

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 932
(I-19)

Introduced by: Pennsylvania

Subject: Source and Quality of Medications Critical to National Health and Security

Referred to: Reference Committee K

1 Whereas, On September 13, 2018 Bloomberg reported carcinogens have been found in generic
2 as well as brand name forms of ranitidine Zantac¹; and
3
4 Whereas, There are no entities within the United States that presently produce Penicillin,
5 Doxycycline or Ciprofloxacin or other medications critical to public health and security against
6 biowarfare agents such as Anthrax²; and
7
8 Whereas, It is the duty of the Federal Government through its U.S. Food and Drug
9 Administration (FDA) to oversee compounding, production, quality and supply of pharmaceuticals
10 and their chemical substrates, regardless of their geographic origin³; and
11
12 Whereas, There are several medications in shortage which endangers public health and
13 security⁴; and
14
15 Whereas, Pharmaceuticals and their chemical substrates may be manufactured in geographies
16 not under adequate supervision by the FDA⁴; and
17
18 Whereas, Over 80% of USA pharmaceuticals and their chemical substrates originate in China²;
19 and
20
21 Whereas, There is a history of toxic and carcinogenic pharmaceuticals and their chemical
22 substrates supplied by China^{5,6,7}; and
23
24 Whereas, Pharmaceuticals manufactured in a foreign country may source substrates supplied by
25 yet another foreign country neither of which may have a chain of quality assurance⁸; therefore
26 be it

¹ <https://www.msn.com/en-us/finance/companies/carcinogen-in-zantac-and-generics-triggers-fda-eu-probes/ar-AAHfEO5>

² China Rx by Rosemary Gibson, Janardan Prasad Singh Publisher: Prometheus; 1st Edition (April 17, 2018) Language: English ISBN-10: 1633883817 ISBN-13: 978-1633883819

³ <https://www.fda.gov/drugs/human-drug-compounding/compounding-oversight>

⁴ <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

⁵ FDA requirement to oversee china laboratories <https://www.fiercepharma.com/regulatory/fda-adding-inspectors-china-but-for-now-it-has-only-2-B>

⁶ FDA warning letters to Chinese companies <https://www.cnn.com/2018/08/06/chinas-growing-drug-scandal-is-having-a-ripple-effect-around-the-world.html>

⁷ Carcinogens Have Infiltrated the Generic Drug Supply in the U.S.: An FDA quality-control nightmare reveals how impurities and up in America's blood pressure pills. By Anna Edney, Susan Berfield, and Evelyn Yu Set 12, 2019 Bloomberg Business Week

⁸ Bottle of Lies: The Inside Story of the Generic Drug Boom by [Katherine Eban](#) Publisher: Ecco; 1 edition (May 14, 2019) Language: English ISBN-10: 0062338781 ISBN-13: 978-0062338785

- 1 RESOLVED, That our American Medical Association support studies that identify the extent to
2 which the United States is dependent on foreign supplied pharmaceuticals and chemical
3 substrates (New HOD Policy); and be it further
4
5 RESOLVED, That our AMA support legislative and regulatory initiatives that help to ensure
6 proper domestic capacity, production and quality of pharmaceutical and chemical substrates as
7 a matter of public well-being and national security (New HOD Policy); and be it further
8
9 RESOLVED, That our AMA encourage the development and enforcement of standards that
10 make the sources of pharmaceuticals and their chemical substrates used in the United States of
11 America transparent to prescribers and the general public. (New HOD Policy)

Fiscal Note: Not yet determined

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