

# Conclusion of GAO Study

“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 that is available tends to undermine the contention that major benefits are being obtained in the countries that have such a class. This conclusion is substantiated by six points.”

GAO Report, August 1995

# Six Points In GAO Study

- Reliable and valid studies that examine the effect of different drug distribution systems on overall health and health care system costs do not exist.
- 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.

## Six Points, Continued

- The European Union has decided not to impose any particular drug distribution system on its member countries because it has found no evidence of the superiority of one system over another.
- There is no clear pattern of increased or decreased access to drugs as nonprescription products where a pharmacist or pharmacy class exists.

## Six Points, Continued

- 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, and studies show that pharmacist counseling is infrequent and incomplete.
- 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.

## Other findings from the GAO Study

- “The results of the studies in the United States are rather similar to those in countries where the sale of at least some nonprescription drugs is restricted to pharmacies. **In general, the theory of pharmacy practice diverges from the reality** (emphasis added). The advice of pharmacists is often appropriate but not universally given. In addition, it is often incomplete, with little information being given to customers on such items as possible side effects. In other words, what information is given is accurate, but not enough was passed on to consumers. Researchers consistently found a lack of information-gathering on the part of pharmacists. For instance, information is often not gathered on symptoms and other medications.”

## 1/18/08 Letter from Congressmen Dingell and Stupak to the GAO Comptroller General

“Therefore, we ask that GAO update their 1995 study by examining any new data available since the original study.\* We do not expect on-the-ground investigations in countries that have established a “Behind-the-Counter” class as in the previous study, but rather a rigorous examination of any additional data since the original study that may allow us to evaluate the effects of a third class of drugs.”

**GAO Report 8/95: “Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated.”**

# The Proverbial Elephant in the Room

The major problem: The inadequate recognition of the value of pharmacists and appropriate reimbursement for their consulting services

The solution: Establishing a third class of behind-the-counter drugs?

# Let Us Make Some Assumptions

- If the update of the GAO study were to refute the earlier finding that major benefits were not being obtained in the countries that have such a class and...
- based on the knowledge and training of pharmacists and the careful selection of only those drugs that could reasonably be put in a third class, such a class were made legal in the United States, then.....

# There would still be a problem

The implementation of a behind-the-counter program in the U.S. would be seriously handicapped—if not made impossible---by the primary problem of inadequate recognition of pharmacists' value and reimbursement.

# Has there been any effort to solve the major problem?

- Ontario, Canada has recently (2007) implemented a *Meds Check* program that designates a role for pharmacists in the provision of primary care. All Ontario patients are offered the opportunity to a medication counseling session. The Province reimburses the pharmacy owner, not the individual pharmacist, \$50.00 per patient for the session.

# What do pharmacists think of this program?

According to an official of the Ontario Pharmacists Association, “The program is unique to Ontario as it is an example of the recognition by the Ministry of Health of the value of the pharmacists and reimbursement for those services.”

# Why is Canada different from the United States?

- Health care is a legally-mandated right: the country has decided that health care is primarily a crucial service, not just a business
- The simpler and much less expensive single payer system controls drug prices and can implement programs like *Meds Check*
- The Ontario Ministry of Health recognizes the value of the pharmacists and reimbursement for those services

# Elements of Canada's System

- EpiPens, Polysporin eye or ear drops, the strongest lice shampoos and Tylenol No. 1 with codeine are available behind-the-counter (list from Ontario).
- Pharmacists counsel patients about the use of the drugs and are reimbursed for their time through dispensing fees that are established by the provinces.

# Questions about Canada's System

(based on research in the mid-1990's)

“The purpose of this study was to measure and explain pharmacists' readiness to adopt a proposed new standard for assessing the appropriateness of consumer product selections involving pharmacist-only OTC agents.”

Pharmacists' Readiness to Assess Consumers' Over-the-Counter Product Selections. J Am Pharm Assoc 40(4):487-494, 2000

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Ontario pharmacists surveyed were categorized into the following stages of readiness: precontemplation -- 57.6%, contemplation -- 4.3%, preparation -- 24.4%, action -- 1.2%, maintenance -- 12.5%. The majority of respondents, therefore, had no intention (in the next 6 months) of intervening every time a product was requested by name.

Pharmacists' Readiness to Assess Consumers' Over-the-Counter Product Selections. J Am Pharm Assoc 40(4):487-494, 2000

## Surveys of UK pharmacists after the 2004 UK decision to make simvastatin available in a pharmacist-only setting.

- “very few sales had actually taken place during the study period....[there were] major concerns relating to the need for full cardiovascular risk assessment, access to full clinical information prior to simvastatin use and the lack of an evidence base for the licensed dose reflect reservations voiced by the medical profession”