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American Pharmacists Association
House of Delegates – Baltimore, MD
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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Elise Barry for the New Jersey Pharmacists Association
(Name)

01/20/2016
(Date)

New Jersey Pharmacists Association
(Organization)

Subject: Generic solid dosage forms

Motion: Move to adopt the following policy statement:

APhA encourages the FDA, USP and other appropriate organizations and agencies to standardize the identification and appearance of generic solid dosage forms.

Background:

Generic bioequivalent drug substitutions have become the mainstay of cost control in the US healthcare system. Generic drugs comprise 70% of total US prescriptions and 20% of total prescription costs in 2011¹. However, generic drugs are most often differentiated from brand name products through shape, color, and size depending upon manufacturer. In the realm of mandatory generic substitutions and multiple generic manufacturers, these differences between appearances of interchangeable products can lead to patient confusion, reduced medication adherence, reduced contribution of the placebo effect and increased likelihood of prescription errors. Patients may become confused from receiving differently appearing pills upon refill of chronic medications, if the dispensing pharmacy changes manufacturers for that medication. If the patient questions the validity of differently appearing pills, the patient may wait or not even take the medication dispensed due to appearance discrepancy from previous fill, and thus leading to reduced medication adherence. Studies have shown that there is influence in therapy from the placebo effect of taking medications¹. In this scenario, a patient may not receive the equivalent therapeutic effect from a generic medication if the patient perceives the generic medication to be of lower quality/equivalence from the branded medication. Lastly, a pharmacy that frequently changes generic manufacturers may lose the ability to recognize/differentiate an appropriate product substitution based upon appearance and thus loses 1 level of verification within the dispensing process. This may increase the likelihood of a medication error occurring within the dispensing process.

A study by Kesselheim et al, Burden of changes in pill appearance for patients receiving generic cardiovascular medications after myocardial infarction: cohort and nested case-control studies, investigated the impact of proper medication use and switching between differently appearing generic equivalent substitutions from multiple manufacturers. “29% of patients had a change in pill shape, color or size during the study. A total of 4573 episodes of nonpersistence were matched to 19,881 control episodes. The odds of nonpersistence in case patients increased by 34% after a change in pill color (adjusted odds ratio, 1.34 [95% CI, 1.12 to 1.59]) and 66% after a change in pill shape (adjusted odds ratio, 1.66

[CI, 1.43 to 1.94)]².” The authors concluded that changes in appearance of generic pills are associated with reduced adherence to medication regimen. Therefore, standardization of medication adherence should help to alleviate some of the negative effects on patient adherence.

There is a legal basis to differentiation between generic and branded drug products and this is in the form of trade dress regulation. To qualify for protection under trade dress regulation, the attribute must meet 3 criteria: it must be non-functional, it must lead to confusion (or deception) if imitated and it must have a secondary association with the product for the consumer¹. In regards to pharmaceutical trade dress, functionality becomes the question and issue. In 2003, the Third Circuit Court of Appeals in *Shire v. Barr* heard the case that Barr had potentially violated trade dress by manufacturing generic Adderall in the same shape, size and color for different corresponding strengths¹. Shire’s promotions highlighted how differences in the color, size, and shape of the various doses of Adderall promoted the ability of children with ADHD to adhere to their regimens¹. The court agreed with Barr that the functionality of the color, shape and size of Adderall were not protectable under trade dress¹. This decision diminishes the legal basis for branded and generic drugs to have differing appearances.

Standardization of appearance of generic and branded medications may reduce patient confusion, increase medication adherence, promote the placebo effect in patients and reduce medication-dispensing errors. Therefore, the standardization of medication appearance serves a functional role in promoting patient safety and outcomes, and does not infringe upon trade dress protection. The NJPhA supports a shift in the pharmaceutical industry towards standardization of medication appearance between generic and branded products.

Recommendation follows an NJPhA resolution from 2002:

NEW JERSEY PHARMACISTS ASSOCIATION HOUSE OF DELEGATES ATLANTIC CITY, NEW JERSEY JUNE 19, 2002

RESOLUTION NUMBER 4

Subject: Standardization for Identification and Appearance of Generic Solid Dosage Forms

Motion: NJPHA encourages the FDA, USP and other appropriate organizations and agencies to standardize the identification and appearance of generic solid dosage forms where multiple strengths are available.

References:

- 1) Greene J, Kesselheim A. Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health. *N Engl J Med* 2011; 365:83-89 July 7, 2011 DOI: 10.1056/NEJMhle1101722
- 2) Kesselheim S, Bykov K, Avorn J, et al. Burden of changes in pill appearance for patients receiving generic cardiovascular medications after myocardial infarction: cohort and nested case-control studies. *Ann Intern Med*. 2014 Jul 15;161(2):96-103. doi: 10.7326/M13-2381.
- 3) [Annals of Internal Medicine article](http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/175/original_policy_proposal_article-annuals_of_internal_medicine-pill_appearance.pdf): http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/175/original_policy_proposal_article-annuals_of_internal_medicine-pill_appearance.pdf
- 4) [New England Journal of Medicine article](http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/181/original_nejmhle1101722.pdf): http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/181/original_nejmhle1101722.pdf

Current APhA Policy & Bylaws:

No current policy exists.

New Business Items are due to the Speaker of the House by **February 3, 2016** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.