

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 922
(I-18)

Introduced by: Georgia
Subject: Full Information on Generic Drugs
Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

- 1 Whereas, There is no longer a U.S. Food and Drug Administration (FDA) requirement that the
2 generic drug needs to be tested in patients: just 24 – 36 adult volunteers! Patient testing was
3 abandoned in 1984; and
4
- 5 Whereas, While New Drug Applications (NDA) to the FDA require patient testing, generic drugs
6 are considered under Abbreviated New Drug Applications (ANDA) and no patient testing is
7 required; and
8
- 9 Whereas, Current FDA protocol allows generic drugs to be marketed after having met the
10 criteria for bioequivalence to brand-name drugs; and
11
- 12 Whereas, The generic drug product must have “data demonstrating that the drug product is
13 bioequivalent to the pioneer (innovator = AKA Brand Product) drug product;” and
14
- 15 Whereas, The active ingredient is tested using PK measurements that are performed and
16 include area under the plasma concentration-time curve (AUC) and the maximum or peak drug
17 concentrations (Cmax). If there is a difference of greater than 20% for each of the tests, then
18 this is determined to be significant and thus undesirable. This is expressed as a limit of each of
19 these two tests of 80% and by convention that all of the data is expressed as a ratio of the
20 average response (AUC and Cmax) and the limit for the second statistical test is 125%
21 (reciprocal of 80%); and
22
- 23 Whereas, The FDA feels that bioequivalent products and therapeutically equivalent products
24 can be substituted for each other without any adjustment in dose. ANDA drugs brought to
25 market are compared to the innovator drug, but one generic is not compared to another generic;
26 and
27
- 28 Whereas, Two generic drugs – both classified by the FDA as bioequivalent to the brand-name
29 drug – can be significantly different while still falling within the FDA’s specified range for
30 bioequivalence; thus, demonstrating concern over whether the two drugs should be deemed
31 therapeutically different¹; and
32
- 33 Whereas, The data collected at the FDA compares generic substitution of generic X or generic
34 Y versus Brand Name but does not compare Generic X versus Generic Y. Clinically physicians
35 are often substituting Generic X for Generic Y and have no scientific data to compare these
36 two¹; therefore be it

- 1 RESOLVED, That our American Medical Association advocate that generic drugs have an FDA-
- 2 approved package insert available when dispensed that discloses active and inactive
- 3 ingredients and clear language with bio-equivalent data as compared to parent branded drug.
- 4 (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

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RELEVANT AMA POLICY

Generic Drugs H-125.984

Our AMA believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice.

(2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name products.

(3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.

(4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program.

(5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products.

(6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength).

(7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

Citation: (CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmation A-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 525, A-10; Reaffirmed in lieu of Res. 224, I-14)

Prescription Labeling H-115.974

Our AMA recommends (1) That when a physician desires to prescribe a brand name drug product, he or she do so by designating the brand name drug product and the phrase "Do Not Substitute" (or comparable phrase or designation, as required by state law or regulation) on the prescription; and when a physician desires to prescribe a generic drug product, he or she do so by designating the USAN-assigned generic name of the drug on the prescription.

(2) That, except where the prescribing physician has indicated otherwise, the pharmacist should include the following information on the label affixed to the container in which a prescription drug is dispensed: in the absence of product substitution, (a) the brand and generic name of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; and (d) the name of the manufacturer or distributor.

(3) When generic substitution occurs: (a) the generic name (or, when applicable, the brand name of the generic substitute ["branded" generic name]) of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; (d) the manufacturer or distributor; and (e) either the phrase "generic for [brand name prescribed]" or the phrase "substituted for [brand name prescribed]".

(4) When a prescription for a generic drug product is refilled (e.g., for a patient with a chronic disease), changing the manufacturer or distributor should be discouraged to avoid confusion for the patient; when this is not possible, the dispensing pharmacist should satisfy the following conditions: (a) orally explain to the patient that the generic drug product being dispensed is from a different manufacturer or distributor and, if possible (e.g., for solid oral dosage forms), visually show the product being dispensed to the patient; (b) replace the name of the prior generic drug manufacturer or distributor on the label affixed to the prescription drug container with the name of the new generic drug manufacturer or distributor and, show this to the patient; (c) affix to the primary label an auxiliary (sticker) label that states, "This is the same medication you have been getting. Color, size, or shape may appear different;" and (d) place a notation on the prescription record that contains the name of the new generic drug manufacturer or distributor and the date the product was dispensed.

Citation: BOT Rep. 1, A-95; Amended: CSA Rep. 2, I-99; Modified Res. 512, I-00; Reaffirmed: CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmed: Sub. Res. 509, A-07; Reaffirmed: CSAPH Rep. 01, A-17

References

¹Information and the following supporting figure reprinted by permission of American College of Rheumatology:

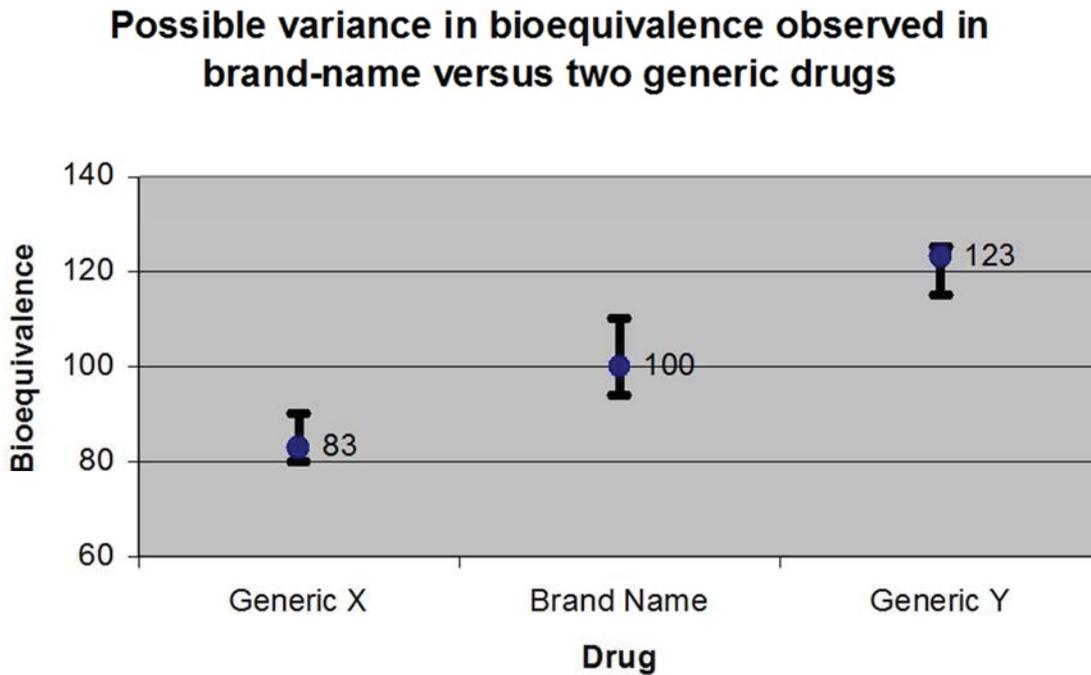


Figure 1: Possible variance in bioequivalence observed in brand-name versus two generic drugs