



BEHIND-THE-COUNTER AVAILABILITY OF CERTAIN DRUGS

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APhA Statement of Support

“APhA strongly supports the FDA establishing a standardized, objective and science-driven process, based on clinical evidence of efficacy and safety, whereby select medications that otherwise would be available only by prescription are stored behind the counter and made available without a prescription only after an FDA-required clinical intervention by a pharmacist.”

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APhA Comment Development

An Environmental Scan of Current Factors

- Uninsured Americans
- Medication misuse
- Consumer behavior
- Pharmacist expertise, impact and accessibility
- Adoption of HIT/EHR
- Expanding pharmacist role
 - Immunizations
 - Collaborative practice agreements
- Evolving FDA activity/authority
 - Plan B
 - Pseudoephedrine
 - RiskMAPs



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APhA Assertions

The Benefits of BTC

- Expanded consumer access to formerly prescription-only drugs
- Increased patient adherence
- Enhanced patient safety
- Improved health outcomes
- Increased identification of other untreated conditions and referrals to physicians
- Cost savings for both consumers and the health care system



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APhA Recommendations

Making it work

- Science-based categorization decisions
- Positive public health risk-benefit
- Patient self-diagnosis and management
- Uniform processes for drug availability
- Consumer education
- Maintain pharmacist-patient-physician triad
- Pharmacist-patient clinical intervention
- Pharmacist compensation (separate from product)



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APhA Practice Model Development

What actually happens?

- Patient presentation with self-diagnosed condition
- Clarification of patient complaints and symptoms to determine suitability of BTC drug
- Pharmacist conducted medication review
- Development of medication action plan in conjunction with patient and patient's physician as required
- Referral to physician for further evaluation
- Patient monitoring of response
- Documentation and billing



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