

Political interference at FDA?

New policy raises fears of meddling

Washington

For the second time in as many months, the Reagan Administration is being accused of injecting politics into the selection of scientists for independent advisory panels. According to an official at the Food and Drug Administration (FDA), appointment authority over its scientific advisory panels is gradually being taken away from the FDA commissioner and given to the Department of Health and Human Services (HHS). What worries FDA officials is that HHS recently suggested at least two scientists whom FDA believes are unqualified and who were proposed for political reasons.

Earlier this year, the Department of Agriculture admitted that it had been running security checks and "political" checks on scientists nominated for peer-review panels to evaluate proposals for its competitive grants programme but the political checks have since been dropped.

The troubles at FDA, however, seem more serious. Although the secretary of HHS has always had authority to appoint the advisory panels at FDA, that function has traditionally been delegated to FDA itself. One FDA official said that although HHS has given general directions on the numerical balance of the committees; approval by HHS was generally a formality.

Over the past several months, however, HHS has rewritten the panels' charters as they come up for renewal, retracting FDA's delegated control over them. Although FDA is still being asked to identify possible candidates it is also, for the first time, being told to furnish a list of alternatives. And the final decisions are apparently now being made in the office of HHS secretary Richard S. Schweiker.

Of even greater concern to FDA is that the secretary's office has begun to offer suggestions of its own. According to a report in the *Washington Post* last week, which was confirmed by FDA, these suggestions included a woman psychiatrist who was a founder of the "California Pro-Life Council," an anti-abortion group. She was suggested by HHS as the consumer representative on a panel that evaluates contraceptive and abortion drugs. FDA told the secretary's office that she was unqualified, but whether FDA's opinion will be considered is still uncertain.

The *Washington Post* also reported that HHS suggested a California physician whose main qualification, according to

FDA scientists, was apparently that he listed Dr Loyal Davis — Nancy Reagan's stepfather — as a reference.

The Department of Health and Human Services claims that it is doing nothing improper. An HHS official said the department is merely continuing the centralization of appointment authority begun under President Carter. The official also denied that the secretary's office was making its own recommendations for committee positions, and said it was simply passing on to FDA all names that it receives from congressmen and senators of both parties.

That interpretation was contradicted by an FDA official, who said that while names had occasionally been passed on before, what was happening now was quite different. The official said that HHS was coming back with new names *after* FDA had submitted its list of candidates, and was specifically asking if these new names were qualified for specific positions. Mr Garret Cuneo, the HHS official now apparently in charge of the selection process, refused to comment on the matter.

The effects of the new appointment policy remain to be seen; no obviously political appointments have been made so far. But even if political manipulation does not occur, FDA is worried that the new

procedures will make putting together an advisory panel even harder. The aim in the past has been to get not only leading scientists in a range of specialities, but also to have different geographical regions and women and minorities represented on each panel. FDA officials wonder how these goals can still be met when it is cut out of the process and when it is limited to saying whether the HHS candidates are qualified or not.

Meanwhile, at the Department of Agriculture, the dust seems to have settled. According to the office of Agriculture Secretary John R. Block, the decision to run political checks on scientists nominated for peer-review panels was really the result of a misunderstanding. Political checks are normally run on policy advisers; last autumn, the Office of Management and Budget ordered the department to bring the peer-review panels under the same federal act that governs policy panels. Agriculture department officials then assumed that political checks would have to be run for them as well.

After disclosure of the political checks on scientists, Block ordered them to be stopped. The scientists who had not yet been cleared by Block's office were then all approved at once. Block's office maintains, however, that none of the information

NIH urged to act on germ war

Washington

In response to rumour that the US Army and Navy are seeking to develop "defensive biological weapons systems" using recombinant DNA techniques, two American biomedical scientists have called on the National Institutes of Health (NIH) specifically to prohibit such work.

Dr Richard Goldstein of Harvard Medical School and Dr Richard Novick of the Public Health Research Institute of New York City are proposing an amendment to the NIH recombinant DNA guidelines to ban "the construction of biological weapons by molecular cloning". The proposal will be considered at the next meeting of the Recombinant DNA Advisory Committee on 28 June.

According to Dr Goldstein, several scientists have recently been approached by the military about the possibility of using cloning techniques to produce biological warfare agents. The United States signed the 1982 Biological Weapons Convention, agreeing "never in any circumstances to develop, produce [or] stockpile" biological agents for other than peaceful purposes. But Dr Goldstein says the military apparently interprets this as not covering the development in the laboratory of suitable organisms for "defensive" — by which is meant deterrent — purposes.

In a statement describing their proposed

amendment, the scientists argue that "the use of molecular cloning for the deliberate construction of biological weapons is, *per se*, the most serious biohazard imaginable for this technology", and that "it constitutes an egregious misuse of scientific knowledge".

Although the NIH guidelines strictly apply only to researchers working under NIH grants, the Defense Department has so far agreed to follow them. But the amendment's sponsors say that even if their proposed ban is not binding on military research, it would "provide automatic public support for a refusal of the scientific community to participate in the development of biological weapons and it may convince governments that the 1982 prohibition should be construed as applying to laboratory research".

Under the recent relaxation of the DNA guidelines (see *Nature* 29 April, p.793), the previous ban on cloning of toxin genes and on release of recombinant organisms into the environment was lifted, although permission from NIH is required before proceeding with either. The amendment would restore the ban in these two areas when the aim is construction of biological warfare agents, and extend it to previously unregulated activities such as the cloning of viruses for this purpose.

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