

## S23-2 Conflicts of interest in human subjects research -Recent trends in American law-

○Tomoko MISE<sup>1,2</sup>

<sup>1</sup>Japan Society for the Promotion of Science, <sup>2</sup>Sophia University

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Industry-university cooperation has been known to be efficient for medical study and drug development. However, financial contracts between private companies and doctors (scientists) include financial incentives for the doctors which may endanger the welfare of patients (human subjects) and the society as a whole which will be affected by the study outcome. This issue is known as “Conflict of interest”.

In U.S., this issue gained public attention after the Gelsinger incident. An 18 years old young man, Jesse Gelsinger, died while participating in a clinical trial at the University of Pennsylvania's Institute for Human Gene Therapy. According to media reports, there were considerable financial conflicts of interest among the study's principal investigator and the University.

From 1980, U.S. government used financial incentives for scientists to encourage greater production of commercially valuable research to keep up with international competition of drug development. After the Gelsinger incident, the government has searched the way to get rid of the issue of conflicts of interest.

Industry-university cooperation has been the national policy in Japan, too. And the issue of conflicts of interest is becoming the hot issue. After the incident of Tamiflu, MHLW had set up 2 working groups to draft guidelines and the final ones were publicized in last March.

This presentation will analyze the rule making process and the case laws of U.S. on this issue.