



NEWS from U.S. Senator Bob Dole

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HEW VIOLATING REGULATIONS ON PATENT ISSUANCE, DOLE CHARGES; AMENDMENT OFFERED

WASHINGTON - Sen. Bob Dole (R-Kan.) today offered an amendment that he said would enable HEW to better cooperate with the private sector in the development of biomedical research projects undertaken by major universities and medical research institutes with government support.

The amendment to Sen. Edward Kennedy's bill establishing the National Institutes of Health Care Research (S. 2466) would transfer the duty of issuing patents on these inventions from the HEW General Counsel's Office to the Office of the Assistant Secretary of Health. The Assistant Secretary's Office would fall under the new Office of Health Technology created by the bill.

On Friday, Sen. Dole charged that HEW's General Counsel was suppressing 29 lifesaving drugs and medical devices developed with support from the National Institutes of Health because of the unwillingness of the General Counsel's Office to extend limited patents to these research projects.

He stated that HEW was "stonewalling" requests and ignoring petitions from the universities and research institutes seeking patents in order to gain funding from private sources.

Dole said today that HEW has been violating federal regulations in allowing the General Counsel to interfere in the patent process.

"The General Counsel's decision to intervene in the allocation of patent rights is in clear violation of the Department of Health, Education and Welfare's regulations governing patent activities," he said. "According to Chapter 1-901 of the DHEW Organizational Manual, 'The Assistant Secretary for Health is responsible for evaluation and development of current patent policy, and makes the determination of rights in inventions and patents involving important policy considerations.

"It is abundantly clear that the Assistant Secretary for Health, who serves as the chairman of HEW's Patent Board, is delegated the authority for allocation of patent rights. The General Counsel's assumption of this authority effectively undercuts the Assistant Secretary for Health and is totally contrary to DHEW regulations."

Dole's amendment would transfer all of the administrative responsibility for development of projects, including patents, technical data, copyrights and other material, to the Office of Health Technology.