

MAINE STATE LEGISLATURE

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DATE: 5/17/5

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HEALTH AND HUMAN SERVICES

Majority

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STATE OF MAINE
HOUSE OF REPRESENTATIVES
122ND LEGISLATURE
FIRST SPECIAL SESSION

COMMITTEE AMENDMENT "A" to H.P. 505, L.D. 710, Bill, "An Act To Require Notice of Clinical Trials"

Amend the bill by striking out the title and substituting the following:

'Resolve, Regarding Clinical Trials of Pharmaceuticals, Treatment Options and Medical Devices'

Further amend the bill by striking out everything after the title and before the summary and inserting in its place the following:

'Sec. 1. Study of clinical trials; posting of Internet links. Resolved: That the Department of Health and Human Services shall study the accessibility of information regarding the results of certain clinical trials of pharmaceuticals, treatment options and medical devices and the enrollment of certain persons in those trials. The study must include a review of the registration of clinical trials with the website developed by the National Library of Medicine as a service of the United States National Institutes of Health to provide regularly updated information about federally and privately supported clinical research in human volunteers and access to the results of those trials for physicians, health care providers and the public. The study must include a review of the enrollment as subjects of persons enrolled at institutions of higher education in the State, persons incarcerated at correctional facilities within the State, persons hospitalized at state mental health institutes and persons receiving medical treatment reimbursed in whole or in part with state funds. By January 30, 2006, the department shall report to the Joint Standing Committee on Health and Human Services the results of the study. By November 15, 2005, the Department of Health and

COMMITTEE AMENDMENT

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COMMITTEE AMENDMENT "A" to H.P. 505, L.D. 710

2 Human Services shall post on its website links to public
information regarding clinical trials of pharmaceuticals,
4 treatment options and medical devices.'

6 **SUMMARY**

8 This amendment is the majority report of the committee. It
changes the bill to a resolve and changes the title. The
10 amendment directs the Department of Health and Human Services to
study the accessibility of information regarding the results of
12 certain clinical trials of pharmaceuticals, treatment options and
medical devices and the enrollment of certain persons in those
14 trials. The amendment requires a report by January 30, 2006 to
the Joint Standing Committee on Health and Human Services with
16 the results of the study. The amendment requires the Department
of Health and Human Services to post on its website links to
18 public information regarding clinical trials of pharmaceuticals,
treatment options and medical devices by November 15, 2005.

20
22 **FISCAL NOTE REQUIRED**
(See attached)

COMMITTEE AMENDMENT



122nd MAINE LEGISLATURE

LD 710

LR 2041(02)

An Act To Require Notice of Clinical Trials

Fiscal Note for Bill as Amended by Committee Amendment "A"

Committee: Health and Human Services

Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - General Fund

Fiscal Detail and Notes

Any additional costs to the Department of Health and Human Services in implementing this bill can be absorbed by the department utilizing existing budgetary resources.