

A Middle Class in the United States? Behind the Counter (BTC) Drugs

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FDA's Regulation of Drugs

- Federal Food, Drug and Cosmetic Act (FDCA) passed by Congress in 1938 required for the first time that drugs be proven safe before marketing.
- 1951 FDCA Durham Humphrey Amendments provided statutory basis for two-tier drug classification system. § 503(b)(1); 21 USC § 353(b)(1)
- Decision of how a product may be marketed (Rx or OTC) is vested with the Food and Drug Administration (FDA).



Classification of Drugs in U.S.

- Two Classes under FDCA

Prescription (Rx) – requires the order of a physician to a pharmacist for the delivery of certain medications to patients.

Non Prescription (OTC) – medications patients purchase directly and use without professional supervision.

Rx to OTC switch under FDCA

- Rx dispensing required of any drug “... not safe for use except under the supervision of a practitioner licensed by law to administer such drug or... limited by an approved application...” 21 U.S.C. § 353(b)(1).

Rx to OTC switch under FDCA (cont'd)

- Sponsor may submit a supplemental application to “switch” an Rx drug to OTC status. FDA will grant a supplemental application to “switch” when it finds that Rx dispensing is: “not necessary for the protection of the *public health* by reason of the drug's *toxicity* or other potentiality for *harmful effect*, or the *method of its use*, or the collateral measures necessary to its use, and . . . the drug is *safe and effective* for use in *self-medication* as directed in proposed *labeling*” 21 C.F.R. § 310.200(b).

What is “Behind the Counter (BTC)”?

- The behind-the-counter class, or BTC, resides in a regulatory limbo between over-the-counter and prescription.
- Behind-the-counter drugs require concurrence by a pharmacist, but not a physician, before they may be purchased.
- Rationale: To limit a drug’s use by those who might misuse them, while maintaining reasonable access for legitimate use by patients without requiring a prescription.

Views: For BTC

- **National Consumers League**
 - Favors a BTC drug class to increase patient access to medications they can safely use, after consultation with a pharmacist, to self-treat conditions they can self-diagnose.
 - Would expand the range of conditions that patients can self-treat without spending time or money for doctor's visit.
 - Concerns about (1) privacy regarding medications (whether consumer is comfortable discussing with pharmacist) and (2) whether insurance will cover Rx to BTC switched drugs.

Views: For BTC (cont'd)

- **National Association of Boards of Pharmacy**
 - Advocated for the recognition of a transitional or behind-the-counter class of drugs since 1995, noting that a number of prescription drugs considered for OTC status have serious side effects and need appropriate pharmacist intervention for their effective use; and
 - Establishment of a behind-the-counter class of drugs would increase patient access to needed medications and improve patient care and patient safety

Views: Against BTC

- **American Medical Association**
 - FDA lacks legal authority to establish BTC class without new legislation.
 - Most concerned about the types of drugs moved to BTC class, particularly for patients with chronic illnesses, where it is critical that there be diagnosis and management by a physician.

Views: Against BTC (cont'd)

- **Consumer Healthcare Products Association**
 - Existing system works well for consumers; gives consumers choice and convenience in a competitive environment that keeps costs down.
 - Existing system has flexibility so if there are challenges to a specific drug switch, sponsors can address the issues.
 - Negative ramification: creating a class that does not empower consumers to take control.

BTC in Foreign Countries

- Several countries, including the United Kingdom (UK), Canada, and Australia, have an official class for drugs available from BTC, referred to as "pharmacy (P)," "pharmacist only," or "Schedule 3."
- Countries have used the following criteria for switching a drug from prescription to intermediate class: (1) Indications suitable for *self-medication*, including *self-diagnosis* with the *intervention* of a pharmacist and (2) the medicine has a *low potential* for side effects or overdose, and *intervention* by a pharmacist could minimize these risks.
- In the UK, half the medicines available without a prescription fall into this category.

1995 GAO Report

- Congress considered a third class of drugs, when it commissioned the US General Accountability Office (GAO) to report on how third-class drugs fared in other countries.
- GAO analyzed similar systems in 10 countries.
- GAO concluded the experience of other countries "does not support a fundamental change in the US system," noting risks of *inadequate counseling* by pharmacists and *costs* associated with adding an additional class.
- House Energy and Commerce Committee Chairman John Dingell (D-Mich.) and Oversight and Investigations Subcommittee Chairman Bart Stupak (D-Mich.) are requesting an update of August 1995 report.

1995 GAO Report (cont'd)

Objective: Whether there would be significant advantages to creating an additional [third] class of drugs.

Analyzed two types of intermediate classes in 10 countries:

- **Fixed class** – a class of nonprescription drugs which a drug would be *permanently* placed and be restricted to sale in pharmacies or by pharmacists.
- **Transition class** - class of nonprescription drugs into which a drug could be *temporarily* placed while its suitability for less restrictive sale was being assessed. Drugs available for sale without a Rx but only from a *pharmacist*. The class would be used for assessing the appropriateness of selling a drug in a retail outlet.

1995 GAO Report (cont'd)

- **Results of Report:**

“Little *evidence* supports the establishment of a pharmacy or pharmacist class of drugs in the United States at this time, as either a fixed or a transition class. The *evidence*...tends to *undermine* the contention that major benefits are being obtained in the countries that have such a class.”

1995 GAO Report (cont'd)

- **Results of Report:**

GAO's Six Points:

Foreign

1. Reliable and valid studies that examine the effect of different drug distribution systems on overall health and health care system costs do not exist.
2. While a pharmacy or pharmacist class exists in all 10 countries, it is not used with any frequency in any of them to facilitate the movement of drugs to sale outside specialized drug outlets.
3. The European Union has decided not to impose any particular drug distribution system on member countries (no superior system).

1995 GAO Report (cont'd)

- **Results of Report:**

GAO's Six Points:

Foreign

4. There is *no clear pattern* of increased or decreased access to drugs as nonprescription products where a pharmacist or pharmacy class exists.
5. While a pharmacy or pharmacist class is *assumed* by some to improve safeguards against drug misuse and abuse, in the 10 countries these safeguards are easily *circumvented*.

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1995 GAO Report (cont'd)

- **Results of Report:**

GAO's Six Points:

Florida

6. Experience in Florida with a class of drugs similar to a pharmacist class has not been successful; pharmacists have *not regularly prescribed* these drugs, and *recordkeeping* requirements have *not* been followed.

***De facto* BTC - Plan B: Rx to BTC**

- April 16, 2003, Barr Pharmaceuticals filed a supplement to NDA 21-045 for Plan B®, (levonorgestrel) Tablets, 0.75 mg, to *switch to OTC* status.
- May 6, 2004, FDA issued a *Not Approvable letter*. the supplement lacked data that product was *safe and effective* for OTC use by women under *age 16*.
- July 21, 2004, Barr *resubmitted* its supplement to NDA 21-045, S-011, seeking to switch Plan B®'s prescription (Rx) status to OTC for women *16 years* of age and *older*, and with Plan B® to remain *Rx* for women *under 16 years* of age.



***De facto* BTC - Plan B: Rx to BTC**

August 26, 2005, FDA Letter:

From former FDA Commissioner Lester M. Crawford to Barr stating FDA completed its review of the sNDA, and concluded scientific data are sufficient to support the safe use of Plan B® as an OTC product, *but* only for women 17 years and older.

FDA was unable to reach a decision on the approvability of the application due to unresolved issues that related to the NDA.



De facto BTC - Plan B: Rx to BTC

August 26, 2005 FDA Letter cited three issues:

1. Whether the same active ingredient could be marketed both Rx and OTC based solely on the age of the individual using the drug;
2. How, as a practical matter, an age-based distinction could be enforced; and
3. Whether the Rx and OTC versions of the same active ingredient may be marketed in a single package.



De facto BTC - Plan B: Rx to BTC

August 26, 2005 FDA Letter:

Advised FDA would ask for public comments on whether to initiate a rulemaking to codify its interpretation of § 503(b) of the Act regarding when an active ingredient can be marketed simultaneously as an Rx drug product and an OTC drug product.

September 1, 2005, Advance Notice of Proposed Rulemaking (ANPRM) published. (70 FR 52050).

***De facto* Plan B: Rx to BTC**

July 31, 2006, FDA Letter:

Dr. Andrew von Eschenbach advised FDA reviewed responses to ANPRM; determined it was unnecessary to engage in rulemaking to resolve the novel regulatory issues raised by the sNDA; and FDA was proceeding with further evaluation of the sNDA.

August 8, 2006, CDER staff met with Barr to discuss: how to address the restriction on OTC sales of Plan B® to ages 18 and over; packaging of prescription and OTC Plan B® in one package; and Convenient Access Responsible Education (CARE) Program.

De facto Plan B: Rx to BTC

- **August 17, 18, and 23, 2006**, Barr amended its application proposing revisions to the labeling and to the CARE Program
- **August 24, 2006**, FDA approved OTC access for Plan B for women 18 and older with an Rx requirement for those 17 and under.

***De facto* Plan B: Rx to BTC**

- FDA explained the Convenient Access, Responsible Education (CARE) program was sufficiently rigorous to prevent young women from obtaining Plan B® over-the-counter without the supervision of a practitioner licensed by law to prescribe the drug. (S. Galston Memorandum, 8-24-06).
- **Under the CARE program, Barr committed to:**
 - Provide *consumers and healthcare professionals* with *labeling and education* about the appropriate use of prescription and OTC Plan B, including an informational toll-free number for questions about Plan B;

***De facto* Plan B: Rx to BTC**

Under the CARE program, Barr committed to:

- Ensure distribution of Plan B will only be through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners, and *not* through convenience stores or other retail outlets where it could be made available to younger women without a prescription;

***De facto* Plan B: Rx to BTC**

Under the CARE program, Barr committed to:

- Packaging designed to hold both OTC and prescription Plan B. Plan B will be stocked by pharmacies *behind the counter* because it cannot be dispensed without a prescription or proof of age; and
- Monitor the effectiveness of the age restriction and the safe distribution of OTC Plan B to consumers 18 and above and prescription Plan B to women under 18.

***De facto* BTC - Pseudoephedrine (PSE)**

Combat Methamphetamine Epidemic Act of 2005

- Popular and effective decongestant, recommended by physicians and pharmacists for many years.
- Used to make illegal methamphetamine, PSE moved BTC to discourage bulk sales and shoplifting of the drug.
- Patients must present IDs and sign log books to access the medication. Inconvenience deterring patients off PSE altogether.
- Some patients, confused by replacement drugs that substitute phenylephrine (PE) for PSE are packaged similarly to the original products.
- Some claim this a possible explanation for the drop in sales of PSE products as Sudafed and generic equivalents.

BTC FDA Public Meeting

- November 14, 2007, FDA convened a public meeting seeking public opinion on establishing a “BTC” class of drugs.
- Proponents: improve access to pharmaceuticals, especially those without health insurance; collection of additional data on drugs, as with Phase IV clinical trials.
- Critics: risks associated with drugs require medical supervision.
- Lack of consensus on whether BTC drugs would raise or decrease health care costs.
- Professional liability: impact upon the viability of the learned intermediary defense for products sold BTC. Pharmacist, like a doctor, would become a learned intermediary. *Duty to warn* respecting BTC products would run to health care providers, including *pharmacists*.

Legal Authority to Create BTC Class?

- **Two options:**
 1. FDA administrative rulemaking creating BTC class or
 2. Congress amends FDCA to create BTC class.

- FDA has not formally addressed whether it has legal authority under FDCA to create BTC class.

- FDA proposed then rejected rulemaking with Plan B approval to BTC.

Legal Authority to Create BTC Class?

- FDA Press Conference on November 14, 2007
 - Randall Lutter, FDA Deputy Commissioner for Policy: “[t]he word class is not one we’d opined on directly. Clearly there are instances in which drugs in this country are already sold behind the counter. In that sense, the track record on this is clear that some drugs are being sold behind the counter. And at this point *we haven’t evaluated any sort of authority with respect to the use of the word class per se.*”

Legal Approaches to Creating BTC Class

Formal Rulemaking Approach

- FDA must demonstrate FDCA permits BTC class.
- Argue that BTC determination is similar to the traditional Rx to OTC switch.
- Use advisory panel to issue BTC monographs for safety and effectiveness similar to OTC drugs.
- FDA did not utilize formal rulemaking in issuing Plan B approval leading to lawsuits contending that FDA did not have authority to make Rx to BTC switch.

Legal Approaches to Creating BTC Class

Legislative Amendment

- FDCA arguably lacks authority for FDA to establish a new [third] class of drugs.
 - FDCA is written and implemented on a two class system; silent as to BTC class, as written.
 - FDA has interpreted “OTC drug” to mean any drug not meeting the definition of a Rx drug. § 503(b)(1).
 - In Rx to OTC switches, drug is *removed* from Rx status and becomes an OTC drug *or* the drug remains Rx.

Federal Issues

- FDCA Language § 503(b)(1)
- De facto Classification as BTC
- FDA Inspections
- Voluntary vs. Involuntary Switches
- New labeling regulations/ monographs (FDA burden)



State Issues

- Preemption
- FDA Inspections
- Pharmacist training/ retraining
- Recordkeeping – Patient, Pharmacist, Physician
- NABP Survey



Thank You