

FDA to clarify rules on advisory committee members

Janice Hopkins Tanne *New York*

The US Food and Drug Administration announced last week that it is to develop guidelines to clarify the relationships between members of its advisory committees and pharmaceutical companies. The aim is to make advisory committee processes more effective and to reassure the public about the integrity of the process.

There will be a period for public comment on the proposed new rules.

Some scientists with industry ties are granted waivers to allow them to participate in advisory committees, but the process is unclear.

The advisory committees provide expert advice and recommend whether the agency

should approve new drugs and devices. The FDA usually, but not always, follows the committees' advice.

Some critics say all experts with ties to industry should be excluded. Many academic researchers have no ties to industry, and they could serve on the advisory committees, say critics such as Merrill Goozner of the Center for Science in the Public Interest and Sidney Wolfe of the Public Citizen's health research group.

Scott Gottlieb, the FDA's deputy commissioner for medical and scientific affairs, said, "Some of the most valuable input often comes from people who are active practitioners but are also heavily engaged in clinical

research, and we need to make sure that we continue to have the ability to recruit top clinical trialists." At a forum organised by the Center for Science in the Public Interest he said that the FDA would be more open about the waivers it granted and the relationships of advisory panel members.

The FDA said that it will issue guidelines in the next few months clarifying the conditions under which conflict of interest waivers are granted, specifying when waivers will be disclosed to the public, and specifying when briefing materials used at advisory committee meetings will be made available to the public. The agency said that it would also provide greater public dissemination of advisory schedules through mailings and electronic notifications and would implement a more streamlined approach to the appointment of advisory committee members.

In April, a study indicated that about one quarter of advisory committee members had conflicts of interests (*JAMA* 2006; 295:1921-8, *BMJ* 2006;332:991).

Meanwhile, the Union of Concerned Scientists has released a study showing that almost 18% of 997 scientists employed at the FDA said that they "have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or their conclusions in an FDA scientific document." And 61% knew of instances where officials at the parent agency, the Department of Health and Human Services, or "FDA political appointees have inappropriately injected themselves into FDA determinations or actions."

A Democratic Congressional representative, Maurice Hinchey of New York, proposed legislation to bar anyone with industry ties from serving on an FDA advisory board. □

Two Albanians die from black widow spider bites

Rudina Hoxha *Tirana*

At least two people have died from spider bites in Albania, as health officials investigate claims that one of the more venomous species of black widow spider has gained a foothold in southern Europe.

Several species of black widow, including *Latrodectus tredecimguttatus*, are already

found around the Mediterranean, but Albanian officials believe that rising temperatures have created the perfect conditions for one of the other widow species.

The Albanian media claim that four people have died in the north of the country after black widow bites, although health officials have so far confirmed that only two of the alleged deaths were from black widow bites.

The news has led to hundreds of people visiting emergency wards to have insect bites checked.

Several hundred doses of antidote for the spider bites have been sent from nearby Croatia,

including 100 that will be used to treat the symptoms of people suspected of having been bitten by the spider.

The antidote was ordered after the head of the Albanian ministry of health's clinic of toxicology, Zihni Sulaj, alerted health minister Maksim Cikuli.

Dr Sulaj said, "Every effort is being made to get the antidote out to all the main hospitals, considering the many cases which have been reported lately.

"We have confirmed that 17 patients have been attacked by the black widow spider, and, of these, two have lost their lives, including a 17 year old boy from the village of Bardhaj in Shkodra and a 27 year old woman from Berat. Both the confirmed deaths were within the same week, and both were otherwise healthy."

Dr Sulaj added, "These deaths have caused a considerable amount of concern as there has not been a single death attributed to spider bites for many years, and then we have two in less than a week."

The first recorded spider bites to have caused health problems needing hospital treatment in Albania were reported in 1999. Since then Albanian toxicologists have recorded 136 cases of spider bites reported to officials, of which 98 needed hospital treatment. None resulted in death.

Between 1999 and 2003, all the cases were in an area including Kavaja, Durres, and Myzeqe, near the country's Adriatic coast. Subsequent cases have been more widely spread from north to south. The worst year was 2001, when 70 cases were reported.

Speaking of the country's first recorded deaths from spider bites, Dr Sulaj said, "The main worry is our belief they have been bitten by a black widow spider imported from abroad. It is well documented that... species are able to relocate, and we believe that the bites are from a species new to Albania that has come in from a ship.

"At this stage it is very important to raise public awareness about this situation as well as to establish a network of information and registration in order to better forecast the toxicological situation of the country in the future."

A spokesman at the Albanian Veterinary Research Institute in Tirana said, "There is no doubt the opening up of trade routes has resulted in the import of unwanted insects.

"Before 1996 Albania's international trade was limited due to the restrictive regime but since then the country has opened up to imports from all over the world." □



One of the more venomous species of the black widow spider is apparently now in southern Europe

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