### RESOLUTION

## Subject: Support for the Establishment of a State Program for Wholesale Importation of Prescription Drugs

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Referred to: Reference Committee

WHEREAS, seven of the eight top-selling drugs in the United States cost more than in countries abroad, even after pharmaceutical company discounts<sup>1</sup>; and

WHEREAS, 70% of the top-selling brand name drugs are manufactured outside the country, and are sold for up to 87% less in Canada and 97% less in other countries<sup>2</sup>; and

WHEREAS, in 2016, an estimated 45 million Americans did not fill a prescription due to the cost of pharmaceuticals<sup>3</sup>; and

WHEREAS, Kentucky ranks first in number of retail prescription drugs filled at pharmacies and has the second highest per capita spending on prescription drugs<sup>4,5</sup>; and

WHEREAS, to pay for drugs, Medicaid programs takes the lowest price negotiated by private payers and states can further negotiate, however due to federal laws they are limited in that capacity<sup>6,7</sup>; and

WHEREAS, Kentucky Medicaid spending has been increasing over the past several years and pharmacy costs are the fastest growing budget items<sup>6</sup>; and

WHEREAS, a 2016 poll from Kaiser Family Foundation found that 8% of respondents, or someone in their household, have imported a drug in the past, despite it being illegal in most circumstances<sup>8,9,10</sup>; and

WHEREAS, the major risk associated with importing drugs from other countries comes from purchasing them online, where the suppliers can misrepresent the safety, quality, and licensing of their products<sup>11</sup>; and

WHEREAS, a wholesale importation program is a state-administered "program where the State is the licensed wholesaler, importing drugs from a licensed, regulated Canadian supplier, solely for distribution to voluntarily participating, state-licensed, in-state, pharmacies and administering providers for the exclusive purpose of dispensing to state residents with a valid prescription."<sup>12</sup>; and

WHEREAS, all the suppliers would be FDA approved and therefore consumers in Kentucky would not be at risk of substandard or fake drugs<sup>12</sup>; and

WHEREAS, the Federal Food, Drug, and Cosmetic Act allows for importation of drugs as long as safety and consumer savings are guaranteed<sup>13</sup>; and

WHEREAS, wholesale importation programs have bipartisan support and a 2019 Kaiser Family Foundation poll put public support for drug importation at 70%<sup>14,15,16</sup>; and

WHEREAS, multiple states have pending legislation for prescription drug importation and Vermont has passed legislation for an importation program with an estimated savings of between \$1-5 million dollars for commercial insurers<sup>14,17</sup>; and

WHEREAS, a wholesale importation program as defined above would fit AMA policy

D-100.983 regarding importing pharmaceuticals; now, therefore, be it

RESOLVED, that the Kentucky Medical Association support a program for the

wholesale importation of pharmaceutical drugs in the Commonwealth of Kentucky.

## References

<sup>4</sup> Which States' Residents Spend the Most on Prescriptions? The Senior List. https://www.theseniorlist.com/data/prescription-spending/. Accessed August 19, 2019.

<sup>5</sup> Retail Prescription Drugs Filled at Pharmacies per Capita. The Henry J Kaiser Family Foundation. February 2019. https://www.kff.org/health-costs/state-indicator/retail-rx-drugs-per-capita/. Accessed August 19, 2019.

<sup>6</sup> CHFS Medicaid Pharmacy Pricing.

https://chfs.ky.gov/agencies/ohda/Documents1/CHFS\_Medicaid\_Pharmacy\_Pricing.pdf. Accessed August 16, 2019.

- <sup>7</sup> Chan K. How Do Medicaid and Medicare Set Drug Prices? Medium. https://medium.com/unraveling-healthcare/howdo-medicaid-and-medicare-set-drug-prices-83411811d632. Published February 25, 2016. Accessed August 19, 2019.
- <sup>8</sup> Looking For Bargains, Many Americans Buy Medicines Abroad. NPR.org. https://www.npr.org/sections/healthshots/2016/12/17/505690791/looking-for-bargains-many-americans-buy-medicines-abroad. Accessed August 16, 2019.

<sup>9</sup> Bluth R. Faced With Unaffordable Drug Prices, Tens Of Millions Buy Medicine Outside U.S. Kaiser Health News. December 2016. https://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-us/. Accessed August 16, 2019.

 <sup>10</sup> Commissioner O of the. Is it legal for me to personally import drugs? FDA. November 2018. http://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs. Accessed August 16, 2019.
<sup>11</sup> Commissioner Letter. March 16, 2017.

https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017\_03\_16\_commissioners\_letter\_final\_signed.pdf. Accessed August 19, 2019.

<sup>12</sup> Drug Importation Model Legislation and Toolkits. NASHP. https://nashp.org/drug-importation/. Accessed August 16, 2019.

<sup>13</sup> [USC02] 21 USC 384: Importation of prescription drugs. https://uscode.house.gov/view.xhtml?req=granuleid:USCprelim-title21-section384&num=0&edition=prelim. Accessed August 19, 2019.

- <sup>14</sup> Bulk Purchasing of Prescription Drugs NCSL. http://www.ncsl.org/research/health/bulk-purchasing-of-prescriptiondrugs.aspx. Accessed August 16, 2019.
- <sup>15</sup> Grassley C. Text S.61 116th Congress (2019-2020): Safe and Affordable Drugs from Canada Act of 2019. https://www.congress.gov/bill/116th-congress/senate-bill/61/text. Published January 9, 2019. Accessed August 16, 2019.
- <sup>16</sup> Lopes L, Wu B, 2019. KFF Health Tracking Poll February 2019: Prescription Drugs. The Henry J Kaiser Family Foundation. March 2019. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019prescription-drugs/. Accessed August 16, 2019.

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<sup>&</sup>lt;sup>1</sup> The U.S. Pays a Lot More for Top Drugs Than Other Countries. Bloomberg.com. http://www.bloomberg.com/graphics/2015-drug-prices/. Accessed August 16, 2019.

<sup>&</sup>lt;sup>2</sup> 70% of Popular Brand Name Drugs Sold in U.S. Pharmacies Are Imported; Cost Up to 87% Less in Canada. PharmacyChecker.com. https://www.pharmacychecker.com/news/70-percent-of-brand-name-drugs-are-imported-cost-87-percent-less-in-canada/. Accessed August 16, 2019.

<sup>&</sup>lt;sup>3</sup> 45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK. Prescription Justice. February 2017. https://prescriptionjustice.org/press\_release/45-million-americans-foregomedications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/. Accessed August 16, 2019.

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<sup>17</sup> Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1\_3\_2019.pdf. https://nashp.org/wpcontent/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1\_3\_2019.pdf. Accessed August 16, 2019.

#### RELEVANT AMA POLICY

#### Policy D-100.983

(1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported;

(2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured;

(3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation;

(4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts;

(5) support the in-person purchase and importation of Health Canada-approved prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity;

(6) advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured; and

(7) support the personal importation of prescription drugs only if: (a) patient safety can be assured; (b) product quality, authenticity and integrity can be assured; (c) prescription drug products are subject to reliable, "electronic" track and trace technology; and (d) prescription drug products are obtained directly from a licensed foreign pharmacy, located in a country that has statutory and/or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States.

### Policy H-110.987

1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.

2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.

4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.

5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.

6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.

7. Our AMA supports legislation to shorten the exclusivity period for biologics.

8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.

9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.

10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a

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drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.

13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.

### **RELEVANT KMA POLICY**

#### Res 2016-9, 2016 HOD

8) Prescription Drug Cost:

KMA seeks opportunities to advocate for more affordable prescription medications.

KMA, in cooperation with other key stakeholders (e.g. the Kentucky Pharmacists Association, the Kentucky

Nurses Association, and the Kentucky Hospital Association), urge the Pharmaceutical Research and

Manufacturers of America® and its member companies to reign in the cost of medications.

KMA educates state legislators and the state's congressional delegation on the severity and importance of rising prescription drug costs so that lawmakers can more effectively address the problem on behalf of Kentucky citizens.

KMA urges state policymakers to evaluate drug pricing and value to assess possible benefits for patients and physicians. (*Res 2016-9, 2016 HOD*)