

STATEMENT OF PURPOSE

RS23834

This bill allows for the Department of Health and Welfare to administer an Expanded Access Program to treat severely ill children suffering from intractable epilepsy who do not respond to standard medications with a drug that has met Federal Drug Administration (FDA) requirements for safety in pre-clinical research while clinical trials take place, and to gather preliminary information for phased trials that will determine whether Epidiolex® can reduce epileptic seizures more effectively than standard medications. The Expanded Access Program's oversight and dosing guidance is provided by neurologist licensed in the state of Idaho as well as monitoring of potential drug interactions and side effects. This program would be conducted in addition to any clinical trials that may be taking place within the state of Idaho.

FISCAL NOTE

\$223,500 State General Funds one time to be appropriated to DHW Physical Health Services annually for two to three years, depending on the FDA approval of the program, site and drug (anticipated to be a three year maximum). The funds would provide for DHW to contract for the program site administration and enrollment of 25 children per year. The cost per enrollee will include all 7 required visits, laboratory tests, screening, diary review, education, and other clinical services, as required by the Expanded Access Program protocol. It is presumed costs for year two will be less as initial start-up fees will not recur. Clinical trial programs typically cost \$15,000-\$20,000 per enrollee.

Breakdown of Year One Costs:

Contractor Administrative Costs	\$11,000
Enrollment Cost Per Child (\$8,500)	<u>\$212,000</u>
	\$223,500

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