

## AIDS

# German HIV-Blood Scandal Reveals Flaws in the System

"AIDS tests for 15 million Germans," screamed the headline in the *Bild* newspaper on 4 November as Germany was gripped by an HIV-infected blood scandal, and testing centers across the country were overrun by anxious members of the public. The reason? On 25 October, the small Koblenz-based company UB-Plasma was shut down for conducting inadequate HIV tests on the plasma it had sold to hospitals and blood product manufacturers. And the panic was fueled further last week when a second company, Haemoplas of Osterode near Göttingen, was closed for similarly deficient HIV screening. "Now the population thinks that blood equals HIV," says clinical virologist Otto Habermehl of the Free University of Berlin.

Habermehl and other German AIDS experts dismiss as wild exaggeration the predictions that millions are at risk. They estimate that very few cases of HIV infection will have been caused by the two companies' activities. Nevertheless, the extent of the firms' alleged malpractice has shocked the country and the scandal has exposed serious flaws in Germany's system for regulating the distribution of blood and blood-derived products—both in the inspection of labs collecting blood or plasma and in the ability of the distribution system to track individual donations through to their recipients. "To be honest, we needed this case to learn the lesson," says virologist Reinhard Kurth, president of the Paul Ehrlich Institute in Langen, near Frankfurt.

UB-Plasma and Haemoplas collected blood plasma from paid donors and retransfused the blood cells, allowing their donors to give plasma at regular intervals. Both reportedly cut costs by failing to test donations individually for HIV. UB-Plasma apparently tested pooled samples from several donations—and then judged results by eye, rather than using a photometer to detect the yellow coloration that indicates a positive result; Haemoplas is alleged to have tested only about every fifth donation from each individual, and so could not have known immediately if one of its donors became HIV-positive.

*Bild's* estimate that 15 million people may be at risk of infection is based on the fact that both companies sold plasma to manufacturers of products such as clotting factors and immunoglobulins. But Kurth points out that heat inactivation procedures used in the production of these pharmaceuticals should have killed any HIV in the plasma.

That may be reassuring for the millions

of recipients of blood products in Germany and elsewhere in Europe (some of the products made from suspect plasma were exported). But it is little comfort for patients who received transfusions of raw plasma supplied to German hospitals by the two companies. AIDS experts point out, however, that



**Expensive lesson.** Reinhard Kurth says the scandal should prompt reforms.

the number of people infected by this route should be small. Currently, there are about 50,000 HIV-positive people among Germany's 80 million population. Paid donors have been shown in U.S. studies to have viral infection rates about 10 times as high as the general population, but even for a worst case in which the companies' donors were 20 times more likely to be infected by HIV than the average German, only about 1% would be HIV-positive, says virologist Georg Pauli of the National AIDS Center in Berlin. UB-Plasma had around 5000 regular donors, and—even with its inadequate testing procedures—should have identified many of those that became HIV-positive. Which leads Habermehl to predict that the number of people infected by the two companies will be "a handful, not hundreds."

UB-Plasma has already been linked with three confirmed cases of HIV infection, and firm data on the number of tainted donations should soon be available. As *Science* went to press, the public prosecutor in Koblenz was preparing to release the results of HIV tests on some 25,000 back samples of plasma collected by UB-Plasma over the past 2 years.

But this process has highlighted a further problem: Will it be possible to trace all of the

recipients of HIV-infected plasma? Although it is a legal requirement in Germany to be able to track individual donations through the blood distribution system, "I'm relatively sure that we can't find 100% of these patients," says Erika Keller, deputy director of the Red Cross Blood Transfusion Center in Berlin. The problem? Variable standards of record keeping in German hospitals. Officials in the United States, and in some European countries such as Britain, routinely check that such tracking is possible, but transfusion specialists warn that Germany is not alone in being lax in this regard. Even in the Netherlands, generally thought to have one of Europe's better blood distribution systems, Dutch transfusion officials say they fear that some hospitals are not yet able to track donations to individual patients.

Another worrisome question is whether the two companies identified so far are the tip of an iceberg. In Germany, blood- and plasma-collecting labs are regulated by the governments of the 15 German states, or *Länder*. UB-Plasma, from Rheinland-Pfalz, and Haemoplas, from Lower Saxony, were operating in different states, which leads German AIDS experts to suspect that the *Länder* may in general lack the expertise to regulate such centers. "From what I know," says Meinrad Koch, head of the National AIDS Center, "this is a problem."

Under Germany's federal constitution, health minister Horst Seehofer can do little to tighten the oversight of companies like UB-Plasma and Haemoplas, beyond urging the *Länder* to improve their procedures. But to calm public anxiety, he is now arguing that blood and plasma for transfusions should in future be kept in frozen storage for at least 4 months—and used only if the donor then passes a second HIV test.

The proposal, however, has already been dismissed as unworkable by German blood centers. And foreign transfusion experts say that a better plan would be to outlaw the use in transfusions of blood and plasma collected from paid donors. (In the United States, for instance, paid donations are used only in the manufacture of heat-inactivated products.) John Cash, scientific director of the Scottish National Blood Transfusion Service, says he was shocked to learn that paid donations are apparently sent directly to German hospitals. "If confirmed," he says, "this is just not acceptable practice."

The past few weeks' panic may result in more acceptable practices in future, as Seehofer is now working to prepare a new German blood transfusion law. But even if the AIDS experts are correct that only a handful of HIV infections have resulted from the two companies' inadequate screening, it will have been a costly lesson in the deficiencies of the current German system.

—Peter Aldhous