AMERICAN LEGION BOYS NATION

RESOLUTION SUMMARY

Note: This form must be completed and accompany all Resolutions submitted for consideration by The American Legion Boys Nation Senate.

DELEGATE NAME: Ryan Leone

DELEGATE STATE: New York

NAME OF RESOLUTION: Adjustment to the FDA Process of Drug Testing and Approval in Phase I of the Clinical Trial Stage

BRIEF SUMMARY OF RESOLUTION: Phase I of the Clinical Trial Stage in the FDA drug approval process should have an increased sample size since Phase I tests the safety of the drug. A small population tested does not give varied results and skews the justification for continuing testing.

To Be Completed By
The Clerk Of The Senate

RESOLUTION NO.

SR-11

AMERICAN LEGION BOYS NATION SENATE

IN THE SENATE OF AMERICAN LEGION BOYS NATION

Senator **Ryan Leone** of **New York** introduced the following Resolution, which was read twice and referred to the following American Legion Boys Nation Senate Committee:

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a Resolution

to ensure the safety of drugs before they pass on to later FDA drug test trials...

BE IT ENACTED BY THE AMERICAN LEGION BOYS NATION SENATE ASSEMBLED, THAT

there be a minimum restriction for the Phase I trial of 50 subjects in order to ensure that there is more diversity genetically and behaviorally among the subjects. A test of 20 subjects in the typical 20 to 80 subject range for Phase I seems somewhat limited and would not give a broad enough conclusion on the drug's possible side effects before it enters Phase II. In order to provide more evidence of safety in Phase I, a larger group of individuals should be tested so that way unusual side effects will be spotted before the drug is tested on groups of up to 300 in Phase II.

By expanding the number of subjects involved in Phase I testing, there will be greater health and economic benefits than there are with the current process. If a problem with the drug is spotted in certain classes of individuals due to the increase in testing, then the subjects that would have been tested in Phase II are protected from problems that could have resulted if an unvaried group was used in Phase I. Additionally, the drug companies and the FDA will save money by eliminating more unsafe drugs in Phase I and not allowing them to use up valuable resources in later phases. There will be a reduced likelihood of unsafe drugs passing on to later phases if Phase I is expanded. Furthermore, there will be more empirical data available in this early phase to analyze as the trials continue, leading to potentially quicker approvals in the later phases. It could also increase the likelihood of long-term side effects being noticed earlier on since diverse subjects may respond to the drug differently. Funding for this increase in Phase I would come from the funding originally set aside for Phase II, resulting in a slightly smaller

population size in Phase II and a greater size in Phase I. The decrease in Phase II would have minimal long-term impact because it is simply a basic test of efficacy to preface the large-scale tests of thousands of subjects for efficacy in Phase III.

Essentially, increasing the size of the group tested in Phase I gives greater diversity to the subject group and offers further support in the conclusion of whether or not a drug is safe enough to advance to later stages.