Whereas, The Food and Drug Administration (FDA) relies on Advisory Committees, composed of pharmacology and other healthcare experts, to review scientific studies of a proposed new drugs or medical devices;1,2,3 and

Whereas, The FDA formally prohibits the hiring of Advisory Committee members with conflicts of interest including employment by the sponsor of the drug under review and stock in the sponsoring company but routinely grants waivers instead of disqualifying such individuals;1-3 and

Whereas, The FDA only considers individuals to be conflicted if they have conflicts of interest that occurred in the past 12 months, which is shorter than the standard 36 month period that is customary in the scientific community;3,4,5,6 and

Whereas, The FDA in 2007 imposed a cap on the number of conflict of interest waivers that may be granted to Advisory Committee members through the FDA Amendments Act (FDAAA);3,4 and

Whereas, The FDA loosened conflict of interest restrictions with the passage of the Food and Drug Safety and Innovation Act (FDASIA) in 2012 by lifting the 2007 cap imposed by the FDAAA on the number of available conflict of interest waivers;3,4 and

Whereas, The FDASIA deprioritized conflicts of interest by eliminating the weight a financial disclosure had on a candidate’s selection;3,4,7,8,9,10,11 and

Whereas, The impact of Advisory Committee conflicts of interest on voting tendencies introduces bias to the review process and has led to the passage of drugs that were later

recalled due to safety concerns or linked to significant adverse effects such as with the Vioxx and Yaz/Yasmin scandals, respectively;3,7-12and

Whereas, The use of Advisory Committee Members with direct conflicts of interest undermines public trust in drug safety and presents a possible danger to the public health and safety;13,14and

Whereas, Research suggests there are a sufficient number of non-conflicted medical experts to fill Advisory Committee vacancies;3,15and

Whereas, Our AMA has policy advocating for the use of sound scientific evidence as the basis of drug evaluations (AMA Policy H-100.992) and policy stating that it will monitor and respond to drug safety practices at the FDA (D-100.978); therefore be it

RESOLVED, That our American Medical Association advocate that the Food and Drug Administration place a greater emphasis on a candidate’s conflict of interest when selecting members for advisory committees (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for a reduction in conflict of interest waivers granted to Advisory Committee candidates. (New HOD Policy)

Fiscal Note: not yet determined

Date Received: 04/26/18

RELEVANT AMA POLICY

**H-100.992 FDA**

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug’s approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA’s decision-making process in the course of FDA devising either general or product specific drug regulation.

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

Citation: (Res. 119, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmation A-06; Appendix: Sub. Res. 509, A-06; Reaffirmation I-07; Reaffirmation I-09; Reaffirmation I-10)

See also: FDA Drug Safety Policies D-100.978

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