OLSSON, FRANK AND WEEDA, P.C.

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, NW
WASHINGTON, D.C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

Mr. Frank's Direct Phone (202) 518-6363
Mr. Frank's Direct Facsimile (202) 234-2686

Mr. Bode's Direct Phone (202) 518-6323
Mr. Bode's Direct Facsimile (202) 234-1560

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER

TISH E. PAHL
ROBERT A. HAHN
NAOMI J. L. HALPERN
STEPHEN L. LACEY
SHARON D. BROOKS
RYAN W. STROSCHEIN
EVAN P. PHELPS
VALERIE B. SOLOMON*

OF COUNSEL
JUR T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES

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BY FEDERAL EXPRESS

Daniel E. Troy, Esq. (GCF-1)
Chief Counsel
Food and Drug Administration
5600 Fishers Lane, Room 657
Rockville, Maryland 20857

Thomas W. Abrams, R.Ph., MBA (HFD-42)
Director of Drug Marketing, Advertising & Communications
Food and Drug Administration
5600 Fishers Lane, Room 8B45
Rockville, Maryland 20857

Re: A Change to Accompanying Information For In-Pharmacy Direct-to-Patient Communications – A Prescription For Reform
2003N-0344

Dear Messrs. Troy and Abrams:

We are writing to you on behalf of our client Catalina Health Resource (CHR) regarding the need for reform of current Food and Drug Administration (FDA) interpretations that require all prescription drug print promotions to be accompanied by a brief summary (if "advertising") or full labeling (if "promotional labeling"). As FDA moves to issue a draft guidance on reform of accompanying information requirements for direct-to-consumer (DTC) prescription drug promotion, we urge the agency to recognize and address the special issues that in-pharmacy direct-to-patient (DTP) communications raise.

Executive Summary: Prescription for Reform – In-Pharmacy DTP Communications

- Exempting In-Pharmacy DTP Communications
  - CHR believes that the traditional accompanying information requirements for print promotions should not be imposed upon in-pharmacy DTP communications, particularly educational compliance/adherence messages. In-pharmacy DTP

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communications are distinguishable from common DTC print promotion on many grounds – the face-to-face interaction in the health care environment; the patient's existing relationship with a physician and a pharmacist; the pharmacist's involvement in the message communicated; and the limitations existing within the pharmacy itself. For these reasons, in-pharmacy DTP communications messages should not trigger accompanying information requirements at all.

- If, however, FDA continues to adhere to the policy that even in-pharmacy DTP communications must include accompanying information, CHR proposes that FDA look to alternatives to satisfy these requirements.

- Compliance or adherence messages

  - FDA should recognize that it serves no useful purpose to require in-pharmacy communications to include the full product labeling when the communication is a compliance or adherence message for the drug being dispensed. The dispensed drug is already accompanied by "useful written information," which should serve as the accompanying information. Providing the full package labeling intended for health care professionals is certainly not useful to consumers.

- Adjunctive/alternative therapy and awareness messages

  - When adjunctive/alternative therapy or awareness messages accompany the drug being dispensed in a face-to-face encounter in the pharmacy, there is no need or use for the brief summary.

  - Alternatives should be considered to the brief summary for in-pharmacy DTP communications – the most straight forward and logical of which is to apply the same standards used for broadcast ads. Under this approach, "adequate provision" would be satisfied by making a variety of information (full product labeling, patient labeling) readily and easily available via a toll-free number, a website address, and, most importantly for this type of unique communication, from the pharmacist during this face-to-face interaction.

Catalina Health Resource, The Pharmacy Newsletter, And In-Pharmacy DTP Communication

CHR fills a unique niche in the process by which a consumer becomes informed about his or her prescription drugs. CHR currently helps over 15,000 pharmacies publish a customized pharmacy Newsletter that provides a vehicle for communication between the pharmacies and their millions of patients.

The pharmacy, using CHR software, provides a customized educational Newsletter to the patient at the time he or she fills or refills a prescription. We provide several samples for your review. (Attachment 1) The first panel of the Newsletter typically provides important information about the proper use of the drug dispensed to the patient, including the name of the drug, indications for use, drug interaction precautions, adverse reactions, and possible side effects. This section of the Newsletter is intended to satisfy the "useful written information" criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information." Typically, the pharmacy contracts with an independent information provider, such as First Data Bank, which generates the "useful written information" to accompany all of the pharmacy's dispensed prescriptions.

Other panels of the Newsletter provide additional *educational* messages for the patient. There may be information about the prescribed medication or the disease or condition the medication treats. Frequently, the Newsletter contains *compliance and adherence* advice about how to take the drug properly, and information about the importance of completing the course of treatment prescribed by the physician, as well as the importance of having prescriptions refilled (again, in accordance with the physician's directions). The public health benefits of these *compliance and adherence* messages are widely recognized. For example, patients who do not comply with drug regimens as prescribed face increased hospital or nursing home admissions, lost workdays, and even death. [1]

The Newsletter may also carry educational information about general disease states, information about alternative or adjunctive treatments to the prescribed therapy (including the option of generic drugs), "awareness" messages about related conditions, information referred to as "health tips," and information about over-the-counter drugs and consumer products. Recently, the Newsletter has started carrying *public service announcements* and health messages FDA has developed. (*See* Attachment 1 Atenolol Newsletter)

The Newsletter is easily distinguishable from typical, ubiquitous DTC promotion. The pharmacy customer receives the Newsletter from his or her pharmacist (or possibly the pharmacy technician) in a face-to-face transaction. Importantly, the pharmacy has reviewed the contents of the

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[1] One recent study estimated that the direct and indirect costs to society resulting from patients who do not adhere to prescribed drug therapy are about $177 billion annually. Ernst FR and Grizzle AJ, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," 41 *Journal of the American Pharmaceutical Assn* 192 (March/April 2001). *See also* Berg, *et al.*, *The Annals of Pharmacotherapy*, 27 (9): S3-S22 (1993) (estimating that patients who do not adhere to drug therapy cost the U.S. health care system an additional $100 billion each year). In January 2003, the World Health Organization issued a major report that stated that "[i]ncreasing the effectiveness of adherence interventions may have a far greater impact on the health of [a given] population than any improvements in specific medical treatments." World Health Organization (WHO), "Adherence To Long-Term Therapies: Evidence For Action" (2003) at 21. *See also* "The Real Drug Problem: Forgetting to Take Them," Wall Street Journal, October 21, 2003, Section D, p. 1 (Attachment 2).

Newsletter to assure that it is accurate, consistent with their sound pharmacy practices and contributing to the pharmacy's communications with its patients. Moreover, the in-store pharmacist determines whether or not it is medically appropriate for his or her patient to receive a particular Newsletter. The Newsletter's content is also distinct from DTC promotion in that it is part of an educational program to encourage patients who already have existing relationships with a physician and a pharmacist to comply with their prescribed and dispensed regimens. Finally, the Newsletter, with its check lists, health tips, and other educational content, fosters more informed discussions between patients and their physicians and pharmacists.

FDA's Accompanying Information Requirements And The Need For Reform

Print advertising for prescription drugs must be accompanied by a "brief summary" of the drug's side effects, warnings, and contraindications. 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(3)(iii). Although not explicitly set forth in any agency regulation, FDA interprets its regulations so that print promotional labeling (promotional material that "accompanies" the drug) must be accompanied by the drug's full professional labeling, even when the promotional labeling is directed to consumers, rather than health care professionals.

FDA has announced that it intends to publish a new guidance to reform these accompanying information requirements. We note there is little dispute on the need for reform of accompanying information requirements for DTC prescription drug promotion overall. In comments submitted to FDA in 2002 on First Amendment issues, and again as recently as September 2003 at the DTC promotion public meeting, there was near unanimous agreement that the typical brief summary for print promotion is overly long, too technical, too difficult to read, and not useful to consumers. Requiring that DTC print communications be accompanied by the full product labeling intended for medical professionals is even less meaningful for consumers.

While reform of accompanying information is an admirable and important step in improving the quality of DTC print promotions, CHR is concerned that in-pharmacy DTP communications will be swept within the ambit of this broader DTC print guidance. For in-pharmacy DTP communications, such as the Newsletter, inclusion of the full package labeling or brief summary poses unique and significant obstacles. We believe in-pharmacy DTP communications should be addressed in the new guidance, but in a manner that recognizes their benefits and distinguishes them from ubiquitous DTC print promotions.

FDA's Traditional Accompanying Information Requirements Should Not Be Applied To The In-Pharmacy Newsletter

CHR believes that the traditional accompanying information requirements for print promotions should not be imposed upon in-pharmacy DTP communications, particularly those involving compliance/adherence messages.

First, strict application of the agency's accompanying information requirement has a stifling effect on the valuable messages communicated by the Newsletter. The Newsletter typically consists of a tri-folded 8½ by 14 inch sheet of paper. Because of space limitations, it is not possible for the full labeling – or even the full brief summary – to appear in the Newsletter.

Second, in CHR's experience, there are significant barriers to providing the full product labeling or typical brief summary with in-pharmacy DTC communications that extend well beyond the concern of too little space in which to fit, legibly and coherently, all the accompanying information. The chief opposition arises from the pharmacists themselves. Pharmacists are very reluctant to provide the full product labeling or brief summary to their patients, even though they may have the capability to print it separately on in-store computers. Of concern to pharmacists is the length and complexity of the full product labeling or brief summary, as the documents typically print on several pages at the pharmacy printer. Busy pharmacists worry that pages will be lost or, far worse, mixed up or given to the wrong patient, with potentially severe repercussions to their patients.

Pharmacists are also very concerned that if their patients review full product labeling or brief summaries, they will not understand the reasons for the extensive risk disclosures relative to the benefits of the drug, and will not fully adhere to or will discontinue therapy. While pharmacists will, of course, provide the full product labeling or brief summary when a patient asks for it, they try to provide that information within an appropriate context so that their patients are better informed without being frightened away from their prescribed and dispensed therapies. For these very compelling reasons, it has been CHR's experience that pharmacists are very reluctant to provide full product labeling or brief summaries with their routine, in-pharmacy DTP communications.

Third, the accompanying information requirements that apply to traditional print promotion should not automatically apply to in-pharmacy communications because vehicles such as the Newsletter are very different from traditional DTC print promotion in magazines and newspapers. As discussed above, the Newsletter is disseminated as part of a face-to-face interaction between the pharmacist (or pharmacy technician) and the pharmacy customer at the time the customer picks up the prescription. The pharmacist is physically present when the consumer receives the Newsletter and is available to answer the patient's questions and/or provide additional information (such as a copy of the full labeling) if the patient requests it.

Additionally, in-pharmacy DTP communications such as the Newsletter are uniquely personalized: the pharmacy has prepared the message that appears in the Newsletter; that message has been tailored and targeted to that particular patient; and the pharmacist or technician presents that message personally to the patient. For example, an individual filling a prescription for a beta-blocker may receive a Newsletter that includes information about the importance of adhering to the prescribed therapy. (*See* Attachment 1, Atenolol Newsletter) The Newsletter may also contain information about generic drugs (*See* Atenolol Newsletter) or the potential benefits to the patient of sound nutritional habits and exercise. In short, a physician has already diagnosed the disease or condition the Newsletter discusses and the individual can ask questions or obtain information from

his or her existing physician or pharmacist about the condition, drug, or information the Newsletter describes.

In contrast to the Newsletter, traditional print promotions are not presented to the patient in an established health care environment or even within the context of an ongoing and pre-existing health care dialogue. Traditional promotional messages are not highly targeted. No pharmacist is present when the individual receives the communication. Also, the individual may not have an existing relationship with a physician regarding the disease or condition discussed in the communication.

Fourth, in contrast to DTC print advertising where the sponsoring pharmaceutical company controls the message's content, with in-pharmacy DTP communications, the pharmacy has final say regarding the message's content and the pharmacist makes the ultimate determination of whether to give the message to his or her customer. In-pharmacy DTP communications are disseminated by or on behalf of a licensed pharmacist who acts as the "learned intermediary" between the pharmaceutical company and the consumer. Indeed, recognizing their public health benefit, the Department of Health and Human Services' HIPAA Privacy Rule specifically defines refill reminder and other similar educational communications as "treatment" rather than "marketing," even when a manufacturer or other third party sponsors the message. 67 Fed. Reg. 53,182, 53,184 (Aug. 14, 2002).

For all these reasons, we believe that a compelling argument is made that these valuable, educational in-pharmacy DTP communications messages should not trigger accompanying information requirements at all. We urge FDA to consider the serious potential for patient harm that can arise if in-pharmacy DTP communications must be accompanied by multiple pages of highly technical risk information. Compliance and adherence messages, in particular, should be exempt from accompanying information requirements given their educational content and contribution to a patient's overall treatment plan. However, if FDA continues to require accompanying information for in-pharmacy DTP promotions, we propose below alternative methods for conveying that information.

"Useful Written Information" Should Serve As The Accompanying Information For In-Pharmacy Communications For The Drug Being Dispensed

Nowhere are the accompanying information problems for in-pharmacy communications more apparent than when the Newsletter contains a compliance, or adherence message for the drug the pharmacist dispenses to the patient. We attach as an example a Newsletter for ACTOS®. (Attachment 3) On the first panel of the Newsletter is the "useful written information" intended to comply with Public Law No. 104-180. This is the information the patient needs to know to take ACTOS® safely and effectively. On another panel of the Newsletter is a short message discussing the importance of following the doctor's course of treatment for glycemic control by taking ACTOS® in a timely manner, keeping with a diet and exercise plan, filling and refilling prescriptions and informing the physician of adverse events. Because such messages *may* be considered by FDA

to be "promotional" in nature (we believe such messages instead should be deemed educational), the FDA-approved patient labeling for ACTOS® is presented.[2]

Plainly, the Newsletter contains *redundant information*, as risk information is repeated several times in a single document. This is the result of an agency policy that does not look at messages such as in-pharmacy DTP communications within the context in which they are presented to the consumer. When viewed as a whole, information throughout the Newsletter accompanies and supplements the message, to address the safe and effective use of the drug being dispensed.

For in-pharmacy DTP communications that bear messages for the drug being dispensed (compliance/adherence messages in particular), we suggest that FDA recognize in the draft guidance that the "useful written information" fulfills accompanying information requirements. This "useful written information" is sufficient to inform a patient who is actually taking the drug. It therefore follows that this same quantum of information is appropriate to accompany a message that supports and reinforces the overall treatment plan a physician has already prescribed.

The "Adequate Provision" Approach Should Be Permitted As Accompanying Information For In-Pharmacy DTP Communications About A Drug Other Than The One Dispensed

The Newsletter may also contain messages for a drug other than the one dispensed. These messages may direct the consumer to information about adjunctive therapies (*e.g.*, for a dispensed allergy nasal spray, there may be a message for a non-sedating antihistamine). The Newsletter may have a message building awareness of diseases that may be associated with the condition for which the drug is prescribed, *e.g.*, diabetes information accompanying a statin drug. Or, the Newsletter may have a message suggesting that the customer speak to his or her doctor about an alternative therapy. Under FDA's current policies, these messages trigger the brief summary. We enclose examples of these awareness, adjunctive and alternative therapy messages. (Attachment 4)

The most straightforward alternative to the brief summary otherwise required for this type of communication is to hold such communications to the same standard as broadcast advertising, as described in FDA's Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999).[3] The awareness, adjunctive or alternative therapy communication should be fairly balanced, include a major statement of risks, and, most importantly, take advantage of the fact that the consumer is already in the pharmacy. An in-pharmacy adjunctive, awareness, or alternative therapy

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[2] This sample Newsletter was prepared on the basis of FDA's draft guidance that would allow FDA-approved patient labeling to satisfy brief summary requirements. 66 Fed. Reg. 20,468 (April 23, 2001).

[3] At the September 2003 DTC public meeting, CHR proposed FDA also consider permitting a standardized "Rx Facts" box or the "useful written information" that accompanies a dispensed prescription as alternatives to the current brief summary.

message should also include adequate provision for the patient to receive additional information. With the communication occurring within the pharmacy, vehicles such as the Newsletter can refer the patient to at least four different places for the FDA-approved patient labeling (if it exists), full product labeling or other information: (1) the pharmacist, from whom the patient has just received the communication; (2) the physician, with whom the patient already has a relationship; (3) a website address; and (4) a toll free number.

There is support for this multi-faceted approach to communication of prescription drug information. Several commentators at FDA's DTC promotion meeting in September 2003 urged FDA to recognize one recurrent shortcoming in its approach to accompanying information requirements – the belief that a single accompanying information vehicle must provide everything a consumer wants or needs to know about a prescription drug. Instead of requiring that every single print communication be accompanied by essentially all risk and effectiveness information, and trying to weigh what a particular communication vehicle may or may not omit, FDA should look at communication vehicles such as in-pharmacy newsletters as part of a greater whole. The goal should be to make quality prescription drug information available in a variety of formats, of varying complexity, in different media, and in locations easily accessible to consumers.

The Broadcast Guidance itself recognizes what FDA's current interpretation of the accompanying information requirements for print promotion does not – every promotion does not have to be accompanied by very detailed, technical information that likely is of little to no use to the consumer. The Broadcast Guidance's "adequate provision" approach emphasizes flexibility and understandability over completeness. The ad's major statement communicates the most significant risk information in understandable language. Completeness is addressed by informing consumers they can obtain more information through other easily accessible means, including 800 numbers, website addresses, and asking doctors and pharmacists (where the consumer would have to go regardless to have the drug prescribed and dispensed).

CHR believes that a similar model for providing accompanying information – one that emphasizes flexibility and utility to patients – is appropriate for in-pharmacy DTP communications as well. Such an approach would be very beneficial to fostering and improving in-pharmacy DTP communications such as the Newsletter. Space now devoted to recitation of lengthy and technical accompanying information could be devoted instead to useful and relevant information for the patient. We note also that in the case of providing accompanying information for a drug other than the one dispensed, including the full brief summary or even a shortened, modified form of the brief summary could prove confusing to the patient who is receiving this information at the same time he or she receives a prescription for a *different* medication. For this reason, reliance on the principles applicable to broadcast makes the most sense for in-pharmacy DTP communications.

Conclusion

We urge FDA to consider the special nature of in-pharmacy DTP communications and in particular those involving compliance/adherence messages for the drug being dispensed. These are

useful, meaningful educational communications that augment the pharmacist/patient dialogue. FDA should be interested in encouraging these communications, not stifling them under burdensome accompanying information requirements. The different role in-pharmacy communications play, and the circumstances under which patients receive them warrant different treatment than what is applicable to other, conventional DTC print promotions.

In particular, in the forthcoming draft guidance, FDA should provide that:

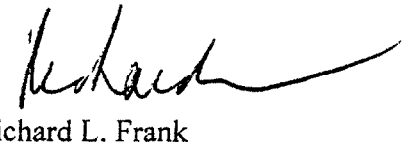
- In-pharmacy DTP communications, and compliance/adherence messages in particular, do not trigger accompanying information requirements at all.

- If FDA determines otherwise, FDA should recognize that compliance/adherence messages that accompany the drug dispensed satisfy accompanying information requirements if they include the "useful written information."

- With respect to adjunctive/awareness/ alternative therapy messages in in-pharmacy DTP communications, FDA should seriously consider application of the broadcast guidance principles. Alternatively FDA should allow alternatives such as Rx Facts (a proposal CHR presented at the DTC hearing) or the "useful written information" format to be used in the pharmacy and evaluated as to their effectiveness.

CHR applauds FDA for proceeding to update and improve its accompanying information requirements for print promotion.

Respectfully submitted,



Richard L. Frank
John W. Bode
Counsel to Catalina Health Resource

RLF/JWB:zkf

Attachments

cc: Commissioner Mark B. McClellan, M.D., Ph.D.
Docket No. 2003N-0344
Ellen Shapiro, Director, Division of Public Affairs, CDER