ASSEMBLY JOINT RESOLUTION NO. 14–COMMITTEE ON HEALTH AND HUMAN SERVICES

MARCH 29, 2005

Referred to Committee on Health and Human Services

SUMMARY—Urges Nevada Congressional Delegation to introduce and to support federal legislation mandating reporting of results of all clinical trials and collection and analysis of data by appropriate federal agencies. (BDR R-1011)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State: No.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets ~~[omitted material]~~ is material to be omitted.

ASSEMBLY JOINT RESOLUTION—Urging the Nevada Congressional Delegation to introduce and to support federal legislation mandating the reporting of results of all clinical trials and the collection and analysis of the data by the appropriate federal agencies.

WHEREAS, A clinical trial is a research study involving the participation and observation of human volunteers to determine the safety and effectiveness of drugs, biological products or medical devices; and

WHEREAS, There is no comprehensive system for tracking, organizing and disseminating information about ongoing clinical trials, and it is estimated that only half of the approximately 1 million trials conducted over the past 56 years have been reported; and

WHEREAS, One consequence of this lack of reporting is "publication bias" wherein positive results of trials are reported in order to get a drug approved, while trials which show harmful effects are not reported, resulting in a distortion of evidence on which to base medical determinations, allowing physicians to unwittingly prescribe drugs that may have hazardous side effects; and

WHEREAS, There are many reasons that volunteers participate in trials, such as gaining access to new treatments before they are widely available, obtaining expert medical care at leading health care facilities, playing an active role in their own health care and helping others by contributing to medical research; and

WHEREAS, There are many risks to participation in these trials, including possible unpleasant and even life-threatening side effects, and with a voluntary registry such as suggested by the pharmaceutical industry, companies may not report results that are unfavorable to their products, betraying the volunteers' trust, and without this information, there cannot be a true scientific evaluation of the study of that drug; and

WHEREAS, Many trials that are performed by academic researchers are sponsored by pharmaceutical companies, presenting a conflict of interest when reporting the results of the trials, and nearly one-fifth of government scientists say they have been pressured to support approval of a drug despite having concerns about its safety; and

WHEREAS, Each clinical trial in the United States must be approved and monitored by an institutional review board, which is an independent committee of physicians, statisticians, community advocates and others, to ensure that the trial is ethical and that the rights of the volunteers are protected; and

WHEREAS, Prescription drugs are regulated by the Food and Drug Administration, but with the discovery that some of the drugs developed for arthritis have been found to increase the risk of heart attacks and that some patients, especially children and teenagers, who were prescribed antidepressants had increased rates of suicide and violence, with substantial evidence of the suppression of negative data concerning these drugs in clinical trials, there is a growing movement supporting a national registry of all clinical trials; and

WHEREAS, The pharmaceutical industry opposes full disclosure because of concerns that competitors would learn their research and development secrets and it would affect their profits, but the pharmaceutical industry is consistently one of the most profitable industries in the Fortune 500 list, and the welfare of the public must take precedence over all else; and

WHEREAS, For these reasons, the American Medical Association has called for all clinical trials to be registered with the Federal Government; and

WHEREAS, The International Committee of Medical Journal Editors has issued a statement that, as of July 1, 2005, they will require registration in a public trials registry for all clinical studies

that involve human patients as a condition of consideration for publication in member journals; and

WHEREAS, In the 108th Session of Congress, H.R. 5252 and S. 2933 were introduced which required researchers to enter their clinical trials into a federal registry before starting them and to report the results of the trials at the conclusion, but these bills died in committee; and

WHEREAS, Under current law, pharmaceutical companies are required to post information only about trials of drugs for serious or life-threatening diseases or conditions which are then posted on an existing government website, www.ClinicalTrials.gov, that currently has a database of such studies conducted in all 50 states and in over 100 countries; and

WHEREAS, This website could be expanded to include information about the purpose, duration and outcomes of all clinical trials; and

WHEREAS, It is imperative that federal legislation be introduced to create a centralized and comprehensive national registry for mandatory reporting of all publicly and privately funded clinical trials involving drugs, biological products or medical devices; and

WHEREAS, Since it has been shown that unfavorable trial results which placed financial interests at risk are particularly likely to remain unpublished and hidden from public view, any legislation must require that the results of all clinical trials be reported, whether those results are positive or negative, because selective reporting of results distorts the body of evidence available for decision making; and

WHEREAS, By creating a single, comprehensive database of clinical studies and their results, scientific information is easily available, in a timely fashion, for use by researchers, journalists, public interest organizations, health care providers, patients seeking to enroll as subjects in clinical trials and the general public so that they may make informed decisions, resulting in safer and more responsible clinical trials; and

WHEREAS, Since many adverse effects do not surface until a drug is taken over a long period of time, periodic updates must be included in the registry to improve knowledge of the risks of long-term use; and

WHEREAS, To be effective, legislation would need to require that institutional review boards deny a stamp of approval to a clinical trial unless it is registered in the database; and

WHEREAS, To regain the public's trust in the clinical trials procedure, there must be full disclosure of the results of all clinical trials, allowing physicians and patients to make safe, appropriate

and effective health care decisions by having all relevant information available; now, therefore, be it

RESOLVED BY THE ASSEMBLY AND SENATE OF THE STATE OF NEVADA, JOINTLY, That, because carefully conducted clinical trials are recognized as a necessary and valuable tool in determining the efficacy and safety of products, the members of the Nevada Legislature hereby express their strong support for a national registry of clinical trials for the health and well-being of the public; and be it further

RESOLVED, That, since there is no pending legislation requiring a national registry of clinical trials before the 109th Session of Congress, the Legislature of the State of Nevada urges the Nevada Congressional Delegation to introduce and to support federal legislation which mandates registration of all clinical trials before they are begun and full disclosure of the results; and be it further

RESOLVED, That the Chief Clerk of the Assembly prepare and transmit a copy of this resolution to the Vice President of the United States as the presiding officer of the Senate, to the Speaker of the House of Representatives and to each member of the Nevada Congressional Delegation; and be it further

RESOLVED, That this resolution becomes effective upon passage.

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