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HEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

August 15, 1978

Statement of
F. Peter Libassi, General Counsel
Department of Health, Education, and Welfare

The Department of Health, Education, and Welfare is not suppressing critical lifesaving drugs and medical devices developed with support from the National Institutes of Health. Nor has the Department reversed its present flexible policy of permitting universities and medical research institutes to collaborate appropriately with the private sector in the further development of inventions initiated with NIH funds.

Under that policy, HEW determines on a case by case basis the merits of assigning to universities and research institutes the patent rights for inventions developed with NIH funds.

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. We must make sure that assignment of patent rights to universities and research institutes does not stifle competition in the private sector in those cases where competition can bring the fruits of research to the public faster and more economically.

Prior to August 1977, patent rights determinations were referred to the Patent Branch of the Business and Administrative Law Division of the HEW General Counsel's Office for initial evaluation. That Branch would seek comments from the appropriate institutes of NIH and then prepare a

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recommendation and a determination for the signature of the Assistant Secretary for Health. These were forwarded directly to the Assistant Secretary without additional review. In August 1977, the procedure was changed to require that all such determinations be reviewed by the Assistant General Counsel for Business and Administrative Law, before being forwarded to the Assistant Secretary.

Since that time 50 determinations have been sent from the Patent Branch to the Assistant General Counsel. Of these 28 are still pending in that office, half of which have been received within the past four months. The review in that office entails a careful review of the file and, on occasion, seeking additional information. Determinations that appear to be sound on the initial review are forwarded to the Assistant Secretary for Health. Others are held for further study.

We have been aware for some time that the process of establishing this new, more careful review has resulted in a backlog of cases; and our Office of General Counsel staff has been making a concerted effort to eliminate it. Pursuant to my directive, all cases referred to the Assistant General Counsel will be processed within 60 days. If there are any delays beyond 60 days, I am to be notified personally.

The problem is only temporary, and we fully expect that our review of patent determinations will be current within the very near future.

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