Missouri State Medical Association
House of Delegates

Resolution #16
(A-18)

Introduced by: Gary M. Gaddis, MD PhD

Subject: Content of Advertisements for Pharmaceuticals, which Appear in Medical Journals

Referred to: Reference Committee A

WHEREAS, every year, various newly developed medications are marketed to physicians in various medical journals; and

WHEREAS, some of these new medications are members of previously established pharmaceutical groupings[&]; and

WHEREAS, other of these new medications are members of entirely new pharmacologic groupings, groupings which did not exist when many current physicians and pharmacists had attended schools of medicine or pharmacy, and were students studying the discipline of Pharmacology[#]; and

WHEREAS, physicians who prescribe medications typically receive the bulk of their training regarding the discipline of Pharmacology while they are attending a School of Medicine; and

WHEREAS, pharmacists who dispense medications typically receive the bulk of their training regarding the discipline of Pharmacology while they are attending a School of Pharmacy; and

WHEREAS, rational prescribing of any medication by physicians would be enhanced if physicians could more easily come to understand the pharmacologic mechanism of action of any medication that they might prescribe; and

WHEREAS, rational dispensing of medications by pharmacists would be enhanced if pharmacists could more easily come to understand the pharmacologic mechanism of action of any medication that they might dispense; and

WHEREAS, current FDA regulations do not require that the pharmacologic mechanism of action for advertised medications be explicitly stated within the advertisements for these medications, and Whereas current regulations governing these advertisements, which appear in medical journals or in pharmacy journals for any medication, require that such advertising must list extensively the various indication(s) and contraindication(s) for that medication; and

WHEREAS, these pharmaceutical advertisements are also required to list the numerous and various types of adverse events that have been observed, or that are believed to have been observed, in relation to the administration of these medications, as deemed relevant by the Food and Drug Administration (FDA); and

WHEREAS, no requirement exists that these advertisements list a medication's pharmacologic mechanism of action; and

WHEREAS, medication advertisements therefore do not describe a medication's pharmacologic mechanism of action; and

WHEREAS, this state of affairs makes it is more difficult for physicians and pharmacists to place a medication's advertised indications, a medication's contraindications, and a medication's adverse event profile in appropriate scientific and clinical context; and

WHEREAS, this state of affairs also impairs the transfer of important pharmacologic information to the medical community; and

WHEREAS, it would be within the powers of the FDA to mandate regulatory change, such that in the future, all pharmaceutical advertising for any medication also must include a clear description of the pharmacologic mechanism of action of that medication, within *every* advertisement for that medication, in any medical or pharmacy journal; and

WHEREAS, such change would enhance more rational prescribing and dispensing of that medication; therefore be it

RESOLVED, that representatives of your Missouri State Medical Association shall propose Federal regulatory change, to be implemented by the FDA, to enact new regulatory language which mandates that all advertisements for medications must describe that medication's pharmacologic mechanism of action; and be it further

RESOLVED, that representatives of your Missouri State Medical Association (MSMA) shall carry forward a resolution designed to advocate for this regulatory change, to be considered by the American Medical Association (AMA) at the next meeting of its House of Delegates, in Chicago, in June of 2018, and Resolved, that the explicit purpose of such a resolution will be to promote regulatory change within the FDA, via governmental outreach by agents such as lobbyists employed by your AMA, to cause there to be a new regulation that requires that a medication's pharmacologic mechanism of action be stated clearly within the product advertising; and be it further

RESOLVED, that delegates from your MSMA to the next meeting of the House of Delegates of your AMA shall make a reporting of the action, or lack thereof, taken by the AMA House of Delegates, toward this resolution, in a timely fashion.

Fiscal Note:

Current Policy:

Footnotes:
The symbol "&" is exemplified by that which occurred in the United States when ranitidine (Zantac™) joined cimetidine (Tagamet™) as marketed members of the medication class called "H-2 blockers".
The symbol "#" exemplifies that which occurred with the development of fluoroquinolone antibiotics, of which CiproTM (Ciprofloxacin) was the first to be marketed in the United States. Fluoroquinolones act by inhibiting the activity of an enzyme called "DNA Gyrase". This is a protein crucial to enable cell division. No previously marketed antibiotic had exploited this mechanism of action, and this mechanism of action was unknown by most initial

prescribers of ciprofloxacin. Therefore these physicians would not have been able to scientifically describe a rational prescribing and use plan for members of this medication class.
For "%", see Attachments, which clearly demonstrate the lack of any statement of any of these pharmaceutical agents' pharmacologic mechanism of action. Examples of advertisements for Canagliflozin (Invokana™) and Patiromer (Veltassa™) are provided as representative examples.