



# Behind-the-Counter Class of Drugs in the United States

Perspective of the American  
Medical Association





## AMA Opposes a BTC Class



- No legal basis for establishment
- No demonstration of need
- Impact of BTC class unknown
- Potential to jeopardize patient health





## No Legal Basis for BTC Class

- FDCA establishes only two classes of drugs in U.S., Rx-only and OTC
- FDA lacks statutory authority to establish BTC class by regulation or guidance
- Restricted distribution provision in FDAAA does not give FDA authority

*“Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable.”*



## Need for BTC Class NOT Shown

- AMA unaware of any good evidence to support the need for a BTC class
- *“Little evidence supports the establishment of a pharmacy or pharmacist class of drugs in the U.S. at this time, as either a fixed or transitional class. The evidence that is available tends to undermine the contention that major benefits are being obtained in the countries that have such a class” (GAO, 1995)*



## Impact of BTC Class is Unknown

- Could increase access (e.g., Rx-to-BTC) or reduce access (e.g., OTC-to-BTC)
- Could increase out-of-pocket costs (e.g., OTC-to-BTC reduces competition OR third-party payers refuse to pay for Rx-to-BTC switched drug) or reduce costs (e.g., third-party payers pay for BTC drugs)
- Will pharmacists be paid for service?
- What is the impact of removing physician oversight on both outcomes and costs?



# Concern about Patient Safety



- BTC class entirely removes physician from vital steps of diagnosis and treatment of the patient – what the physician is trained to do!



- Pharmacist now diagnoses and prescribes, but is NOT trained to do either!



- Potential to further increase fragmentation of healthcare





## Rx-to-BTC Switches of Drugs for Chronic Diseases of Particular Concern

- Examples: antihypertensive, cholesterol-lowering, antidiabetic, antiasthma drugs
- Only physician trained to do history and clinical evaluation, including for co-morbidities, and lab testing to make correct differential diagnosis and to recommend best treatment strategy
- Pharmacists are NOT trained to examine, diagnose, and prescribe.



# Roles for Pharmacists



- Dispensing – checks-and-balances
- Counseling about medicines – not done
- Medication therapy management of individual patient under collaborative practice agreement with physician (e.g., the Ashville model)
- NOT diagnosis or prescribing



