

Date: February 16, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

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

At its 02/16/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of newer sedative hypnotic agents for adults with insomnia.

**Newer sedative hypnotic agents under consideration include the following:**

Eszopiclone [Lunesta]  
Ramelteon [Rozarem]  
Zaleplon [Sonata]  
Zolpidem [Ambien and Ambien CR]

**Indications under consideration in adults**

Insomnia

Based upon the bulk of the best available evidence pertaining to the aforementioned agents the Committee concluded the following:

The agents do not differ in terms of either safety considerations or frequency of adverse events to the extent that one or more should be excluded from consideration.

At least two of the agents should be available. If only two are available, they should include no more than one of the following: ramelteon and zaleplon.

None of the agents appear to be associated with either special benefits or special risks on the basis of demographics.

Henry F. Simmons, Jr.  
February 16, 2006