HEW accused of delay on new drug

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WASHINGTON — A new drug developed by two Harvard scientists is one of several discoveries tied up in a dispute over the release of patent rights to inventions created through government-funded research.

US Sen. Bob Dole (R-Kan.) has charged that the Department of Health, Education and Welfare (HEW) is deliberately "stonewalling" requests from universities and medical research institutes to obtain ownership rights to these inventions. Dole claims HEW is worried that, if it relinquishes the patent rights, a drug firm will develop the technology at a large profit and increase the cost of medical care for Americans.

Drs. Karl F. Austin and Edward J. Goetzel of the Harvard Medical School asked HEW in January 1977 to waive its patent rights so they could continue with development of a new drug for the treatment of rheumatoid arthritis and bronchial asthma. The patent release is needed so the scientists may enter agreements with a pharmaceutical firm willing to provide capital for needed research and testing.

HEW is still reviewing Harvard's application, along with those for some 28 other inventions from various academic and medical institutions, according to Harvard patent administrater Stephen Atkinson.

"If we don't get it (the patent) out soon it could create problems," he said.

The Hoffmann-Laroche drug laboratory has given Austin and Goetzel some nominal financial support for the research, Atkinson said, but will not begin negotiations for a licensing agreement until HEW releases the patent rights.

In a recent interview, Austin said he was unaware of the clash between Dole and HEW over the 29 inventions, including the drug developed by him and Goetzel. He said there is "an immense amount of development work to be done" on the drug and that Hoffman-Laroche would decide next year whether to make a larger financial commitment for its development.

Austin said he and Goetzel isolated a human molecule, synthesized it and made a "structurally related compound" that would help trigger a "turn off" response in diseased cells.

The Food and Drug Administration must clear the drug before any clinical tests on humans can begin.

Dole says that HEW has suddenly reversed a 10-year-old policy of allowing universities to secure ownership rights to inventions they have made with the help of Federal grants from the National Institutes of Health (NIH) and other agencies.

In a statement released early this week, HEW general counsel F. Peter Libassi denied that the department is suppressing critical drugs and medical devices developed with NIH support.

He added that HEW still has a "flexible policy" of releasing patent rights on a case-by-case basis.

"The department has, however, altered its procedures for making this determination, in order to further assure that the public interest is served by the assignment of patent rights," Libassi said.

Libassi also recently directed his staff to notify him of any applications that are not processed within 60 days. A HEW spokesman said he could not say whether that directive came before or after Dole's statement of Aug. 4 criticizing the department.