



PHARMACY  
access  
partnership

A Center  
of the Public  
Health Institute

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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: Docket No. 2007N-0356 in the October 4, 2007 *Federal Register* (Vol 72; No 192)

Pharmacy Access Partnership, an independent center of the nonprofit Public Health Institute, works to increase access to reproductive health services and supplies in pharmacy settings. Since its inception in 1999, Pharmacy Access Partnership has been a recognized leader in promoting the role of pharmacists as community health providers, and pharmacies as an additional, convenient and integral point of healthcare access that meets the reproductive health needs of diverse communities.

Through our policy initiatives, pharmacist training and community outreach, we understand the intricacies and implications of creating a behind-the-counter (BTC) class of drugs. Pharmacy Access Partnership supports the creation of a BTC class of drugs in the United States if classification determinations are made on sound, evidence-based research and not on political ideology. Variations of a BTC class of drugs already exist in numerous countries worldwide, including Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, New Zealand, Sweden, Switzerland and the United Kingdom.

A BTC class of drugs could potentially address some of the most significant inequities in the American healthcare system, namely broadening quality healthcare services to those who don't have them and most need them. For example, according to a recent Kaiser Family Foundation study, nearly 20% of Americans (46.5 million) under the age of 65 do not have health insurance. Moreover, 60% of uninsured adults say that they do not have access to regular healthcare services.

In cases when scientific evidence merits a switch from prescription-only to BTC status, we believe making BTC services available in pharmacies could reduce these barriers to healthcare access for all consumers, especially those most in need. Moreover, we encourage the FDA to minimize financial, age-related and geographical barriers during its exploration of broadening healthcare access through a third, BTC class of drugs.

Availability, extended hours of operation, and the fact that they are geographically accessible make pharmacies a logical place for provision of time-sensitive medications and services. This is especially true for consumers who, for geographic or financial reasons, do not have access to a doctor or clinic. By allowing appropriate drugs to be classified as BTC, consumers can seek counseling services directly from a trained pharmacist in order to determine if a BTC drug is appropriate. This prevents unnecessary delays often experienced when waiting for doctor or clinic appointments. According to a recently published national survey, one-quarter of women reported experiencing long waits to get a doctor's appointment or doctors' offices being inconvenient as major obstacles to obtaining their needed prescriptions.

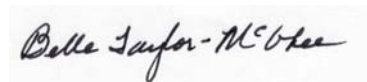
U.S. pharmacies currently provide myriad healthcare services beyond filling prescriptions, and consumers have come to trust pharmacists as valuable members of the healthcare team. Among services already provided in pharmacies are contraceptive services, immunizations, chronic disease management (e.g., diabetes and asthma), smoking cessation programs, obesity management and cardiovascular treatment and services. Research with pharmacists has shown that many pharmacists are interested in providing additional clinical services in their pharmacies. Providing specialized training would enable pharmacists to offer additional services in their pharmacies and thereby improve consumer access to healthcare.

For example, in California and eight other states (AK, HI, MA, ME, NH, NM, WA, VT), pharmacists can provide direct pharmacy access to emergency contraception (EC) to all women regardless of age without requiring an advance prescription from a doctor or clinic – a model called EC pharmacy access. In California, pharmacists provide pharmacy access to EC more than any other clinical service. Moreover, research shows that among women who use these pharmacy services, the overwhelming majority report satisfaction with the pharmacists' provision of care, and are interested in receiving additional pharmacy-based services. Nationally, research shows strong support and interest among women in receiving hormonal contraceptives directly from a pharmacy without an advance prescription, if the pharmacist provides screening services.

In August 2006, the U.S. Food and Drug Administration decided to make Plan B EC available without a prescription to women and men 18 and older. This decision sent a clear message that pharmacists are qualified and trusted to provide essential reproductive healthcare information and services in pharmacies. Plan B must still be kept behind pharmacy counters and consumers must request it from the pharmacist. Reducing barriers to EC and giving pharmacists a stronger role has improved access and, inevitably, health outcomes.

The FDA should thoroughly review and consider the essential systems and policy changes that would need to be in place to support a BTC class of drugs, including reimbursement for pharmacists providing BTC products and services. With proper classification and systems in place, a BTC class of drugs has the potential to open the door to broader health care services for consumers nationwide.

Sincerely,



Belle Taylor-McGhee  
Executive Director  
Pharmacy Access Partnership