Doctors join protest over change to FDA rules on conflict of interest

Jeanne Lenzer

A doctors’ group has joined a growing number of individuals and organisations protesting against a loosening of rules on conflicts of interest at the US Food and Drug Administration. The National Physicians Alliance, which represents some 20,000 US medical students and doctors and is based in Washington, DC, sent a strongly worded letter on 7 August to the FDA’s commissioner, Margaret Hamburg, stating that it was “dismayed” to learn of the suggestion of a rule change for its advisers.

The alliance, which accepts no funding from drug or device manufacturers, described its organisation’s “first guiding principle” in the letter to Dr Hamburg. It said, “We place the best interests of our patients above all others and avoid conflicts of interest and financial entanglements. The health of our patients is our first concern.”

Citing a study by Amy Wang and colleagues published in the BMJ (2010;340:c1344, doi:10.1136/bmj.c1344), the alliance wrote, “Multiple studies... continue to show how an expert’s industry affiliations will affect his or her position on a drug’s risk profile.”

As other organisations have done, the alliance also included a link to another BMJ article (2008;337:a930, doi:10.1136/bmj.a930) that listed some 100 experts who are without industry ties and urged Dr Hamburg to use these experts. It said, “We endorse this list, which includes some of the most renowned researchers, epidemiologists, and specialists in the world.” The letter named some of the experts, such as Barnett Kramer, newly appointed director of the National Cancer Institute’s division of cancer prevention and current editor of the Journal of the National Cancer Institute, and Bruce Psaty, professor of medicine and epidemiology at the cardiovascular health research unit at the University of Washington, Seattle.

The Project on Government Oversight, an independent watchdog group in Washington, DC, issued a news release on 11 August about the “uproar” over attempts to loosen conflict of interest rules at the FDA. It suggested that the FDA should heed the comments of the BMJ’s editor in chief, Fiona Godlee, in an editorial she wrote about the findings by Wang and colleagues. Dr Godlee said that the paper showed a “significant association” between financial ties to industry and favourable or unfavourable views (doi:10.1136/bmj.c1922).

The FDA issued a statement saying that strict rules on conflicts of interest have “in some cases made it more difficult for FDA to find expert advisers” and that in a few cases advisory committee meetings have been delayed to allow more time to contact and screen experts (BMJ 2011;343:d5070, doi:10.1136/bmj.d5070).

An FDA spokesperson told the BMJ that Congressional approval is required for any changes, but it is not clear at this point whether the FDA will recommend that Congress loosen the conflict of interest rules for advisers.

The spokesperson did not respond to an inquiry by the BMJ asking why the agency has failed to contact members of the list of independent experts sent to it in 2008 and more recently by a number of groups.

Sidney Wolfe, director of the health research group of the consumer watchdog Public Citizen and a member of the list of 100 independent experts, told the BMJ that Congress has failed to contact members of the list shows that “agency complaints about how hard it is to find experts without financial conflicts ring dangerously hollow if FDA has not attempted to use a list provided to it containing contact information for about 100 such people.”

He added, “If the person at the FDA who was sent the list never forwarded it to the Division of Advisory Committee and Consultant Management, this is unacceptable and calls into question the leadership abilities of those running the agency.”

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