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)

Whereas, It was revealed that certain lots of valsartan, losartan and irbesartan tablets contained trace amounts of N-Nitroso-dimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), which are classified as cancer causing substances; and

Whereas, The recalls resulting from identification of these pharmaceutical issues result in generalized recalls to patients as the lots/batches are not identifiable at the patient level; and

Whereas, The FDA has recently announced increasing the allowable nitrosamine contaminant level 100X for 6 months due to drug supply demands and the inability ensure an uncontaminated supply; and

Whereas, The FDA has recently announced the finding that specific lots of losartan/valsartan are contaminant free, emphasizing the importance and resolution of batch-level testing; and

Whereas, There are roughly 3 drug recalls per day, and roughly 100 recalls per year are associated with the risk of death; and

Whereas, A 2015 AMA study outlining factors leading to non-adherence identified mistrust and fear as significant factors leading to medication non-adherence, and a 2018 survey through Google consumer surveys identified mistrust in generics as being a major factor leading to medication non-adherence; and

Whereas, A 2015 FDA white paper reported the FDA has no formal means for quality surveillance, except through inspections; and inspection findings have not been a reliable predictor of the state of quality; and

Whereas, A 2010 Harvard Medical School Study showed lot-to-lot variability in anti-epileptic medications causes a 2.3X increased incidence of seizures; and

Whereas, Medication dissolution analysis has shown significant variability in dissolution from test state to physiological conditions, resulting in potentially clinically relevant differences in patient absorption; and

Whereas, The industry recognizes the importance of tracing lots which was enacted into law via the Drug Supply Chain Security Act of 2013, but the lots are not required to be connected to patients; and

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

RESOLVED, That our American Medical Association do a study and report back by the 2019 Interim Meeting regarding the pharmaceutical variability, both in API and dissolution, the impact on patient care and make recommendations for action from their report findings (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for legislation requiring independent testing and verification of the chemical content of batches of pharmaceuticals (Directive to Take Action); and be it further

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

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

Received: 05/09/19

RELEVANT AMA POLICY