

Attachment B

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518
(A-19)

Introduced by: American College of Cardiology

Subject: Chemical Variability in Pharmaceutical Products

Referred to: Reference Committee E
(Leslie H. Secrest, MD, Chair)

- 1 Whereas, It was revealed that certain lots of valsartan, losartan and irbesartan tablets contained
2 trace amounts of N-Nitroso-dimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), which are
3 classified as cancer causing substances; and
4
- 5 Whereas, The recalls resulting from identification of these pharmaceutical issues result in
6 generalized recalls to patients as the lots/batches are not identifiable at the patient level; and
7
- 8 Whereas, The FDA has recently announced increasing the allowable nitrosamine contaminant
9 level 100X for 6 months due to drug supply demands and the inability ensure an
10 uncontaminated supply; and
11
- 12 Whereas, The FDA has recently announced the finding that specific lots of losartan/valsartan
13 are contaminant free, emphasizing the importance and resolution of batch-level testing; and
14
- 15 Whereas, There are roughly 3 drug recalls per day, and roughly 100 recalls per year are
16 associated with the risk of death; and
17
- 18 Whereas, A 2015 AMA study outlining factors leading to non-adherence identified mistrust and
19 fear as significant factors leading to medication non-adherence, and a 2018 survey through
20 Google consumer surveys identified mistrust in generics as being a major factor leading to
21 medication non-adherence; and
22
- 23 Whereas, A 2015 FDA white paper reported the FDA has no formal means for quality
24 surveillance, except through inspections; and inspection findings have not been a reliable
25 predictor of the state of quality; and
26
- 27 Whereas, A 2010 Harvard Medical School Study showed lot-to-lot variability in anti-epileptic
28 medications causes a 2.3X increased incidence of seizures; and
29
- 30 Whereas, Medication dissolution analysis has shown significant variability in dissolution from
31 test state to physiological conditions, resulting in potentially clinically relevant differences in
32 patient absorption; and
33
- 34 Whereas, The industry recognizes the importance of tracing lots which was enacted into law via
35 the Drug Supply Chain Security Act of 2013, but the lots are not required to be connected to
36 patients; and

1 Whereas, Private industry has started performing batch validation on pharmaceuticals which are
2 documented, and traceable; and these pharmaceuticals are accessible to patients and other
3 pharmaceutical distributors; therefore be it
4

5 RESOLVED, That our American Medical Association do a study and report back by the
6 2019 Interim Meeting regarding the pharmaceutical variability, both in active pharmaceutical
7 ingredient and dissolution, the impact on patient care and make recommendations for action
8 from their report findings (Directive to Take Action); and be it further
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10 RESOLVED, That our AMA advocate for legislation requiring independent testing and
11 verification of the chemical content of batches of pharmaceuticals (Directive to Take Action);
12 and be it further
13

14 RESOLVED, That our AMA advocate for the logging of batches at the patient level, so the
15 batches can be traced and connected to patient outcomes or adverse events. (Directive to Take
16 Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

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[RELEVANT AMA POLICY](#)