

Scott M. Lassman  
Assistant General Counsel



June 23, 2003

Ms. Mary Gross  
Office of Drug Safety (HFD-400)  
Center for Drug Evaluation and Research  
5600 Fishers Lane  
Rockville, MD 20857

Re: Docket Number 02N-0201; Minimizing Medication Errors – Methods  
for Evaluating Proprietary Names for Their Confusion Potential;  
Public Meeting

Dear Ms. Gross:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests an extension of the comment period for written comments on the issue of similarity in drug naming, including the questions posed by the Food and Drug Administration (FDA) on the meeting announcement website. Full public input on these issues will be critical to the FDA as the Agency moves forward with developing a draft guidance on this topic. PhRMA is pleased to have the opportunity to sponsor this meeting with FDA and hopes that the oral presentations of our company experts will be of use to FDA as it moves forward on this matter.

PhRMA believes that the technical and legal issues that will be discussed at the June 26 Public Meeting require more time to respond to than the FDA has allotted in the published Federal Register notice of May 30, 2003. In that notice, FDA announced that written comments would be accepted by July 15, 2003. This deadline falls only nineteen (19) days after the Public Meeting, much less than the 60 to 90 days that FDA routinely allows for comments on regulatory documents. Moreover, the Fourth of July holiday falls squarely within this 19 day period, further limiting the time to prepare comments. PhRMA does not believe this provides sufficient time for industry to incorporate the comments and learning from the Public Meeting into its written comments to FDA. FDA will be ill-served if the Agency does not receive detailed comments on all of the critical issues raised not only by the list of questions provided by FDA but also during the Public Meeting. To this end, PhRMA requests a 30 day extension of the comment period so that we can best inform the Agency on these issues.

02N-0201

EX 71

*Pharmaceutical Research and Manufacturers of America*

Ms. Mary Gross  
June 23, 2003  
Page Two

I look forward to the Agency's prompt response on this matter given that the deadline for written comments is fast approaching.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott M. Lassman", with a long horizontal flourish extending to the right.

Scott M. Lassman

cc: Dockets Management Branch (HFA-305)

**Statement of the American Pharmacists Association (APhA)  
to the Food and Drug Administration,  
Pharmaceutical Research and Manufacturers of America,  
and the Institute for Safe Medication Practices  
Public Meeting on  
Evaluating Drug Names for Similarities: Methods and Approaches  
June 26, 2003**

**Susan C. Winckler, RPh, JD  
Vice President, Policy & Communications  
Staff Counsel  
American Pharmacists Association**

Good morning. Thank you for the opportunity to present the views of the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, is the first-established and largest national association of pharmacists. I am Susan C. Winckler, a pharmacist and an attorney, and APhA's Vice President of Policy and Communications.

APhA's 50,000 members include practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice and the military. In each of these settings, we work to ensure that patients have access to safe and effective medication therapy. The ability to correctly identify, dispense, and administer drug products is crucial to our ability to accomplish this goal.

The similarity between drug names that sound or look like the names of other medical products has been identified as the source of many medication errors.<sup>1</sup> According to the 1999 Institute of Medicine (IOM) report "To Err is Human: Building a Safer Health System," which focused on medical errors in the hospital setting, an estimated 44,000 to 98,000 Americans die annually because of medical mistakes.<sup>2</sup> While we do not know how many medical mistakes are directly attributed to sound-alike or look-alike drugs, approximately 25% of all medication errors reported to the U.S. Pharmacopeia (USP) Medication Errors Reporting (MER) Program are due to similarity in drug names.<sup>3</sup> That is a frightening statistic – and the number will grow if we don't employ a systematic approach.

The number of new drugs entering the market is increasing. Last year, the Food and Drug Administration (FDA) approved 89 new medications and 172 new indications for existing products – up from 24 new drugs in 2001.<sup>4</sup> Each of those new drugs requires a new name. It is becoming harder and harder for manufacturers to develop new names that are both short and catchy (to meet marketing concerns), and more importantly, unique.

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<sup>1</sup> 68 FR at 325,30.

<sup>2</sup> Institute of Medicine Report "To Err is Human: Building a Safer Health System," 1999.

<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention. "Recommendations to Reduce Medication Errors Associated with Verbal Medication Orders and Prescriptions." Adopted February 20, 2001.

<sup>4</sup> Pharmaceutical Research and Manufacturers Association website. "New Drug Approvals."  
[www.phrma.org/newmedicines/approvals/](http://www.phrma.org/newmedicines/approvals/).

We are pleased that the FDA, the Pharmaceutical Research and Manufacturers of America, and the Institute for Safe Medication Practices are examining methods to decrease similarities between drug names. Any effort to decrease confusion related to drug names is a welcome step. While we do not claim to have the specific solution to this public health problem, we offer the following thoughts for your consideration.

#### ***Methods Currently Employed to Evaluate Drug Names***

One of the questions posed by the Agency for this meeting concerns the current methods employed by drug sponsors and the FDA to evaluate drug names. As we understand the current system, there is no consistent method of name development or evaluation currently in use. Historically, sponsors of proprietary drugs developed a drug name, submitted it to the FDA for consideration, and the FDA Labeling and Nomenclature Committee—and subsequently the Office of Drug Safety—reviewed the proposed name. However, in the past few years, manufacturers of proprietary drug products began conducting their own name studies. This follows the IOM recommendation that the Agency shift the responsibility for performing drug name testing back to the manufacturer, allowing the FDA to review data submitted by the sponsor.<sup>5</sup> While this step frees the Agency from conducting naming studies of its own, it raises concerns about the consistency of methods used to identify safety concerns when developing and testing drug names. Current guidelines for drug name development provide sponsors with significant leeway and few restrictions.

This system differs vastly from the drug naming process for nonproprietary names. The United States Adopted Names Program, also known as the USAN Council, has specific guidelines for assigning generic nonproprietary names. The guidelines must be followed when developing the generic name. Before the USAN Council will approve the generic name, it must undergo extensive analysis and testing to ensure that the drug name is appropriate for the product, and that it is not too similar to an already existing name.<sup>6</sup> While the USAN method is not foolproof—as no system is—the system relies on a much more standardized process. We recommend that the Agency and the industry examine the USAN process, and adopt a more systematic process with standardized tools to develop and evaluate drug names for proprietary drugs.

#### ***Evaluation Procedures for Different Classes of Drugs***

Another question posed by the FDA for today's meeting concerns evaluation procedures for different types of drug classes such as prescription and over-the-counter (OTC) medications. We feel strongly that drug name safety testing for all medications—regardless of their class—should be held to the same high standards. Medication errors due to name confusion can occur with proprietary and nonproprietary prescription drugs, as well as OTCs. Consumers selecting an OTC may select the incorrect product due to confusion generated by similar product names or brand name line extensions. Eliminating confusing nomenclature practices for all medication products is an important step toward reducing medication errors of all kinds.

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<sup>5</sup> 68 FR at 32,530.

<sup>6</sup> American Medical Association website. "United States Adopted Names." [www.ama-assn.org/ama/pub/category/2956.html](http://www.ama-assn.org/ama/pub/category/2956.html).

### ***What Kind of Information Should be Included in Drug Studies***

The last question I will address concerns the kind of information that should be included in oral and handwritten prescription drug studies. This is a difficult question that does not have a "one size fits all" answer. In an ideal world, prescriptions and medication orders would be typed or transmitted electronically, and would include all relevant information such as the drug name, strength, quantity, patient directions, and indication for use. If that scenario reflected a realistic prescribing environment, it would be appropriate to include all of that information in drug name tests.

However, this is not an ideal world. In reality, prescriptions are often transmitted orally – from a noisy prescriber's office to a noisy pharmacy. The majority of paper prescriptions are handwritten and many are hard to read. Many prescriptions do not contain all of the relevant information – lacking information such as the drug's strength, dosage form, or indication for use. And on occasion, prescriptions arrive with the drug product's name misspelled. This reality needs to be considered when designing drug naming tests. In order to accurately assess the potential for name confusion in a real practice environment, a number of tests should be conducted that include a minimum of or misleading drug information. A pharmacist or other health care practitioner is more likely to select the wrong medication when the drug product's name is misspelled or when the information available to them is minimal such as a prescription containing only the drug product's name. For example, an APhA member working in a hospital pharmacy has noted that prescription orders for Celebrex™ (celecoxib) and Cerebyx™ (fosphenytoin sodium) often sound the same when transmitted to the pharmacy over the phone. If the name of the drug is the only information the pharmacist receives, the opportunity for drug name confusion is high. However, if the prescription order includes additional relevant information such as the route of administration (oral versus injection), the trade name accompanied with the nonproprietary name, or the intended use (for pain relief versus anticonvulsant), the opportunity for a medication error decreases dramatically.

Although today's meeting is solely focused on methods to evaluate drug names, it is impossible to disregard other factors that may contribute to medication errors. As the aforementioned example illustrates, factors such as the means of prescription transmission (oral, handwritten, or electronic), and possession of more complete prescribing and patient information such as intended use, route of administration, or nonproprietary name can have a significant impact on the number of medication errors. When a pharmacist or other health care practitioner makes a medication error, he or she is likely not aware of the error at the time it is committed. A study of 500 pharmacist malpractice claims by the Pharmacists Mutual Insurance Company, found that 52% of the errors were related to dispensing the wrong drug.<sup>7</sup> The practitioners involved selected the medication believing that they had the correct drug. Having additional information may make the practitioner question the drug selection. Returning to our previous example – If the hospital pharmacist receives an oral order for what she hears as Ccelebrex™, the pharmacist may not question the drug selection. However, if the pharmacist receives an oral order for Celebrex™ for intravenous administration, the pharmacist may be more likely to question the order and verify that the prescriber actually ordered Cerebyx™, because the additional

<sup>7</sup> Voice of the Injured.Com. "Pharmacists and Pharmacies Make Prescription Errors that Kill or Injure." [www.voiceoftheinjured.com/a-mm-pharm2.html](http://www.voiceoftheinjured.com/a-mm-pharm2.html)

information gave the pharmacist a reason to question what she heard. While these factors are not the subject of today's discussion, their ability to impact medication errors is obvious and they cannot be ignored.

In conclusion, I would like to reiterate our support for the activities of the groups gathered here today. Measures to decrease medication errors and increase patient safety are a top priority for APhA and our members. With confusion over look-alike and sound-alike drug names responsible for a significant portion of medication errors, the development of a standardized evaluation system that makes use of standardized tools is critical to improved patient safety. The system should set standards for both proprietary drugs and OTCs that is comparable to the requirements established by the USAN Council. Each drug name should be extensively examined for any similarity to an existing drug name and evaluated as it would be used in a real practice environment. While developing a name for a drug is driven by many different factors, the primary measure for evaluating a name must always be safety.

Thank you for your consideration of the views of the nation's pharmacists.

*Beston Jack Abrams*

BRAMS  
CONSULTING  
TECHNOLOGIES  
INCORPORATED

Trademarks with PHARMA Power

June 3, 2003

Mary Gross  
FDA Center for Drug Evaluation and Research

FAX: 301-443-9664

Dear Ms. Gross:

I would like to respond to question number four re: the June 26 meeting on "Minimizing Medication Errors". As part of the pre-marketing risk management program, there would be a benefit to ask the end user what they think the proposed trademark means, implies or connotes. For example, if the proposed trademark might have unintended meanings this could lead to errors beyond the aural and orthographic issues. We might ask if the proposed trademark should provide internal markers to help guide the user.

This leads to question five. The influence of Direct To Consumer (DTC) promotional programs for ethical products suggests that product names should respect this DTC development and provide some guidance to the consumer as well as the health professional regarding the product's actions and or benefits. The trademark could signal users to focus more intently on the product and its intended benefits thus reducing medication errors.

I believe these comments would take no more than three to five minutes.

I look forward to meeting you and your colleagues on June 26.

Very truly yours,

*Beston Jack Abrams*

Beston Jack Abrams  
President ACT, Inc.

BJA/ats

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Evaluating Drug Names for Similarities: Methods and Approaches Public Meeting  
June 26, 2003

Request for opportunity to make a presentation  
Suzanne A. Coffman, Pharm.D.  
Product Manager  
NDCHealth  
3 Gamecock Ave Suite 307  
Charleston, SC 29407  
(843)769-2366 office  
(843)729-0151 cell

While I have some comments on several questions, the one I'd like to have the opportunity to address at the meeting is number 4 about effective risk management programs and their evaluation. I would like to have 10 minutes for my presentation and 5 for question/answer.

Responses to questions:

**1: Methods for evaluating drug names:** focus is on names of new proprietary products. Older drugs and generic names are also routinely involved in LASA errors (example hydroxyzine/hydralazine).

**2: Study methodologies for evaluating potential prescription errors:** we are conducting a study of our error-reduction tool with the Medical University of South Carolina College of Pharmacy. For our first phase we are relying on prescription data and not doing on-site visits. We are comparing serial submissions for the same prescription (or same patient if the prescription number changes) to detect changes in drug, quantity or days supply that could represent correction of a process error/quality related event related to prescribing or dispensing. One outcome of our study will hopefully be a validation of this methodology.

**3: What kind of information should be included in studies:** in addition to drug name, strength, quantity and directions also patient age, and weight for pediatric patients, whether or not voice-mail was used and whether the prescription was faxed or original. Also, studies of electronically transmitted prescriptions are needed to determine the extent to which that methodology decreases errors and introduces new root causes for error not seen with traditional prescribing workflows.

**4: Risk management programs for confusing drug names:**

LASA error prevention alert service: NDCHealth offers a service (RxSafety Advisor) to retail pharmacy outlets using our network (80% of the market) that evaluates prescriptions for the presence of potential look-alike sound-alike drug confusion. The service uses a U.S. patent pending set of rules and a database built around the USP/ISMP list of known look-alike sound-alike drug pairs, and includes a LASA likelihood score developed in conjunction with ISMP. If we detect a prescription where the dose is atypical for the drug submitted but typical for a look-alike sound-alike product we alert the pharmacist to double-check the prescription for a LASA error. In the 5 months since the service was launched we have prevented at least 50 potentially clinically significant errors with only about 200 stores using the service so far. Examples attached at end of report.

Study using claims data. We are doing a study of the impact of our service in the chain pharmacy environment using prescription claims data and comparing initial to subsequent

prescription submissions for the same patient to detect changes that could represent correction of a process error. The study will test the impact of the service in preventing LASA and other types of errors resulting from prescribing, handwriting or phone miscommunications or data entry.

Post-marketing surveillance. If our service were adopted by a wider base of pharmacies (80% of retail pharmacy outlets in the US use our network—chain, independent, hospital outpatient, specialty, and some mail-order) it could be a useful tool for post-marketing surveillance in the case of drugs suspected of being at risk for name-confusion errors. Not only would our alerts PREVENT some of the potential errors, we would track occurrences of how often errors occurred with an accurate denominator of total prescriptions filled.

**5: Different evaluation process for prescription vs OTC drugs? No comments.**

Table 1. Examples of LASA errors corrected to date in response to RxSafety Advisor alerts:

<b>Submitted Drug (LASA Pair)</b>	<b>Submitted Qty/Days</b>	<b>Outcome Qty/Days</b>	<b>Outcome Drug</b>
<b><u>Look-alike Sound-alike Drug Changes</u></b>			
CLARITIN-D 12 HOUR TAB SA (Claritin D/Claritin D 12 hr)	20/20	20/20	CLARITIN-D 24 HOUR TAB SA
ISOSORBIDE DN 20MG TABLET (Inderal/Isordil)	60/5	60/5	PROPRANOLOL 20MG TABLET
HYDRALAZINE 50MG TABLET (hydroxyzine/hydralazine)	15/4	15/5	HYDROXYZINE HCL 50MG TABLET
HYDRALAZINE 10MG TABLET (hydroxyzine/hydralazine)	100/3	100/4	HYDROXYZINE HCL 10MG TABLET
LAMISIL (Lamictal/Lamisl)			LAMICTAL 25MG TABLET
GLYBURIDE 5MG TABLET (glipizide/glyburide)	45/30	45/30	GLIPIZIDE 5MG TABLET
<b><u>Changes in Strength, Formulation Quantity or Days Supply</u></b>			
AZULFIDINE ENTAB 500MG	120/30	120/30	SULFASALAZINE 500MG TABLET
DITROPAN XL 5MG TABLET SA	45/30	45/30	OXYBUTYNIN 5MG TABLET
DITROPAN XL 5MG TABLET SA	45/30	45/30	OXYBUTYNIN 5MG TABLET
PERIOSTAT 20MG CAPSULE	30/30	45/90	DOXYCYCLINE 100MG TABLET
ALBUTEROL SULF 2MG/5ML SYRP	100/10	60/25	ALBUTEROL 5MG/ML SOLUTION
CELEXA 20MG TABLET	60/30	30/30	CELEXA 40MG TABLET
AMITRIPTYLINE HCL 25MG TAB	30/5	30/5	LORAZEPAM 0.5MG TABLET
AVANDIA 2MG TABLET	15/30	15/30	AVANDIA 4MG TABLET
SULINDAC 200MG TABLET	20/7	20/10	SULINDAC 200MG TABLET
VIOXX 25MG TABLET	14/3	14/14	VIOXX 25MG TABLET
SARAFEM 20MG PULVULE	42/84	42/28	SARAFEM 20MG PULVULE
AMERGE 2.5MG TABLET	9/5	9/9	AMERGE 2.5MG TABLET
HALOPERIDOL LAC 2MG/ML CONC	60/30	60/15	HALOPERIDOL LAC 2MG/ML CONC
HYDROXYZINE PAM 25MG CAP	60/5	60/10	HYDROXYZINE PAM 25MG CAP
PROPRANOLOL 40MG TABLET	300/75	300/100	PROPRANOLOL 40MG TABLET
SYNTHROID 100MCG TABLET	45/90	45/30	SYNTHROID 100MCG TABLET
SYNTHROID 75MCG TABLET	45/90	45/30	SYNTHROID 75MCG TABLET
TIZANIDINE HCL 4MG TABLET	15/3	15/7	TIZANIDINE HCL 4MG TABLET
TIZANIDINE HCL 4MG TABLET	15/7	15/14	TIZANIDINE HCL 4MG TABLET
LISINOPRIL 10MG TABLET	60/30	60/30	LISINOPRIL 40MG TABLET
PREDNISONE 20MG TABLET	42/12	42/12	PREDNISONE 10MG TABLET
ATENOLOL 50MG TABLET	15/30	60/30	ATENOLOL 50MG TABLET
AZULFIDINE ENTAB 500MG	120/30	180/30	AZULFIDINE ENTAB 500MG
METHOTREXATE 2.5MG TABLET	16/30	48/30	METHOTREXATE 2.5MG TABLET
GUAIFENESIN 1200 TABLET SA	13/6	20/10	GUAIFENESIN 1200 TABLET SA
HALOPERIDOL LAC 2MG/ML CONC	120/15	60/30	HALOPERIDOL LAC 2MG/ML CONC
DIOVAN 40MG TABLET	30/70	12/10	DIOVAN 40MG TABLET
SARAFEM 20MG PULVULE	42/84	14/28	SARAFEM 20MG PULVULE
CELEXA 20MG TABLET	15/30	30/15	CELEXA 20MG TABLET

## Gross, Mary

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**From:** Bruce L. Lambert, Ph.D. [lambertb@uic.edu]  
**Sent:** Monday, June 02, 2003 2:34 PM  
**To:** Gross, Mary  
**Cc:** lambertb2@attbi.com  
**Subject:** RE: Request to speak at June 26th drug name meeting

At 12:19 PM 6/2/2003 -0400, you wrote:

>Please send me an outline of what you plan to say with an estimate of  
>how much time you will need and I'll register you.

Mary,

Below is a preliminary outline of my comments (30 minutes):

1. Are methods currently employed by sponsors and FDA appropriate for evaluating look-alike and sound-alike names? Examples of methods currently being used include handwriting and voice recognition studies, computer tools, expert committee analyses, and questionnaire/surveys.

The following considerations are important when evaluating any proposed method of evaluation:

(a) The method must be scientifically validated. That is, there

must be some evidence that the method being used can reduce the probability of confusion. Ideally this validation would be based on some form of behavioral test (of memory, perception, or action).

(b) The method must be reproducible and, to the extent possible,

transparent. That is, others must be able to clearly understand and independently reproduce the evaluation. This may be difficult given the competitive, commercial marketplace for safety screening services and the related need/desire to keep some methods as trade secrets.

(c) The method should be, at least in part, objective. Although

the subjective judgments of experts will almost inevitably be relied upon in the final analysis, some of the major inputs to the decision-making process should be objective. We would never consider making safety/toxicity judgments in the absence of objective data, and we should not make naming decisions without objective evidence either.

(d) The circumstances of evaluation should be free from real or apparent conflicts of interest. One potential source of conflict that needs to be dealt with is when the organization who coins the name is also the organization that screens the name for safety. If an organization has a financial interest in the eventual adoption of the name, some safeguards must be put in place to make sure that the safety screening of that name is not unduly influenced by those who would benefit financially by its adoption.

2. In studies designed to evaluate potential prescription errors: (a) What

is an appropriate study design? (b) What is the appropriate size for an expert committee or for a prescription drug (written and voice recognition)

study? (c) What should be the composition of a group of evaluators

(e.g., what proportion of physicians, pharmacists, nurses, consumers)? (d) What are appropriate outcome measures?

(a) I will review several standard study designs commonly used to test the accuracy of short-term memory, visual perception, and auditory perception.

(b) The sample size needed for any experiment depends on the expected effect size of the result and the experimenter's tolerance for false positive and false negative errors. I will present a power analysis

and suggested sample sizes for some likely experimental scenarios, using published estimates of drug name confusion error rates as the basis for my analysis. For example, Flynn, Barker and Carnahan recently reported that

the wrong drug error rate in community pharmacy is approximately 0.13% (6/4481). I will discuss how large a sample is needed to have 80% confidence in detecting even one event under this scenario.

(c) The composition of the group of evaluators should be related to the proportional composition of the population of individuals who will encounter the drug as a professional or patient. Thus, the composition will vary depending on the drug's legal status (Rx vs. OTC), its indication, and its likely context of use. At a minimum, the panel should include a physician, a pharmacist, a nurse, and a patient.

(d) The most meaningful outcome measure is presence or absence of an error on some behavioral test of memory, perception, or action. The most meaningful outcome is an expert judgment on a validated rating scale.

3. What kind of information (e.g., drug name, strength, quantity, directions) should be included in verbal or handwritten prescription drug studies?

Studies should include all of the drug attributes that typically are included on drug orders or prescriptions. This will most commonly include drug name, strength, dosage form, quantity, and administration schedule.

4. Sometimes similar drug names are approved contingent on a pre-marketing agreement for a risk management program. Describe examples of effective risk management programs (e.g., an educational campaign) that could be used to minimize look-alike, sound-alike confusion. How should the effectiveness of a risk management program be evaluated?

Additional evidence is needed as to the effectiveness of post-marketing risk management programs designed to minimize name confusions. Those that have been tried with some anecdotal success include labeling changes, "shelf shouters," computerized alerts, "Dear Doctor" letters, pre-printed prescription pads, and print advertisements. Risk management programs should be evaluated in controlled experiments and real-world quasi-experiments. Dr. Tony Grasha's work exemplifies how such real-world quasi-experiments might be conducted. The outcome in tests of risk-management interventions must be the difference in error rates with

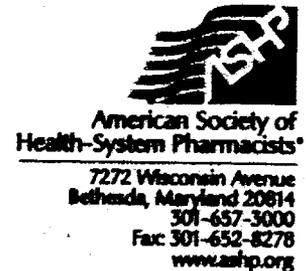
and without the intervention. Pre/post designs are probably not appropriate because time itself affects the error rate. In such studies, error rates must be assessed by direct observation or careful scrutiny, not by self-report.

5. Should there be different trade-name evaluation procedures for different classes of drugs (prescription vs. over-the-counter)?

Since harm reduction is the ultimate goal, and since both Rx and OTC drugs have the potential for serious harm, the OTC/Rx distinction may not be that useful in this context. The evaluation program should aim to reduce harm, where harm is seen as a function of the probability of error, the number of opportunities for error, and the severity of the consequence of each error. In general, high alert drugs (i.e., drugs with a narrow therapeutic index) and drugs that will be very frequently prescribed should receive the greatest scrutiny.

-bruce

**Statement of Kasey Thompson, Pharm.D.  
Director of Patient Safety, American Society  
of Health-System Pharmacists  
Before the Food and Drug Administration Public  
Meeting on Minimizing Medication Errors—  
Evaluating the Drug Naming Process, June 26,  
2003**



My name is Kasey Thompson, and I am the Director of Patient Safety of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of organized health care systems. We are grateful to the FDA for calling this public workshop to receive input on the agency's approach to minimizing medication errors through improving the drug naming process.

Section III(F) of the FDA's recent concept paper entitled "Premarketing Risk Assessment" discusses how drug sponsors can minimize medication errors. Specifically, this section states:

**Ideally, a sponsor would conduct a risk assessment to ensure that a product's proprietary name, established name, container label, carton labeling, package insert, and/or packaging do not inadvertently contribute to medication errors. For example, a sponsor could perform a medication error prevention analysis or MEPA to ... minimize the potential for an error through corrective action including renaming, relabeling or repackaging."**

The concept paper goes on to state that sponsors should assess a product's name, labeling, and packaging by obtaining "first-hand information from physicians, pharmacists, nurses and consumers." This sponsor-initiated assessment would "help to minimize medication errors" and "help speed FDA's review of these issues."

At a public meeting on risk assessment last April, ASHP strongly supported inclusion of this language in any future guidance document relating to premarket risk assessment issued by the FDA, and we urge the agency to quickly implement this concept. We have been encouraging FDA to do this for a long, long time:

In September 1998, we stated at an FDA Health Professional Organization meeting that drug naming, packaging, and labeling was a critical, issue that had not been adequately addressed by the FDA, despite the fact that there had been abundant evidence that poor product design is a major contributing factor in medication errors.

At a meeting in February 1999, we stated that one solution to the problem of medication errors stemming from poor package design and nomenclature is to require real-life submissions from the pharmaceutical industry prior to drug approval, and that before the FDA approves any new

drug or biological product it should require manufacturers to document that it has rigorously tested all packaging, naming, and labeling for their potential to induce errors. This testing should be done using proven methods involving practicing pharmacists, physicians, and nurses in simulated work environments.

In May, 1999, we commented that the FDA has an obligation to quickly review and revise its procedures to eliminate medication errors that occur due to look-alike and sound-alike names, similarities in packaging, and other labeling and packaging problems. We also noted that patients should be considered the partners of health professionals in eliminating medication errors, and they should be involved in providing input into the safety design of drug product labeling. We are pleased that the FDA concept paper includes a provision for patient/consumer input.

In January 2002, in comments to the agency on its performance goals for the reauthorization of the Prescription Drug Marketing Act, we stated that "the most consistent message ASHP hears from its members is that the FDA should be doing more to assure that drugs are safe for patients," and that safety issues must be anticipated through premarket evaluation. One specific, new performance goal that we recommended was for the FDA to engage pharmacists, physicians, nurses, and human factors experts in documented failure-mode-and-effects analyses of prospective product nomenclature and labeling to minimize the opportunities for sound-alike names and look-alike packaging for causing medication errors.

In terms of the specific questions that the FDA asked participants to address for this public meeting, ASHP has the following comments:

*Question 1: Are methods currently employed by sponsors and FDA appropriate for evaluating look-alike and sound-alike names?*

Generally, the kinds of methods being used by the FDA could detect naming problems. Our concern is to what extent FDA staff simulates the range of "real-life," drug order situations common in hospitals and health systems.

Mobility brings together physicians, nurses, and pharmacists from different regions of the US with characteristic dialects, and from other parts of the world with primary languages other than English. Face-to-face and telephone communications are easily confused by these differences.

The methods and forms of medication order writing, capture, and transmission vary considerably among hospitals. Orders can be handwritten imbedded within progress notes or segregated on distinct order sheets that separate the drug name from indication. Orders are transmitted to the pharmacy by NCR copies and internal FAX machines which confound handwriting variations with smear and electronic artifacts.

And, let us not forget that hospital and health system patient populations are also becoming more culturally and linguistically diverse. Communications with patients (consumers) about their medications is an important component of medication error prevention.

*Question 2: In studies designed to evaluate potential prescription errors: (a) What is an appropriate study design? (b) What is the appropriate size for an expert committee or for a prescription drug (written and voice recognition) study? (c) What should be the composition of a group of evaluators (e.g., what proportion of physicians, pharmacists, nurses, consumers)? (d) What are appropriate outcome measures?*

Study designs should, to the extent possible, replicate common medication order situations with experientially known error vulnerabilities. Designs should include multiple detection and interception methods as appropriate for the vulnerabilities in each step of the medication-use process. Expert committees should be representative of those health professionals, especially, physicians, nurses, and pharmacists, who have essential roles in hospital and health system medication-use processes.

*Question 3: What kind of information (e.g., drug name, strength, quantity, directions) should be included in verbal or handwritten prescription drug studies?*

Information requirements alone are insufficient. How medication orders are communicated and the context in which they are communicated either contribute to or reduce the potential for errors. Studies should look at error potentials of propriety names alone and in the context of typical medication orders (dosage regimen) and standardized medication orders that incorporate requirements known to reduce the likelihood of misinterpretation (See ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents).

*Question 5: Should there be different trade-name evaluation procedures for different classes of drugs (prescription vs. over-the-counter)?*

There is no difference between prescription and non-prescription products as far as error potential for interchangeability and subsequent patient harm. ASHP would also like to emphasize the importance of name recognition for high-alert drugs (which is not an official class, but recognized in the medication safety world), such as antineoplastic and other hazardous drugs that have a very low therapeutic index, and therefore a high-probability for patient harm if an error occurs due to name confusion.

ASHP believes that the FDA is taking the right approach to this serious public health issue and appreciates this opportunity present its comments relating to the FDA's program for minimizing medication errors.

Contact Information:

Kasey Thompson, Pharm.D.  
Director of Patient Safety  
American Society of Health-System Pharmacists  
7272 Wisconsin Ave.  
Bethesda, MD 20814  
301-657-3000, ext. 1270

**Sent:** Thursday, June 05, 2003 9:09 AM  
**To:** 'grossm@cdcr.fda.gov'  
**Subject:** Minimizing Medication Errors Convention

To Whom It May Concern:

With regards to the upcoming meeting investigating policy for the naming of medications:

Being unsure of the interdisciplinary nature of the current panel reviewing these naming requests, I will comment that it is "Key" that practicing clinical pharmacists be included in these discussions. Clinical pharmacists are the experts in this area. Being credentialed is not sufficient. Active participation in the workfield, so as to have a working knowledge base of these issues, is critical to identifying these problems proactively.

For example, from the minute that aripiprazole (Abilify) Bristol Myers entered the market, it was obvious to the pharmacy community that the drug would be confused with one of the proton pump inhibitors (ie. omeprazole, lansoprazole, etc...) We basically sat back and waited for the first report of "Sound Alike" error to occur. It is difficult to believe that a pharmacist could possibly sit on the panel making these decisions and allow the above name to be approved.

I would suggest that a sufficient size group of pharmacists be asked to volunteer to review potential drug names via email and/or mailed out survey prior to approval of medication names. Additionally, it might be important to critically review both brand and generic names, as the "Sound Alike" issues cross both these boundaries.

I, myself, would be happy to volunteer.

***Kimberly Schnacky, PharmD***  
**President, Central Florida Society of Health Systems Pharmacists**  
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## **Reviewing Pharmaceutical Trademarks – A New Frontier or Familiar Legal Territory?**

by  
Maury M. Tepper, III  
Womble Carlyle Sandridge & Rice, PLLC  
Raleigh, NC

I would like to thank each of the sponsors of this program for addressing the important topic of how best to review pharmaceutical trademarks in order to minimize the potential for medication errors. My hope is that today's discussion will demonstrate that all of the groups represented here will come to understand that we are working toward a common goal – to maximize patient safety. While there may be some disagreement as to how best to reach that goal, the process of understanding the viewpoints represented by the participants in this conference is an important first step towards developing a more predictable and reliable system. In the field of pharmaceutical trademarks, both trademark attorneys and the FDA have valuable insights that should play a role in reviewing trademarks. The key is to develop a system that capitalizes on the expertise of both. The review of pharmaceutical trademarks can best be accomplished by employing new methodologies within the context of well-settled legal principles, rather than creating an entirely new system of review.

### ***The Trademark Law Perspective***

In developing systems for reviewing proposed pharmaceutical trademarks, it is important not to overlook or to slight the utility of existing legal constructs and the body of expertise that has been developed under the trademark laws and within the U.S. Patent & Trademark Office ("PTO"). For more than a century, the trademark system has been designed to protect consumers against confusion and to facilitate the development and protection of unique brands that manufacturers can use to distinguish their products from those of others and that consumers can rely upon in making purchasing decisions. During this time period, courts and the PTO have developed analytical tools for assessing the likelihood of consumer confusion between trademarks. This analysis employs factors that take into account the way in which products are displayed and purchased, always with the end result of ensuring that consumers will be protected against any likely confusion in the marketplace.

These legal doctrines also establish priority in trademark rights, bringing predictability to the market and providing a clear set of rules for resolving competing claims to similar marks.

### ***The FDA Perspective***

It is clear that prescription drugs are marketed and dispensed in a unique way, as compared to other goods and services. Prescription drugs may be the only products where the ultimate consumer (*i.e.*, the patient) does not make the purchasing decision. Rather, a medication is selected by a physician and dispensed by a pharmacist. In this particular marketplace, the consumer's traditional role in product selection and purchasing control have

been supplanted by third-party prescribers and dispensers. The system is further complicated by the use of handwritten prescriptions, medical abbreviations and other system-related factors that accompany any order for a particular medication. The FDA possesses a detailed understanding of this unique marketplace. For nearly a decade now, the FDA has played an increasingly active role in reviewing and commenting on proposed pharmaceutical trademarks.

### ***The Current System – A Recipe for Conflict***

Unfortunately, the roles of the FDA and the PTO in reviewing proposed trademarks for prescription pharmaceuticals have not been clear in recent years, and the differing analyses employed by these agencies has sometimes led to conflict and to divergent results. Further, the FDA's decisions regarding a sponsor's right to use a proposed trademark do not take into account the existence of any potentially conflicting prior legal rights, creating the potential for discord. While some of this conflict may be unavoidable, it appears that little deference has been given to the decision-making expertise of the PTO, or of that agency's ability to predictably analyze consumer confusion. At the same time, the PTO has not been provided with the benefit of the FDA's familiarity with the prescription market. The expertise of both agencies should be combined in the model for reviewing pharmaceutical trademarks.

### ***Combining the Best of Both Worlds – A System for Pharmaceutical Trademark Review***

Given the unique situation in the prescription market, it is appropriate to analyze trademarks in a way that takes into account prescribing and dispensing conditions. Such an analysis, however, need not represent a radical departure from the trademark system. Indeed, legal tests for trademark infringement look at the way in which marks are encountered in the marketplace. In this connection, the safety review being presented and discussed today can and should be seen as a part of, rather than, a replacement for the legal test for trademark availability.

The tools and approaches being presented at this conference are a useful starting point for any analysis of pharmaceutical trademarks. The touchstone of the analysis must be to determine whether any proposed mark creates a likelihood of consumer confusion in the relevant marketplace. Thus, tests that take into account ways in which the mark will actually be encountered are the most probative. While little may be known about fields such as handwriting analysis or voice recognition, the best learning from these fields should be employed to develop tests that approximate conditions in the relevant prescription market. The FDA has, for several years now, been employing this type of "field testing" in its review process, and this morning's presentations demonstrate ways in which that testing can be conducted as a part of the trademark clearance process.

Once the appropriate tests have been run, the well-developed body of trademark law, with its consumer-based likelihood of confusion test, should be employed by those with experience in the trademark field. The data from these analyses must be combined and weighed in reaching a determination as to whether a particular mark will create an undue risk of confusion. Try though one may, however, one cannot escape the conclusion that this decision is

an inherently subjective determination. Because there are so many different potential causes of a medication error, and because so many different factors, in addition to the name, play into determining whether an actual substitution between products bearing potentially similar names would ever occur in the marketplace, there can be no single formulaic approach to evaluating proposed drug names for safety. Analyzing only the similarity of proposed names falls short by not taking into account market conditions or determining whether the two names at issue could ever actually be encountered in the same clinical settings. Often, factors such as dosing form, dosage strength, indications and practice setting (*i.e.*, hospital or retail pharmacy) play an important role in increasing or eliminating the likelihood that substitution or errors may occur when potentially similar names are involved. These factors may, when appropriately analyzed, reveal that potentially similar names can safely co-exist if they are used on sufficiently distinct products with sufficient differences to preclude any likelihood of substitution. Conversely, these factors may indicate that two marks that otherwise do not appear to be overly similar nevertheless present an unacceptable risk and therefore should not be used.

Trademark attorneys applying the appropriate legal analysis for infringement regularly balance various factors (including market conditions) to arrive at a subjective determination of likelihood of confusion in each case. Their expertise, and that of the trademark system, should not be overlooked. In fact, while FDA has great expertise in understanding the prescription marketplace, the agency does not have expertise in developing or applying appropriate tests to weigh the subjective factors that go into analyzing trademark availability. Given this, the FDA's most appropriate role should be to help refine and establish appropriate tests that take into account actual market conditions. Once these tests have been established and agreed upon, the FDA should ensure that the tests have been employed by a sponsor proposing a new trademark. The FDA should not, however, readily substitute its subjective judgment for that of the sponsor. Indeed, there is no indication that the FDA's subjective judgment is any more reliable or safe than that of the sponsor, which, after all, has a vested interest in establishing a unique identity for its product and ensuring that the product will not be confused with any other.

While we all wish for a predictable objective test that would readily identify and eliminate any potential for medication errors, the real world unfortunately will not provide conditions that allow for such a test. Given that any test to analyze proposed trademarks will involve an inherently subjective determination, the best approach is therefore to develop and refine analytical tools that will approximate market conditions and to ensure that the appropriate analysis is carefully employed by a sponsor. Once the sponsor has made an appropriate analysis of all relevant data and reached a decision, the FDA should be reluctant to replace the sponsor's decision with the Agency's subjective judgment, particularly when the sponsor, utilizing the trademark system, has more extensive expertise and experience in analyzing the likelihood of confusion between two marks.

Further, incorporating these analytical tools into the legal review and clearance of trademarks will remove the potential conflict between trademark priority and FDA priority when competing marks are involved. This would provide a more predictable system for decision making.

Finally, it is important to keep all of these efforts in the appropriate context. While the pharmaceutical industry does, and should continue to do, everything that it can to develop and employ trademarks that will serve as safe, unique product identifiers, we must not lose sight of the fact that trademark similarity is only one of the many factors that contribute to medication errors. Other factors in the system, such as the use of handwriting, the use of medical abbreviations, cramped storage conditions in retail pharmacies, poor lighting, lack of indications on prescriptions and many other factors, play a significant role in medication errors. Efforts to address these other factors would likely have a greater impact on the overall rate of medication errors, and we should be mindful to employ our efforts where they will have the greatest impact. Continuing to refine and employ the best possible tests in order to ensure the adoption of unique, recognizable and safe trademarks should be part of an overall systemic approach to reduce medication errors. This approach should also address the behavior of doctors in writing prescriptions legibly, providing indications and information necessary to enable the pharmacist to understand them, efforts to address pharmacy practices to reduce the likelihood that the wrong medication will be hastily grabbed from a shelf, and patient education efforts to encourage consumers to play a more active role in understanding the products that have been selected and dispensed for them.

Thank you for your time and attention. I look forward to continuing to work with all of you on this important issue.

From: SMjshiyRPh@aol.com  
Sent: Tuesday, June 24, 2003 1:45 AM  
To: fdadockets@oc.fda.gov  
Subject: Comments on Docket No: 02N-0201  
Dear Sirs:

I am writing to provide my comments on Docket No 02N-0201.

As a practicing pharmacist there is not one day that goes by in which I must deal  
The FDA can help my patients and me by screening drug names for similar looking an  
Thank you for listening to my comments.

Sincerely,

Matthew Shivers, R.Ph.  
3112 406 Rd  
W Burlington, Iowa 52655



*Advancing Quality Healthcare  
Through Over-the-Counter Medicines  
and Nutritional Supplements*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

July 9, 2003

Ms. Mary Gross  
Office of Drug Safety (HFD-400)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 2003N-0201; Evaluating Drug Names for similarities; Methods and Approaches (meeting formerly called Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential); Public Meeting; Request for Comments; 68 Fed. Reg. 32529 (May 30, 2003)

Dear Ms Gross:

These comments are submitted in response to the above-referenced public meeting of June 26 on evaluating drug names for similarities, which was co-sponsored by the FDA, PhRMA and the Institute for Safe Medication Practices.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter drugs. CHPA members account for over 90 percent by retail sales of OTC drugs in the United States. CHPA has a long history of working toward improving the OTC drug label. In 1991, CHPA pioneered guidelines on label readability that identified technical factors that could improve the OTC label for consumers. FDA has recognized CHPA's work with the agency to improve the OTC label, and the association also urged FDA to adopt regulations on the subject.<sup>1</sup> CHPA is a frequent partner with FDA and other consumer allies in educational efforts to expand consumer knowledge about using the OTC label to ensure the safe and effective use of OTC medicines. Accordingly, CHPA has an important interest in this matter.

### I. Introduction

The agenda for the public meeting posed one question that addressed OTC drugs: "Should there be different trade-name evaluation procedures for different classes of drugs

<sup>1</sup> See 62 Fed. Reg. 9031 (February 27, 1997).

(prescription vs. over-the-counter)?" Comments were offered by one FDA participant and by a few of the public speakers. Without supporting data or explanation, it was suggested that there is no difference between prescription and OTC drugs from the standpoint of usage patterns and potential for harm, and therefore that the trade name evaluation process for both should be identical. The practice of brand name line extensions was also challenged as confusing, but no data were offered to support this assertion.

## II. Prescription drugs and OTC drugs are different.

There are significant differences between the labeling, purchase, use, and potential for harm of prescription drugs and OTC drugs, which has direct relevance to their trade names.

Prescription drugs and OTC drugs have different safety profiles. A prescription drug is one which because of its toxicity or other potential for harmful effect, or the method of its use or collateral measures necessary to its use, is not safe for use except under the supervision of a physician or other licensed practitioner; or one which for reasons of protection of the public health is limited to use under supervision of a licensed practitioner pursuant to an approved NDA.<sup>2</sup>

An OTC drug is one which must be safe and effective for consumer use without the supervision of a physician or other licensed prescriber, according to a label that contains adequate directions for use and adequate warnings.<sup>3</sup> Thus, an OTC drug must have a wide margin of safety.

Prescription drugs are available only upon the written or verbal order of a physician or other licensed prescriber. Prescription drugs generally are packaged by pharmacists at the point of sale in uniform containers that bear little written information. Such prescription drug dispensing practices have changed hardly at all in over a century. At the public meeting this was reflected in presentations by panelists on issues such as how to avoid look-alike errors attributable to difficult-to-decipher handwriting, how to avoid sound-alike errors in verbal orders using voice recognition systems, and errors that result from undifferentiated point of sale packaging by the pharmacist.

The OTC drug label contains all the information the consumer needs for safe and effective use. OTC drugs are prepackaged by the manufacturer. OTC labels contain comprehensive information that is pervasively regulated by FDA. OTC labels contain

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<sup>2</sup> 21 USC § 353 (b).

<sup>3</sup> 21 USC § 352 (f).

multiple redundancies. Thus, the consumer receives all the information necessary for safe and effective use of the product on the OTC label:

- The Principal Display Panel (PDP) of an OTC must bear a statement of identity as a principal feature. The statement of identity must prominently and conspicuously declare the established name of the drug or in the case of a mixture without an established name, the principal intended action of the drug in terms meaningful to the layman.<sup>4</sup>
- The OTC label must declare active ingredients, inactive ingredients, indications for use, directions for use, warnings and contraindications, and other required information.

Each of these label elements must be presented in a standardized format established by the FDA in its Drug Facts Format and Content rule:<sup>5</sup>

- “Active ingredient[s],” so designated, must be declared first, followed by the established name and the quantity of each active ingredient per dosage unit—repeating information on the PDP for single active ingredient OTCs.
- “Purpose[s],” so designated, must be followed by the general pharmacological category[ies] or principal intended action[s] of the drug—repeating information on the PDP.
- “Use[s],” so designated, must be followed by the indication[s] for the drug—restating information provided in the Purpose section and the PDP.
- “Warning[s],” so designated, must be followed by specific warnings where applicable, each with highlighted subheadings and each in order:

The Reye’s syndrome warning; allergic reaction warnings set forth in any applicable OTC drug monograph or approved NDA; the flammability warning, with appropriate signal words; the water soluble gums warning; the alcohol warning; the sore throat warning; the warning for drugs

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<sup>4</sup> 21 CFR, § 201.61.

<sup>5</sup> 21 CFR § 201.66.

containing sodium phosphates; warnings to consult a doctor before use in the event of certain preexisting conditions; in-use warnings followed by side effects the consumer may experience when using the product; warnings to stop use and ask a doctor if certain signs or reactions occur; warnings required by an applicable OTC drug monograph, OTC regulation, or approved NDA; the pregnancy/breast feeding warning; the third trimester aspirin warning; the third trimester warning for certain other NDA'd NSAIDs; and the warning to keep out of reach of children.

- “Directions,” so designated, must be followed by the directions for use in an applicable OTC monograph or approved NDA.
- “Other information,” so designated, must be followed by additional information that is required or is optional under an applicable OTC monograph, other OTC regulation, or is included in the labeling of an approved NDA.
- “Inactive ingredients,” so designated, must list the established name of each inactive ingredient in alphabetical order (or if the OTC drug product is also a cosmetic, then in descending order of predominance by weight, employing names designated in cosmetic ingredient regulations in 21 CFR Part 701).
- “Questions?” or “Questions or comments?” so designated, must be followed by the telephone number of a source to answer questions about the product.
- These elements must be displayed in a “Drug Facts” box with the heading “Drug Facts.” The rule specifies minimum type sizes and use of sans serif type. It prescribes the use of barlines and hairlines of specific thickness; headings and subheadings; use of upper and lower case letters; the shapes and sizes of “bullets”; left and right justification; and it restricts the use of hyphens.

FDA has also established a list of 100 interchangeable terms and connecting terms that may be used in the labeling of OTC drug products, provided that their use does not alter the meaning of the labeling established in an applicable OTC monograph or by regulation.<sup>6</sup>

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<sup>6</sup> 21 CFR §§ 201.66 (f) and 330.1 (i) and (j).

An OTC drug product that is not in compliance with these requirements is subject to regulatory action as a misbranded drug.<sup>7</sup>

FDA said that it designed the Drug Facts rule to ensure that all material facts about the safe and effective use of OTC drug products are adequately presented to the consumer with such conspicuousness and prominence that they are likely to be read by the ordinary individual under customary conditions of use.<sup>8</sup> The agency explained that the standardized format, in conjunction with content requirements, should help the consumer to readily and meaningfully compare OTC drug products, and minimize potential for consumer confusion when comparing products within the same pharmacological class.<sup>9</sup>

Consumers read OTC drug labels. According to a recent study conducted by Roper Starch Worldwide for CHPA, consumers acknowledge the need to exercise care when selecting and using OTC drugs. Ninety-five percent of respondents report reading OTC label directions before taking an OTC drug for the first time. Ninety-one percent look for information on side effects and interactions, and 89% study labels to choose appropriate OTC drugs for their symptoms or condition.<sup>10</sup>

Against this background, an OTC trade name is unlikely to result in confusion or error. And given the wide margin of safety for OTCs, there is a low potential for harm in the unlikely event of a mistaken selection.

## II. OTC trade names are beneficial to consumers.

OTC trade names, including line extensions, are beneficial to consumers. Line extensions assist consumer purchasing decisions by identifying the source of different products as a known and trusted company. Brand names allow consumers to locate a family of products in which they have faith and experience, and to select from among them the one most appropriate to a current need. The brand name identifies for the consumer a family of related products that are similar in relevant, though obviously not all, respects.

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<sup>7</sup> 21 CFR § 201.66 (g); 62 Fed. Reg. at 9042-9043 (February 27, 1997).

<sup>8</sup> 62 Fed. Reg. at 9043 (February 27, 1997).

<sup>9</sup> Id.

<sup>10</sup> "Self-Care in the New Millennium," Roper Starch Worldwide (March 2001); study conducted for CHPA. Full study available at the association's website, [www.chpa-info.org](http://www.chpa-info.org). This study confirmed the findings of a study conducted in 1992 by the Heller Research Group for the CHPA.

Undue restrictions on OTC trade name line extensions would create a Tower of Babel effect, contributing to consumer confusion by balkanizing and splintering product lines into unpatterned and chaotically named products. Without the helpful shorthand of line extensions, consumers would need to acquire and master separate information about each distinct product, unassisted by the organizing principles that line extensions provide through their use of trademarks. Line extensions facilitate the selection of products that will perform identified tasks, and provide reliable information to enable a consumer to select products effectively.

Complete information about the active and inactive ingredients, indications, purposes, directions, warnings, and other information is available at the point of sale to fine tune the selection process, and accompanies the product once the consumer takes it home and uses it.

Trade name line extensions also facilitate the introduction of useful new OTC products for consumers. Trusted brand names are the principal repository of consumer good will that enables a company to distinguish its products from those offered by others. Undue restrictions on line extensions would raise the cost of introducing products, thereby reducing consumer choice because the expense of establishing new brand names unfamiliar to the public could reduce the introduction of useful new products altogether.

Trade names are costly to create. The start-up costs of producing a memorable brand are high. It is exactly for this reason that line extensions are valuable for both companies and consumers. Line extensions afford a company economies of scale by distributing accumulated consumer good will over a number of related products. Unwarranted limits on OTC line extensions would be disproportionately burdensome to smaller companies in particular, who may lack the resources to launch entirely new brands. Because of the realities of the marketplace, many new products may not be able to be introduced except as line extensions.

Trade names or line extensions may not be prohibited based on the unsupported assertion that they are false or misleading. A line extension must be predicated on firm and reliable evidence that a line extension is, or is likely to be, misleading.<sup>11</sup> CHIPA is unaware of any evidence that actual consumer confusion as a result of trade names or line extensions is an authentic problem.

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<sup>11</sup> 108 Cong. Rec. 21,066 (1962). "[T]he finding ... must be based on a fair evaluation of all material facts[, which requires] objective facts of record that are clear and more definite than simply a matter of individual interpretation." To prevent arbitrary determinations of "misleadingness," Congress said "there must also be, to warrant a disapproval or a revocation, objective facts of record which make the proposed labeling *demonstrably* false or *demonstrably* misleading." [Emphases added.]

There is little reason to believe that consumers are likely to be misled by OTC trade names or line extensions. As described above, OTC drugs are labeled in strict adherence to detailed regulations that require declaration of their active and inactive ingredients, indications, directions, warnings, and more.

In light of the foregoing, any trade name policy must recognize the clear distinctions between prescription drugs and OTC drugs. Unlike the prescription drug setting where little other than the name may be provided to the patient, in the OTC setting the printed label contains all of the information necessary for the consumer to use the OTC drug safely and effectively.

Thank you for your consideration of our views.

Sincerely,



Eve E. Bachrach  
Senior Vice President, General Counsel  
and Secretary



Douglas Ws. Bierer, Ph.D.  
Vice President, Regulatory and Scientific Affairs