmacists to their patients under these programs should not be considered telemarketing subject to the TSR.

### **B. Pharmacies' Calls to Patients Are Treatment Not Telemarketing**

According to the Department of Health and Human Services ("HHS"), marketing communications relate to "a product or service a purpose of which is to encourage recipients . . . to purchase or use the product or service." 45 C.F.R. § 164.501 (defining terms for privacy regulations under the Health Insurance Portability and Accountability Act). But "marketing does not include communications that . . . are tailored to the circumstances of a particular individual and . . . [are] made by a healthcare provider to an individual as a part of the treatment of that individual . . ." *Id.* More specifically, communications "for the purpose of . . . recommending to that individual alternative treatments [and] therapies" are not marketing. *Id.* This includes refill reminders. *See* Standards for Privacy of Individually Identifiable Health Information, Guidance issued July 6, 2001, at 33 (discussing marketing exceptions). Accordingly, it can be concluded that a pharmacy's phone calls to its patients pursuant to its patient-based health improvement programs, which are for treatment purposes and relate to refill reminders and alternative therapy suggestions, are not telemarketing and should not subject to the TSR.

### **C. Subjecting Pharmacies to the TSR Creates a Health Risk**

Application of the TSR to pharmacies would interfere with and obstruct the pharmacist/patient relationship. This would create a real health risk. For instance, the situation may arise in which a pharmacist learns, after a particular drug has been prescribed and dispensed to a patient on the Registry, that the drug is hazardous because of other drugs

being taken or for some other reason. In that case, the pharmacy must be free to call the patient to inform that patient of the danger and to suggest an alternative in consultation with the patient's doctor. But if pharmacies are prohibited from calling a patient on the Registry for treatment purposes, then the pharmacy is faced with either acting in the interest of the patient or violating the TSR restrictions and being subject to civil and criminal penalties. Pharmacies should not have to make this choice, and patients should not be subject to the health risk generated by it. NACDS does not believe this was the intent of the TSR.

#### **D. At A Minimum, Pharmacy Health Care Communications are Exempt**

According to 16 C.F.R. § 310.6(c), when a telephone call "in which the sale of goods or services is not completed, and payment or authorization of payment is not required, until after a face-to-face sales presentation by the seller," such a call is not telemarketing and the TSR does not apply. Generally speaking, in the pharmacy context, refills, generic substitutes, and other healthcare products are not purchased directly over the phone. Rather, in most cases, the patient is informed by the pharmacist of the refill, generic substitute or other healthcare product but has to go to the pharmacy to complete the purchase. Consequently, pharmacy treatment communications should, at a minimum, be exempt from the TSR.

## **II. PHARMACIES SHOULD NOT HAVE TO PAY THE USER FEE**

Because pharmacies are not telemarketers, they should not be obligated to pay the user fee. But even if the FTC were to conclude that pharmacies were telemarketers, pharmacies should not be required to pay any user fee to access the Registry. First of all, pharmacies only call their *existing patients*. They do not make calls to the general public based upon area codes. In other words, unlike general telemarketers who will be obligated to remove everyone listed on the Registry from their area-code-based call list, pharmacies may or may not ever find a patient on the Registry. Therefore, it is not fair to require them to pay the user fee to get access to the Registry which may or may not contain even one patient name.

Second, pharmacies operate at very low margins of profitability, approximately 1-3%. To require them to pay this fee will cut into their already exceedingly narrow profit margins. Consequently, some pharmacies may find that they have to pass along the economic burden of this fee to the patients. This is especially the case since the access fee is based on certain FTC estimates calculated to obtain \$3M to run the Registry, estimates which may not be correct. As a consequence, the user fee could easily increase should those estimates fall short. This could create even a greater financial burden on pharmacies and possibly their patients.

Third, if pharmacies must pay fees to access the Registry before they pursue treatment communications, the cost may deter them from initiating such communications to any patients in the first place. As a consequence, patients would lose their opportunity to gain valuable health information from their pharmacist.

Thank you for considering our comments. If you have any questions, please contact me at (703) 837-4280.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Lawrence Kocot". The signature is fluid and cursive, with a large initial "S" and a long, sweeping underline.

S. Lawrence Kocot  
Senior Vice President, Government Affairs  
and General Counsel