**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
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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.[1] 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.[2] 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.[3] 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.[4] 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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[1] 68 FR at 325,30.
[2] Institute of Medicine Report "To Err is Human: Building a Safer Health System," 1999.
[3] 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.
[4] Pharmaceutical Research and Manufacturers Association website. "New Drug Approvals." 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.[5] 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.[6] 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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[5] 68 FR at 32,530.

[6] American Medical Association website. "United States Adopted Names." 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.[7] 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 Celebrex™, 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

[7] Voice of the Injured.Com. "Pharmacists and Pharmacies Make Prescription Errors that Kill or Injure." 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.