Hairy Problems for New Drug Testing Method

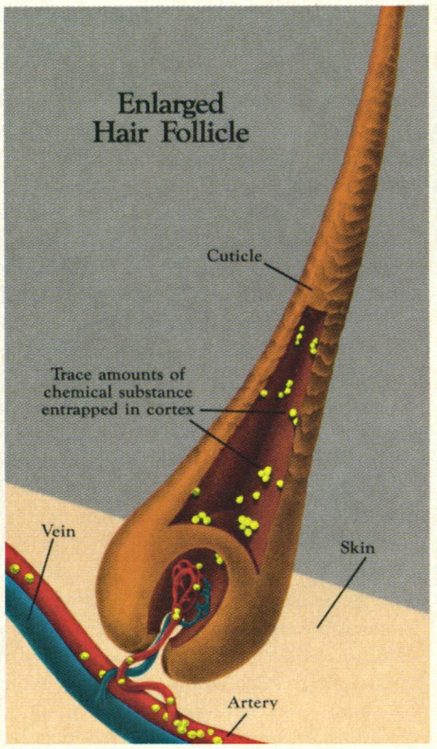
A company set up to test hair for drugs is running into trouble, as government agencies cast doubt on the reliability of its assay

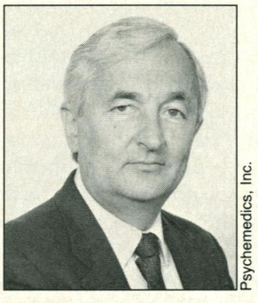
FOUR YEARS AGO PHYSICAL CHEMIST Werner Baumgartner got hold of a lock of hair that once belonged to the poet John Keats. Using a radioimmunoassay Baumgartner and his wife Annette developed in the '70s, he found traces of opiates, presumably from the laudanum the poet used while he was dying of tuberculosis. The test appeared to provide evidence that not only trace elements (such as metals and minerals) but also drugs can become locked in hair strands, yielding a record like rings in a tree.

To Baumgartner, the applications of such a test in a society awash with drugs were obvious. Since he had been languishing, grantless, as director of the radioimmunoassay laboratory at the Veterans' Administration Hospital in Los Angeles, he decided to capitalize on his drug testing technique. In 1987 he founded a company called Psychemedics, which has a growing list of corporate clients, mostly interested in preemployment screening for drug use.

But not everyone around thinks Baumgartner has built a better mousetrap. Considerable skepticism has greeted the relentless proselytizing that he has done with psychiatrist Robert Dupont, former director of the National Institute for Drug Abuse (NIDA), who became the head of Psychemedics' scientific advisory board. Critics say far too little is known about hair testing for the method to be widely accepted. And the critics include heavy hitters—the NIDA and the Food and Drug Administration (FDA).

The FDA can't block hair testing by Psychemedics because the company isn't a government-certified lab and FDA approval would only be required if the company were selling hair analysis kits, which it isn't. In the absence of government proscription, the universe of clients for Psychemedics is expanding rapidly with the boom in workplace drug testing. According to Michael Walsh, until recently acting director of the NIDA division of applied research, the latest full-year data on workplace drug testing with urinalysis show that, in 1988, 5 million drug tests, 80% involving job applicants, were reported by the Bureau of Labor Statistics. Walsh says NIDA-certified labs alone are now analyzing 6 million specimens a year. Toxicologist Kurt Dubowski of the University of Oklahoma, an NIDA lab inspector, thinks the nationwide total may be five times that.





Psychemedics, Inc.

Baumgartner's better mousetrap? *Werner Baumgartner founded a company called Psychemedics to test for drugs in hair. Their assay, which Baumgartner calls RIAH, has been ably promoted (the illustration is from the cover of a company brochure), but critics say the test isn't all it's cracked up to be.*

But urine testing, the commonest method, has drawbacks: it's intrusive, unaesthetic—and vulnerable to cheating. Furthermore, most drugs aren't detectable in urine more than 72 hours after ingestion. By contrast, hair tests are nonintrusive, clean, and difficult to cheat on. What is more, they provide a record of drug use 10 days to 6 months before the test. The test itself involves about 60 hairs, cut in half-inch segments and washed. After washing, the technology is the same as for urine samples: an immunoassay as a preliminary screen, and confirmatory testing for positive samples with gas chromatography and mass spectrometry.

But therein lies the controversy. Although radioimmunoassay has been around since the 1950s, experts say it has not been proved out for hair testing. Some are particularly skeptical of Baumgartner's operation at Psychemedics. No one knows exactly what he does: his particular screen, RIAH, involves a process for dissolving hair he won't describe because he's trying to patent it. Psychemedics has also been criticized for failing to subject results of preemployment screens to confirmatory testing, despite the government's position that all positive drug tests should be confirmed.

But that's just for starters. Psychemedics' real problem is that government agencies say hair testing hasn't yet made the grade. Last November, a report from an NIDA consensus conference on employee drug testing concluded there are "insufficient data" to support hair tests. In May, a conference sponsored by NIDA and the Society of Forensic Toxicologists concluded that use of hair analysis on the job is "premature and cannot be supported by the current information on hair analysis for drugs of abuse." The FDA followed in June with a "compliance policy guide" saying that radioimmunoassay hair testing for drugs of abuse "is unreliable and is not generally recognized by qualified experts as effective."

Government officials and toxicologists say the most serious problem is that external contamination of the hair may lead to false positives. Drug molecules are trapped in the core of hair strands from blood, but, because hair is absorbent, drugs may permeate via sweat as well, some experts say. According to Walsh, it is conceivable that anyone who handles money in Miami (where, it is said, there is cocaine on every dollar bill) and then touches his hair would test positive for cocaine. David A. Kidwell of the Naval Research Laboratory, for example, says his research shows washing does not completely remove contamination and "compounds externally introduced can behave as if they were incorporated during the hair growth."

Another big reservation concerns individual differences. Two people who ingest the same amount of a drug may show quite different concentration in their hair, but there is no research on how sex, race, age, and cosmetic hair treatments may influence absorption. Kidwell has produced one tentative finding on this question: coarse black

hair retains more drug than brown hair. Hence some observers are concerned that the test could discriminate against blacks and other minorities.

Psychemedics isn't short of answers. Baumgartner says washing hair samples removes external contamination—"What goes in easy comes out easy"—whereas "blood-derived stuff is very tightly bound." According to Dupont, contamination is "a totally hokey issue—the only people who are around that stuff are drug abusers."

Nor does Psychemedics see problems from individual differences in hair absorptivity. Says Dupont: "if hair testing finds it's there, it's there." He thinks the government wants to impose a double standard; he notes, for example, that females metabolize alcohol more slowly than men do, but "no one has proposed separate standards" for alcohol testing.

Baumgartner is frustrated by the criticism. "A lot of people say we don't know enough," he says. "You know who doesn't know enough about hair testing? Our critics. They just don't believe what they haven't seen." He sees the government's "campaign" against Psychemedics as symptomatic of an unwillingness to support "creative" science. He complains that the government funds hardly any research on hair testing.

The critics agree that there isn't much funding for hair testing research, but from that point they reach a different conclusion: they say there are too few controlled studies to conclude that hair testing works. Walsh says Baumgartner has been asked for studies to back his assertions, but "every time we ask for data, they [Psychemedics] send another marketing person."

The carping may be affecting Psychemedics, but it has sales offices in four cities and some 80 corporate clients. *Forbes* reports that Psychemedics' fortunes surged after being acquired last year by the A. C. Allen investment group—and the company now has a market value of $42 million.

Indeed, the financial stakes are climbing in the drug testing business. Sales of test kits and reagents reached $200 million in 1989, according to the Boston Biomedical Consulting Group, and that is only a small fraction of the total amount industries are spending to have employees tested. How the field develops will depend on both federal funding and regulation. Psychemedics' future may hinge on the outcome of plans in Congress to extend the guidelines that now apply to federal drug testing programs. The company, fearing a new law might lock out hair testing, has hired a Washington, D.C., firm, says Baumgartner, "to help us not be excluded by the urinalysis lobby."

■ CONSTANCE HOLDEN

Abortion Divides Uniting Germanies

Last week a huge step toward reuniting the two Germanies was taken when the treaty providing the framework for unification was ratified. But many issues still divide the two states, and none is more divisive than those involving human reproduction—both abortion and embryo research. Indeed, until the last minute abortion threatened to hold up ratification of the 1100-page treaty. And related political maneuverings have threatened the freedom of West German scientists to do research on fertility.

The abortion issue hinges on the sharp policy differences between East and West. In East Germany, abortion is free on demand. In West Germany, it is a criminal offense unless a woman can satisfy two reviewers that there are "social or medical reasons" for an abortion. The review often lasts for months, and West German women frequently travel to the Netherlands or Yugoslavia for the procedure. They could now easily go to East Germany—but Chancellor Helmut Kohl had wanted to stop them.

But imposing the West German criminal code on the East would alienate voters there, whereas allowing West German women access to easy abortion in the East would lose Kohl, a Christian Democrat, the support of the right and of fundamentalist churchmen. Kohl's way out of this political bind was to put the problem off. His proposal: for 2 years, former East German states would have liberal abortion, while former West German states would preserve the punitive law. After that, a new Bundestag would decide again for the whole country.

To prevent abortion trips eastward, Kohl had originally proposed that prosecutors would use the woman's home address as the basis for legal action. But using an address rather than a specific act as the basis for punishment turns established legal procedure on its head—and aroused such violent emotions that it threatened the unification treaty.

In the end a compromise was reached. Because Kohl's proposal needed a two-thirds majority to get through the Bundestag, he needed the support of the Social Democrats. In exchange for their support, the Social Democrats insisted no West German women be prosecuted for getting abortions in the East, and that was the form in which the proposal was accepted.

The Social Democrats are also intent on using their political muscle to gain concessions on embryo research. About a year ago a draft embryo protection bill was introduced into the Bundestag. The bill would make a grab bag of activities illegal: cloning humans, crossbreeding humans and other species, surrogate motherhood, egg donation, and experiments on germ line cells or embryos.

Ironically, much of the political furor has centered on a practice that is not rendered illegal by the bill: artificial insemination. As the draft stands, a woman could use sperm from an anonymous donor for artificial insemination. But the Social Democrats want to limit artificial insemination to sperm from a woman's partner. And the government of Bavaria wants to limit insemination to married couples.

While the politicians haggle, reproductive research in Germany has stopped, partly because top scientists in the field voluntarily halted their research 2 years ago so as not to interfere with the legislative process. "De facto, we have a moratorium [on reproductive research]," said Eberhard Nieschlag, who heads the Max Planck clinical research group for reproductive medicine at the University of Muünster and was one of those who stopped their research.

Once the five East German states join the legislative process on 3 October, things are bound to get even more complicated. The East Germans are not likely to sympathize with efforts to outlaw embryo research, and it seems probable the Social Democrats will try to push through a measure before then. Wolf-Michael Catenhusen, the Social Democratic chairman of the Bundestag Committee on Research and Technology, has said that he is determined to legislate against germ line therapy and embryo experiments in the current session of parliament, ending on 2 December.

Meanwhile, even before the compromise was reached on abortion in the treaty, some local authorities were taking matters into their own hands. In Berlin where the East-West differences in abortion policy are most keenly felt, pragmatism rules: East Berlin's Magistrat and West Berlin's Senat—both controlled by Social Democrats—have been applying the liberal East Berlin law citywide.

■ RICHARD SIETMANN

Richard Sietmann is a free-lance science writer based in Berlin.