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3 **RESOLUTION 68-09A**  
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5 **Title: Expanding Access to Essential Medicines in Low and Middle-**  
6 **Income Countries via Equitable Access Licensing Provisions by**  
7 **Universities**  
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9 **Introduced by: Jessica W. Guh for the Medical Student Section**  
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11 **Original Authors: Jessica Guh and Camille Johnson, University of Michigan,**  
12 **and Priyanka Shah, Wayne State University**  
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14 **Referred to: Reference Committee E**  
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16 **House Action: Adopted as Amended**  
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19 **Whereas, approximately 10 million people die needlessly every year because**  
20 **they lack access to existing essential medicines and vaccines<sup>1</sup>, and**  
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22 **Whereas, about 30 percent of the world’s population does not have access to**  
23 **essential medicines and in the poorest parts of Africa and Asia this figure is more**  
24 **than 50 percent,<sup>1</sup> and**  
25

26 **Whereas, AMA policy “supports the protection of fair access to essential**  
27 **medicines in developing countries (H-100.963),” and**  
28

29 **Whereas, generic provision of drugs is a key component of increasing access**  
30 **in low- and middle-income countries<sup>2</sup>:**

- 31 • **is recognized to be the most effective means of affordable pricing and**  
32 **increased access in lower and middle income countries;<sup>3</sup>**
- 33 • **access to HIV/AIDS medicines increased by an estimated 1 million patients**  
34 **from 2007 to 2008 due to new licensing agreements that allowed more**  
35 **generic drug production;<sup>4</sup>**
- 36 • **the dramatic 2005 increase in access to HIV/AIDS medicines in low- and**  
37 **middle-income countries is accredited to the introduction of generic**  
38 **production in Brazil and India;<sup>5</sup>**
- 39 • **AMA policy "expresses concern about... cost of prescription drugs as well**  
40 **as the inability of many patients to afford essential prescription drugs (H-**  
41 **110.995);”**
- 42 • **AMA policy recognizes that “generic drugs frequently can be less costly**  
43 **alternatives to brand-name products (H-125.984);” and**  
44

45 **Whereas, universities and colleges spent \$19.6 billion dollars in 2002<sup>6</sup> on**  
46 **biomedical research, 64 percent of which was from federal sources<sup>6</sup>, and they play a**  
47 **key role in the development of new medicines, and**  
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52           Whereas, universities and colleges are dedicated to conducting research for  
53 the betterment of society at large, not a particular subset of the population, and

54           Whereas, there is evidence that generic provisions limited to low and middle-  
55 income countries do not negatively impact drug company or university profits:  
56           • pharmaceutical companies and universities will still have patent protection  
57           in high-income countries where the vast majority of their revenues are  
58           generated<sup>7</sup>;  
59           • generic companies still provide royalties to the companies and  
60           universities;  
61           • when Yale University opened access for Stavudine, an antiretroviral, Yale’s  
62           Dean of Public Health Michael Merson stated, “the change was made at  
63           Yale without any negative consequences for the University - financial or  
64           otherwise”<sup>8</sup>;  
65           • there is no empirical evidence of substantial movement of medicines from  
66           low- and middle-income countries to high-income countries<sup>7</sup>, especially  
67           with the usage of differential packaging as suggested by the World Trade  
68           Organization<sup>9</sup>;  
69           • generic provisions in communities that would otherwise have no access to  
70           a given drug allow pharmaceutical companies to improve their public  
71           image and relationship with customers in high-income markets, thus  
72           protecting the source of the majority of their profits<sup>10, 11</sup>, and  
73

74           Whereas, the feasibility of using generic licensing to increase access has  
75 been proven by a few major pharmaceutical companies who have agreed to generic  
76 licensing in low- and middle-income countries for certain AIDS drugs:  
77           • in August of 2006, Gilead Sciences opened licensing to allow tenofovir  
78           (Viread), an antiretroviral, to be produced by generic companies in India;<sup>12</sup>  
79           • in 2001 GlaxoSmithKline granted a voluntary license to allow the  
80           distribution of generic versions of three of their antiretroviral, AIDS drugs,  
81           zidovudine (Retrovir), lamivudine (Epivir), and a combination of zidovudine  
82           and lamivudine (Combivir), in South Africa;<sup>13</sup>  
83           • in 2008 Gilead Sciences and Johnson & Johnson endorsed licensing  
84           patents to the UNITAID patent pool, an open licensing mechanism to  
85           increase access to AIDS drugs through generics, partnered with  
86           organizations such as the World Health Organization, Unicef, and the Joint  
87           United Nations Programme on HIV/AIDS,<sup>14</sup> and  
88

89           Whereas, because the major source of revenue for patent-based  
90 pharmaceuticals companies is North America<sup>15</sup>, a high-income region, generic  
91 provisions in low and middle-income countries will not decrease financial incentives  
92 for innovation,<sup>7</sup> and  
93

94           Whereas, allowing generic sales and production limited to low- and middle-  
95 income countries is an accepted framework adopted in the World Trade  
96 Organization’s Doha Declaration<sup>16</sup> as a way to increase health without negatively  
97 impacting industry; therefore be it  
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102           **RESOLVED:** That MSMS strongly encourage universities to adopt policies of  
103 licensing that guarantee third party manufacturers the ability to provide essential  
104 medicines at locally affordable prices in low and middle-income overseas markets;  
105 and be it further  
106

107           **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to strongly  
108 encourage the Association of American Medical Colleges to encourage its medical  
109 schools to adopt policies of licensing that guarantee third party manufacturers the  
110 ability to provide essential medicines at locally affordable prices in low and middle-  
111 income overseas markets; and be it further

112           **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to strongly  
113 encourage universities to adopt policies of licensing that guarantee third party  
114 manufacturers the ability to provide essential medicines at locally affordable prices  
115 in low and middle-income overseas markets; and be it further  
116

117           **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to strongly  
118 encourage pharmaceutical companies to adopt policies of licensing that guarantee  
119 third party manufacturers the ability to provide essential medicines at locally  
120 affordable prices in low and middle-income overseas markets.  
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**WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**

**References:**

<sup>1</sup> World Health Organization. WHO Policy Perspectives on Medicines. "Equitable Access to Essential Medicines: A Framework for Collective Action". 2004. Available: [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_2004.4.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf).

<sup>2</sup> Low- and middle-income countries are defined by the World Bank based on gross national income (GNI). Classification details available: [www.worldbank.org/data/countryclass/countryclass.html](http://www.worldbank.org/data/countryclass/countryclass.html)

<sup>3</sup> Medecins Sans Frontieres. "Surmounting Challenges: Procurement of Anti-Retroviral Medicines in Low and Middle Income Countries". 2003. Available: <http://www.who.int/medicinedocs/en/d/Js4892e/>

<sup>4</sup> Kahn, Michael. "AIDS drugs reach 3 million in developing world-WHO." Reuters. 2 Jun 2008. Available: <http://www.alertnet.org/thenews/newsdesk/L28749290.htm>

<sup>5</sup> Mayne, Ruth. Human Development Report 2005 for the United Nations Development Program. 2005. Available:

[http://hdr.undp.org/en/reports/global/hdr2005/papers/HDR2005\\_Mayne\\_Ruth\\_18.pdf](http://hdr.undp.org/en/reports/global/hdr2005/papers/HDR2005_Mayne_Ruth_18.pdf)

<sup>6</sup> Moses, Hamilton III, Ray Dorsey, David Matheson, and Samuel Thier. "Financial Anatomy of Biomedical Research." The Journal of the American Medical Association. 2005; 294: 133-1342.

<sup>7</sup> Outterson, K. "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets." Yale J Health Policy Law Ethics. 2005: 5, 193-286.

<sup>8</sup> Kapczynski, Amy. "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations," 20 Berkeley Tech L. J. 1031, 1089 2005.

<sup>9</sup> World Trade Organization General Council 2003. "Implementation of paragraph 6 of the Doha Declaration on the TRIPS agreement and public health." Geneva: World Trade Organization. Available: [http://www.wto.org/English/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm)

<sup>10</sup> Porter, MC, and MR Kramer. "Strategy & society: The link between competitive advantage and corporate social responsibility," Harvard Business Review. 2006: vol. 84, no. 12, 78-92.

<sup>11</sup> Stephenson, SK. "The Pursuit of CSR and Business Ethics Policies: Is it a source of competitive advantage for organizations?" The Journal of American Academy of Business, Cambridge. 2009: vol. 14, no 2, 251-262.

<sup>12</sup> Gilead Sciences, Inc. "Gilead Announces Licensing Agreements with Three India-Based Companies for Manufacturing and Distribution of Generic Versions of Viread in the Developing

World." Press Release.14 Aug 2006. Available: [http://www.gilead.com/pr\\_895671](http://www.gilead.com/pr_895671)

<sup>13</sup> Mayor, Susan. "GlaxoSmithKline licenses production of generic AIDS drugs in South Africa." *British Medical Journal*. 13 Oct 2001; 323(7317): 828. Available: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1172970>

<sup>14</sup> Love, James. "The Health Impact Fund and product monopolies." *Knowledge Ecology Notes*. 17 Nov 2008. Available: <http://www.keionline.org/blogs/2008/11/17/health-impact-fund-monopolies/>

<sup>15</sup> Pharmaceutical Research and Manufacturers of America. "Pharmaceutical Industry Profile 2005 - From Laboratory to Patient: Pathways to Biopharmaceutical Innovation." Washington D.C. 2005.

<sup>16</sup> World Trade Organization. Doha WTO Ministerial 2001: Ministerial Declaration. 20 Nov 2001. Available: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm)