RESOLUTION REGARDING CLINICAL TRIALS FOR WOMEN'S HEALTH CARE

2003 GENERAL SESSION

STATE OF UTAH

Sponsor: Paula F. Julander

This concurrent resolution of the Legislature and the Governor urges the Food and Drug Administration to strictly enforce requirements that clinical study sponsors perform subgroup analysis of their studies to ensure that the health concerns of women are appropriately addressed in clinical trial results.

Be it resolved by the Legislature of the state of Utah, the Governor concurring therein:

WHEREAS, there is a pressing need to collect and assess more accurate data regarding the health of women;

WHEREAS, subgroup analysis, a statistical procedure, takes data from a general group of study subjects and looks for differences within a subset of those subjects that share a specific characteristic, such as sex, age, or state of disease;

WHEREAS, studies have shown that, to improve the quality and appropriateness of health services, the gender of those participating in clinical trials must be factored into all levels of biomedical research, creating a new paradigm for data analysis;

WHEREAS, despite the mounting evidence of the need for subgroup data analysis based on gender, recent reports show that analysis is either not being conducted or not being reported;

WHEREAS, although a 1993 policy guideline and a 1998 regulation by the Food and Drug Administration recommends that study sponsors perform subgroup analysis of their studies, it is clear that these recommendations are not being followed;

WHEREAS, a July 2001 report of the General Accounting Office found that about one-third of new drug applications submitted to the Food and Drug Administration by study sponsors failed to provide gender-specific data from subgroup analysis conducted during the clinical trials; and

WHEREAS, without subgroup analyses, researchers and clinicians cannot truly assess

the safety and efficacy of new drugs for women, and the development of potentially life saving drugs may be abandoned if early trials fail to show efficacy in one gender:

NOW, THEREFORE, BE IT RESOLVED that the Legislature of the state of Utah, the Governor concurring therein, strongly urge the Food and Drug Administration to strictly enforce requirements that clinical study sponsors perform subgroup analysis of their studies to ensure that the health concerns of women are appropriately addressed in clinical trial results.

BE IT FURTHER RESOLVED that a copy of this resolution be sent to the Food and Drug Administration, the Utah Department of Health, and the members of Utah's congressional delegation.