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BY ELECTRONIC MAIL

Division of Dockets Management
HFDA-305
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2005N-0354 – Consumer-Directed Promotion of Regulated Medical Products – Responses to Questions 2 and 5

Catalina Health Resource (CHR) is pleased to submit these comments to the Food and Drug Administration (FDA) on the agency's request for comment regarding Consumer-Directed Promotion of Regulated Medical Products, 70 Fed. Reg. 54,054 (Sept. 13, 2005). Specifically, CHR offers comments upon the following questions FDA posed regarding direct-to-consumer (DTC) promotion of prescription drugs:

> Question 2.
> Could changes in certain required prescription drug disclosures – the package insert for print "promotional" labeling and the brief summary for print advertisements – improve the usefulness of this information for consumers?
>
> Question 5.
> As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion?

EXECUTIVE SUMMARY

FDA is to be commended for its continuing efforts to address the regulatory environment in which DTC promotion exists. CHR's comments focus upon a narrow but important and often neglected part of sponsored information about prescription drugs – the communications that pharmacists distribute to their patients and what additional documents, if any, must accompany those communications. To that end, CHR discusses the following issues:

1. **Acknowledgement of and accommodation for in-pharmacy communications.** FDA should recognize that in-pharmacy, direct-to-patient (DTP) communications that pharmacies disseminate to their patients should not necessarily trigger

provision of additional documents, such as the drug's full prescribing information (FPI) or a "brief summary" of the FPI. In many instances, sponsored messages delivered in the pharmacy involved compliance and persistence information about the drug the pharmacist has dispensed or information about adjunctive or alternative therapies available to the patient and these messages should not be deemed promotional.

2. **Alternatives if additional information must accompany DTP communications.** In-pharmacy DTP communications should be permitted to use an "adequate provision" disclosure model to satisfy accompanying information requirements. Alternatively, pharmacies should be able to satisfy accompanying information requirements applicable to sponsored messages about the drug dispensed by providing the Consumer Medication Information (CMI) that accompanies the prescription.

3. **Finalize the January 2004 Brief Summary Draft Guidance.** With the issuance of the final rule on the content and format of the FPI, 71 Fed. Reg. 3,921 (Jan. 24, 2006), FDA should finalize the pending Brief Summary Draft Guidance, 69 Fed. Reg. 6,308 (Feb.10, 2004) and formalize definitively that use of the Highlights section of the FPI will satisfy brief summary accompanying information requirements.

Discussion of these points follows.

ABOUT CHR

CHR fills a unique niche in the process by which a patient becomes informed about prescription drugs, initiates a conversation with his or her health care professional about a potential disease or condition, discusses prescription drug therapy, and, potentially, receives and fills a prescription. CHR publishes a newsletter, called Patient*Link*™ that provides a vehicle for communication between over 12,500 pharmacies nationwide, producing over 1.1 billion prescriptions for approximately 100 million patients per year. The pharmacist provides a customized educational Patient*Link*™ to the patient at the time he or she fills or refills a prescription. Patient*Link*™ is a folded piece of paper with content appearing on different panels of the printed page.

The first panel of Patient*Link*™ may (depending upon pharmacy practice) provide the CMI about the proper use of the drug being dispensed to the patient, including the name of the drug, indications and instructions for use, drug interaction precautions, adverse reactions, and possible side effects. This section of the newsletter is intended to satisfy the criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine

Information" (commonly referred to as the "Keystone Criteria").[1] Typically, the pharmacy contracts with a well-known provider, such as First Data Bank or Wolters Kluwer (formerly Medi-Span), who generates the CMI to accompany all of the pharmacy's dispensed prescriptions.

Other panels of Patient*Link*™ contain additional content for consumers. There may be educational information about the prescribed medication or the condition the medication treats. Patient*Link*™ may contain advice about how to take the drug properly, the benefits of the drug, and the importance of refilling prescriptions for drugs that treat chronic disease. Patient*Link*™ also sometimes carries public service announcements and health messages from the FDA. Last, the Newsletter may also carry disease/therapy awareness messages and information about alternative or adjunctive prescription or over-the-counter (OTC) therapies.

Vehicles like Patient*Link*™ are easily distinguishable from typical, ubiquitous DTC promotion. The pharmacy customer receives the document from his or her pharmacist (or possibly the pharmacist technician) in a face-to-face transaction. The pharmacy or its chain headquarters has reviewed the contents to assure that it is accurate, consistent with its sound pharmacy practices, and is contributing to the pharmacy's communications with its patients. The content is also distinct from DTC promotion in that it is part of an ongoing health care dialogue between patients and their physicians and pharmacists.

DISCUSSION

1. FDA Should Recognize and Accommodate DTP Print Communications In Pharmacies

Pharmacies are being called upon to provide more and better information to their patients about their medicines. These activities include:

- **Mandatory pharmacy counseling**. In 1990, as part of the Omnibus Budget Reconciliation Act, Congress required pharmacists to offer to discuss with patients who receive benefits under Medicaid programs any information that the pharmacist deems significant, including a description of the medication; the duration of drug therapy; common severe side effects or interactions and therapeutic contraindications, and

[1] The Keystone Criteria require that useful written CMI must be: (1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful.

prescription refill information.[2] Several states subsequently adopted laws that require counseling for all consumers.

- **Dissemination of "useful written information."** As mentioned previously, pharmacies are, pursuant to Public Law No. 104-180 and the implementing Keystone criteria, providing useful, written CMI to consumers about the prescription drugs they are receiving.

- **Dissemination of MedGuides.** For an increasing number of drugs, FDA is requiring that drug sponsors create MedGuides that describe important risk information about the dispensed drug and make them available to pharmacies for distribution to patients.

- **Medication Management Therapy Programs.** The Medicare Improvement and Modernization Act of 2003 requires that prescription drug plans under the new Part D benefit provide "medication therapy management programs" (including refill reminder communications) for individuals with multiple chronic diseases who are taking multiple covered drugs and are likely to have high annual drug costs in order to optimize therapeutic outcomes through improved medication use.[3] Many plans use pharmacists to provide these services.

Unfortunately, FDA's current prescription drug print promotion regulations are a substantial impediment to achieving these important goals. As many in the industry interpret DDMAC's current regulations, messages about the importance of complying with the prescribed therapy dispensed, if paid for by the drug manufacturer, may be deemed to be promotional labeling that must be accompanied by the drug's FPI. Messages delivered in the pharmacy about the patient's alternative treatments options, such as new dosage forms, information about adjunctive therapies for treatment of the patient's diagnosed condition, and even a reminder given to the patient picking up a prescription to fill another prescription, must all be accompanied by a brief summary of the drug's FPI. These requirements, intended for conventional print communications such as letters, newspapers, magazines, and journals, are ill suited to and not appropriate for the pharmacy environment.

There are important distinctions between in-pharmacy DTP communications and typical, ubiquitous DTC print promotion. DTP communications are part of the ongoing interaction between the pharmacist (or pharmacy technician) and his or her patient. The pharmacist is physically present and available to answer the patient's questions and/or provide additional

[2] 42 U.S.C. § 1396r-8(g).

[3] 42 U.S.C. § 1395w-104(c).

information (such as a copy of the FPI) if the patient requests it. In-pharmacy DTP communications are also part of the ongoing process of a patient's health care. A physician has already seen the patient, diagnosed a disease or condition, and prescribed a medicine and course of therapy. The pharmacy has prepared a message complimenting that therapy and tailored that message for that particular patient.

Other parts of the United States government have looked at the issue of whether sponsored pharmacy messages are "marketing" and found that the benefits of health care messages are so compelling that they warrant special distinction and support. Specifically, the Department of Health and Human Services (HHS) Privacy Rule implementing the Health Insurance Portability and Accountability Act (HIPAA) deems refill reminders, adherence/compliance communications, and messages about alternative treatment options to be "treatment," rather than "marketing." 67 Fed. Reg. 53,182, 53,184 (Aug. 14, 2002). In the view of HHS, these communications are not marketing even when a pharmaceutical company sponsors them. HHS deems the benefits of informing patients about their drug therapy too important to risk limiting these communications by imposing restrictions that would chill these disseminations if they were characterized as marketing.

For all these reasons, we believe there is a compelling argument that these valuable in-pharmacy DTP communications messages should not be deemed promotional and should not need to be accompanied by a brief summary or FPI. At a minimum, we urge FDA to consider the serious potential for patient harm that can arise if in-pharmacy DTP communications must be accompanied by the multiple pages of highly technical risk information the FPI contains.

Should FDA nevertheless deem it appropriate to mandate that pharmacists provide additional risk information with their sponsored DTP communications, however, we suggest DDMAC allow more practical alternatives for conveying that information. We enumerate options for in-pharmacy DTP prescription drug communications below.

2. Alternatives If Information Must Accompany DTP Communications

CHR suggests two options for conveying accompanying information with in-pharmacy DTP communications, depending upon whether the communication is about the drug dispensed or about an adjunctive or alternative therapy:

- The CMI the pharmacist provides if the message concerns the drug dispensed to the patient ; or

- The application of the "broadcast model" for communications concerning therapies other than the one the pharmacist has dispensed.

a. Accompanying information for DTP messages about the drug dispensed

FDA specifically seeks comment on what information should accompany DTC promotional labeling. Conventional DTC promotional labeling includes materials such brochures, pamphlets, coloring books, questionnaires, and other documents about the drug that are provided to a patient by a healthcare professional. These materials are written for the consumer, and even the pediatric patient, and are not intended for the medical professional, yet these materials have been required to include the FPI. Under some interpretations of FDA requirements, the pharmacist should also disseminate the FPI if he or she counsels a patient to adhere to the prescribed therapy via a sponsored message. FDA notes there is an obvious deficiency with requiring delivery of the FPI to patients: [A]s the [FPI] is written in technical language intended for healthcare professionals, its value for consumers is questionable." 70 Fed. Reg. at 54,058.

The necessity for altering this requirement to provide the FPI to patients is clear. First, FDA recently finalized a rule that alters the format and content of the FPI – changes necessitated in large part because the typical FPI of a prescription drug had become too dense and difficult even for healthcare professionals. For most lay readers, the FPI (even with the new format) will simply have too much technical information, be too long, and will be written in language that is too complex to be useful.[4]

Second, serious problems are arising in health care from patient non-compliance with prescription medicines.[5] At the DTC public hearing, improving patients' compliance with their prescribed regimens was an important and frequently discussed issue for the FDA panelists. For example, Dr. Robert Temple referred to poor patient compliance with statin therapy as a "public health disaster."[6] Sponsored messages urging patients to adhere to their drug therapy and instructing how patients can improve their compliance could be (and are) an important component of what must be a multi-faceted solution to this crisis.

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[4] A drug's FPI is, of course, readily available from many sources for the patient who wishes to review it.

[5] *See, e.g.*, January 2003 World Health Organization (WHO), "Adherence To Long-Term Therapies: Evidence For Action" (2003) at 21 ("[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"); "The Real Drug Problem: Forgetting to Take Them," Wall Street Journal, October 21, 2003, Section D, p. 1; http://www.medicines-partnership.org/research-evidence/major-reviews.

[6] November 1, 2005 Transcript of FDA Public Hearing on DTC Promotion, pg. 96.

These important messages are hampered if they must be accompanied by the FPI. The FPI is logistically burdensome for healthcare professionals to provide; nor do physicians and pharmacists wish to deliver to their patients a lengthy, technical document that is not useful to them. Yet, without the absolute assurance that the healthcare professional will deliver the FPI, the cautious drug manufacturer will not sponsor the message and run the risk of being out of compliance with FDA FPI accompanying information requirements.

CHR urges FDA to reconsider the applicability of its promotional labeling requirements to pharmacy dissemination of information about the drug dispensed to the patient.[7] We believe that such a communication is not promotional when it:

- Concerns the dispensed drug and;
- Conveys compliance or adherence information (*e.g.,* "Be sure to take Drug X every day, even if you begin to feel better; tell your doctor right away if you [identify serious side effects/warnings from professional labeling]").

CHR urges FDA to exempt these messages from accompanying information requirements altogether.

To the extent that FDA believes that compliance/persistence messages are promotional, and should trigger some accompanying risk information, CHR suggests that for DTP, in-pharmacy communications, DDMAC deem dissemination of CMI as satisfying the FPI requirement. The CMI provides the important risk information and explains how to take the medicine safely. Unlike the FPI, the CMI is written for the consumer. Its purpose is to explain the most important information the patient needs in order to take the prescribed drug safely and effectively. To the extent that FDA requires that any in-pharmacy message be accompanied by additional information, CHR believes there are sound reasons for permitting the CMI to satisfy these requirements.

Another alternative, discussed in the FPI rule[8], would be to permit a consumer-friendly version of the Highlights section of the FPI in lieu of the FPI for DTC promotional labeling.

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[7] We note that in DDMAC's view, accompanying information ***is not*** triggered for an FDA-sponsored public service announcement (PSA) attached to the drug the pharmacy dispenses that states: "Take your statin medicine at the same time each day to help get the most out of your therapy." However, accompanying information ***is*** triggered if a drug's manufacturer sponsored the nearly identical message: "Take Statin Brand X at the same time each day to get the most out of your therapy." CHR believes FDA should be looking to the content of the message (educational/informative or promotional), and not who sponsors it.

This option is discussed further in section 3 below. Such an approach would be useful for many DTC promotional labeling communications.[9] However, it is not appropriate for DTP compliance and adherence messages delivered in the pharmacy because a consumer-friendly Highlights is likely to be unnecessarily redundant of the CMI the patient is already receiving from the pharmacist.

b. Accompanying information for DTP messaging

The pharmacy is a very effective venue for dialogue between the patient and healthcare professional. Monitoring a patient's medications and discussing a patient's drug therapy have long been part of the pharmacist's traditional services to his or her patients. In today's automated and computerized pharmacies, pharmacists are able (consistent with privacy laws) to monitor their patients' prescription drugs more accurately. Knowing what prescriptions their patients are filling, pharmacists are able to advise on adjunctive therapies that might be useful for overall management of a patient's condition. When a patient fills a prescription, the pharmacist can advise the patient that he or she is also overdue for a refill of another medication for a chronic condition. The pharmacist can advise patients of improvements to their prescribed therapies, such as approval of a generic substitute, or more convenient dosage forms that have become available.

As useful as this information is to the patient, if a drug manufacturer sponsors the message, FDA deems the message to be advertising that triggers a brief summary of the drug's FPI. Yet, there are difficulties with pharmacy provision of the brief summary. Certainly, the problems with the typical, lengthy and dense brief summary are well documented.[10] Those

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[8] 71 Fed. Reg. at 3,935-3,936.

[9] From the point of view of the consumer, the distinction is between promotional labeling and advertising is meaningless. It makes little sense to require provision of the FPI with a compliance message that accompanies the dispensed drug yet require only a brief summary of the FPI when the identical message runs in a magazine.

[10] As FDA itself stated, "Frequently, to fulfill the brief summary requirement, [DTC] print advertisements for prescription drugs include the complete risk-related sections of the [FPI]. This information is presented verbatim, in small type. Because this labeling is written for ... health care practitioners, it uses highly technical medical terminology. In addition [the FPI] has often included all possible adverse events, including those that are unlikely to be drug related." Draft Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' 69 Fed. Reg. 6,308 (February 10, 2004) ("Brief Summary Draft Guidance") at 2 (footnotes omitted).

problems are confounded in the pharmacy environment if the pharmacist must spend valuable time and resources generating and delivering pages of dense, technical brief summary to his or her patients.

For DTP in-pharmacy communications about adjunctive and alternative therapies, CHR believes that rather than providing a brief summary, the better approach would be to apply the Guidance for Industry -- Consumer-Directed Broadcast Advertisements (August 1999). Under this "adequate provision" model of disclosure set forth in this guidance, a broadcast advertisement must, among other things:

- Present a fair balance between information about effectiveness and information about risk;
- Include a major statement conveying all of the product's most important risk information in consumer-friendly language; and
- Describe the "adequate provision" the sponsor had made for the dissemination of the drug's product labeling through such means as asking pharmacists and physicians for additional information, calling a toll-free number, visiting a website, or referring to a traditional print advertisement.

CHR believes that this "adequate provision" model is especially appropriate for in-pharmacy DTP communications. Space now devoted to recitation of lengthy and technical accompanying information could be devoted instead to useful and relevant information for the patient. With the communication occurring within the pharmacy, vehicles such as the Patient*Link*™ Newsletter can refer the patient to at least six different places for additional information:

- The FDA-approved patient labeling (if it exists) and/or FPI;
- The pharmacist, from whom the patient has received the communication;
- The CMI the patient can request from the pharmacist;
- The physician, with whom the patient already has a relationship;
- A website address; and
- A toll free number.

CHR is in good company in advocating adoption of the "adequate provision" model for in-pharmacy DTP print communications. The Federal Trade Commission (FTC) has also suggested in comments that FDA adopt this model for all DTC print advertising:

> We believe that the FDA should replace the requirement that the DTC print ads include the FDA-approved product labeling with the requirement that such ads include a major statement of risks with

> adequate provision for consumers to receive more complete risk information from other sources. To increase consumer comprehension of important risk information in DTC ads, it is important to display the information in a clear and easily understandable format. By presenting the information in a more accessible format and form, this approach will make it more likely that consumers will actually see and understand the risk information provided. This change would make the brief summary requirement for DTC print ads consistent with the brief summary requirement for DTC broadcast ads.

Docket No. 2003N-0344, Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission (Dec. 1, 2003) at 24-25.[11]

In sum, the unique pharmacy environment and the importance of these vital communications require a different approach. Pharmacies are ill suited to the task of delivering dozens of pages of dense, medical terminology. Pharmacists balk at providing documents to their patients that are daunting even for medical professionals. CHR believes that adoption of the broadcast model mandating that the advertiser make "adequate provision" for the patient to receive additional information should be sufficient to satisfy accompanying information requirements for any sponsored, in-pharmacy DTP messages.

3. <u>In Light Of The FPI Final Rule, FDA Should Finalize The Brief Summary Draft Guidance And Clarify The Use Of The Highlights Section</u>

In January 2004, DDMAC issued the Brief Summary Draft Guidance. That Draft Guidance advocated a "less is more" approach and set out three alternatives for brief summaries that would be more useful to consumers to the dense, technical brief summary that had come to dominate DTC print advertising. One of those alternatives DDMAC proposed was a consumer-friendly version of the risk information in the "Highlights" of the FPI. This Highlights section was derived from an FDA proposed rule to revise the FPI.

[11] Other commentators have suggested this approach as well, including the National Consumers League.

FDA is to be commended for finalizing that proposed rule and revising the content and format requirements for the FPI.[12] The Highlights section of the new FPI in particular will be of an enormous benefit to healthcare professionals. Significantly, FDA required that the Highlights section not exceed one-half a page because "limiting the length of Highlights is critical to preserving its usefulness."[13] Further, in the FPI rule, FDA links the Highlights section to the Brief Summary Draft Guidance and makes statements in the rule that encourage manufacturers to use the Highlights in their DTC advertising.[14]

For consumers and for drug advertisers, a one-half page Highlights of prescribing information, translated into consumer-friendly language, will be a vast improvement over the typical brief summary (usually verbatim excerpts of the medically technical, lengthy FPI) that now accompanies most DTC advertising. A half-page Highlights of prescribing information would be far more helpful for consumers than the FPI.

Given the many benefits of a consumer-friendly Highlights section, CHR urges FDA to "close the loop" by finalizing the Brief Summary Draft Guidance immediately. With the FPI rule now final, FDA should move quickly and explain unequivocally in a final Guidance what the FPI rule already states – that use of a consumer-friendly Highlights section will satisfy brief summary requirements for DTC advertising.

Finally, CHR urges FDA to allow this consumer-friendly Highlights also to satisfy any accompanying information requirements for all DTP promotional labeling. Promotional labeling, particularly messages seeking to improve patient compliance with their prescribed therapies, is enormously burdened by the requirement that they include the FPI. Such a document is, as FDA acknowledged, not useful to the patient. It makes little sense to require the provision of the FPI solely because the message appears in a refill reminder letter or physician office communication, rather than a magazine advertisement. A consumer-friendly Highlights section will enormously improve DTC advertising; it can, similarly, improve DTC promotional labeling.

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[12] 71 Fed. Reg. at 3,921.

[13] 71 Fed. Reg. at 3,958.

[14] For example, FDA states its belief that certain product liability claims predicated on a failure to warn should be preempted so long as the drug sponsor has "used Highlights consistently with FDA draft guidance regarding the 'brief summary' in direct-to-consumer advertising." 71 Fed. Reg. at 3,936.

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CHR thanks FDA for this opportunity to comment on these important issues.

Sincerely,

Craig H. Scott
President
Catalina Health Resource