

Date: May 18, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D. Chairman DRC

At its 05/18/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the agents for overactive bladders in adults.

Specifically considered were
Darifenacin (Enablex)
Flavoxate hydrochloride (Urispas)
Oxybutynin chloride (Ditropan)
Solifenacin succinate (Vesicare)
Tolterodine tartrate (Detrol)
Trospium chloride (Sanctura).

With the understanding that equipotent doses of each drug are used, the Committee reached the following conclusions based upon its perception of the bulk of the best available evidence.

1. None of the captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for adults with overactive bladders.
2. There is insufficient evidence to conclude that any of the captioned agents is superior in efficacy to the others in adults with overactive bladders.
3. Because oxybutynin ER, tolterodine ER and solifenacin produce relatively fewer adverse effects than the other agents, at least one should be available.
4. None of the captioned drugs have been associated with fewer adverse events to adults on the basis of gender, race, pregnancy, co-morbidities or concomitant use of other medications.
5. None of the six drugs has been proven more effective for adults on the basis of gender, race, pregnancy, comorbidities, or concomitant use of other medications.

Henry F. Simmons, Jr.
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