FDA Spars with HHS on Advisory Posts

Tensions have been quietly building up between the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) over appointments to FDA advisory committees. According to FDA officials, the department has on several occasions overridden the agency's recommendations for people to serve on drug safety committees and put forward its own nominees in their place. Some of the department's appointees are said to lack appropriate expertise, and FDA officials and some committee chairmen complain that there are long delays in filling vacancies.

The department began to take a more active role in nominating people to serve on FDA advisory committees early in the Reagan Administration. In previous administrations authority to make appointments was usually delegated to the FDA commissioner, but under the Reagan Administration the department has reassumed this power for several committees. HHS Secretary Margaret Heckler currently has authority to make appointments for 11 FDA committees that advise on the safety and effectiveness of drugs.

Heckler has also changed the selection procedures in a way that has caused considerable delays in filling positions, FDA officials complain. Previously, agency staff would nominate one candidate per position, and the FDA commissioner would sign off on the nomination. Now FDA must send the department the names of two candidates and suggest an alternate for each position. This doubles, to 6 months, the average time taken to complete the process. In addition, when the department and FDA do not agree on the candidate, the selection process becomes more drawn out. Some nominations have been held up for as long as a year.

So far, the department has appointed only 13 of its own nominees, which is a small fraction of the 275 positions on the 16 committees that deal with the safety of drugs. But FDA officials, who decline to be named, are concerned because many vacancies will occur in the near future. The terms of 10 chairmanships will expire by June and 47 positions will become vacant by this fall.

FDA officials generally seek to fill the committees with scientists or clinicians with strong research backgrounds and try to ensure a balanced array of expertise. (The committees also include, by law, one member nominated by a consumer coalition.) But in some cases, they claim that the department's nominees do not have strong research experience or the right expertise to give the committee the correct balance.

FDA staff are upset and puzzled about some of the appointments made by the department. "We don't know what the rules are," says one official. The process is "mysterious." Says another staff person, "All I know is that they send me their names and their c.v.'s. I don't know what the object is."

When asked how the department makes its selection, Kay Reardon, special assistant for advisory committees, said "We get a vast majority of nominations from all over. We take all resumes into consideration. I never put a person on the committee if the agency has said no. We don't pull names out of the hat." Does Reardon have other scientists on her personal staff to help review the nominations? "Absolutely not. We don't need to spend more money on more scientists. [Nominations] go back to the agencies before the final decision is made."

The department has never overridden FDA's nominations for committee chairmanships, and the department has always backed down when FDA officials have strongly objected to nominees that have no scientific credentials. But on several occasions, the department has appointed people who have good qualifications, but in the wrong areas. In one case, for example, the department recently appointed a psychiatrist to a committee after FDA had requested a biostatistician. In another, an endoscopist was chosen rather than a specialist in ulcer drugs. FDA staff say they have had a much tougher time arguing against such appointments. "We can't say the person is unqualified. They're very good people, [but they are] not what we're looking for," one agency official said.

The department has taken a particular interest in appointing candidates to the fertility and maternal health drugs advisory committee. Five of the 11 members have been selected by the department during the Reagan Administration and they include two clinicians who lack strong research backgrounds. A source says that the department's candidates "didn't fulfill the usual criteria." Another individual familiar with the committee says that although he believes the balance of the committee is on the whole satisfactory, "I think I could have found better candidates, but that's life."

FDA officials have found ways to deal partly with department nominations they do not like. When the biostatistician was turned down by the department, for example, FDA hired the scientist as a consultant to the committee. Consultants, however, do not have voting power.

But the problem of delays in filling vacancies is more difficult to get around. Three committee chairmen told *Science* that, although they are not unhappy with the composition of their committees, delays in making appointments have hampered discussions. "My committee is always shorthanded," says Robert Balster, chairman of the drug abuse committee, who is an associate professor at the Medical College of Virginia.

The department has also been sluggish with appointments of advisers at other agencies. At the National Institutes of Health, the appointments for two advisory councils are now 2 months behind schedule. In addition, vacancies on the National Cancer Advisory Board have not been filled in time for the board's next meeting on 14 May, so the members whose terms recently expired have been asked to attend. Board nominations are usually reviewed at the department but are formally appointed by the President.

There is sufficient discontentment at FDA concerning the nominating process that assistant secretary for health Edward Brandt, Jr., has asked Heckler to delegate to his office the authority to make appointments, but apparently no decision has been made as yet. FDA officials are hoping that Brandt will be able to speed up the nominating process and provide more appropriate choices as well.

—MARJORIE SUN