

edited by CONSTANCE HOLDEN

Biotech Drug for Hemophiliacs

The spectre of AIDS has terrified many a citizen but perhaps no group more than hemophiliacs, even though since 1987 the threat of a tainted transfusion has virtually disappeared thanks to improved methods for treating blood products. Over the course of a year, a severe hemophiliac might be exposed to plasma from more than 100,000 people, says Alan Brownstein, director of the National Hemophilia Foundation in New York City. "If you have blood products from thousands of human beings, that's tantamount to having sex with them," he says.

The advanced testing methods have done much to guarantee hemophiliacs safe blood, but until now there has remained a theoretical chance of getting AIDS, hepatitis, and other virus-caused diseases via transfusion—a worry that has caused many nonhemophiliacs to bank their own blood. But last month, the Food and Drug Administration (FDA) approved a recombinant version of factor VIII, the blood protein used to treat the most common form of hemophilia. The new product, recombinant antihemophilic factor (Recombinate), holds a number of advantages over plasma-derived preparations, and safety is only one. Because it takes vast quantities of plasma to yield a dose of natural factor VIII, the stuff has been used to treat hemophiliacs only during a bleeding episode. But the new drug, says Brownstein, can be used preventively, thereby improving the quality of life for hemophiliacs.

Recombinate is the fruit of a 10-year research effort at Genetics Institute of Cambridge, Massachusetts. But Genetics may not end up reaping all the rewards: The company, along with Baxter Healthcare Corp., Scripps Research Institute, and Rhône-Poulenc Rorer Inc., is embroiled in a patent dispute over rights to the process of purifying Recombinate. And another version of recombinant factor VIII, from Miles Inc., awaits FDA approval.



Plains sunflower. *Helianthus petiolaris*, recently rediscovered in New York collection.

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Curatorial assistant Veronica Masson was assigned the task of examining the fragile specimens. "One day in June [1992]," she recalls, "I glanced down at the bottom of a sheet I was filing, and there were the words 'Custer's Expedition, 1874.' I could not believe my eyes at first, but I quickly searched through the Wabash material, and found that we have 42 plants collected on the expedition."

Carnegie's Rx for Environment Policy

Just as the defense and national security establishments are having to abandon their cold war orientation, so must U.S. environmental policy move out of the '70s and deal with the global realities of the next century, according to a report* from the Carnegie Commission on Science,

**Environmental Research and Development: Strengthening the Infrastructure.*

Custer's Last Botanical Stand

In 1874, 1000 soldiers, led by Lieutenant Colonel George Armstrong Custer, made the first expedition by white men into the interior of the Black Hills of South Dakota. The party included a botanist, A. B. Donaldson, and all survived to tell of the expedition because Custer's tragic end was still 2 years into the future. Now, part of Donaldson's collection of

plants from his journey has been rediscovered at the New York Botanical Garden (NYBG). "Everyone remembers Custer for his last foray into

Sioux territory, in 1876," says Patricia Holmgren, director of the NYBG Herbarium, "but few people know about the 1874 trip, or that botanists often accompanied military expeditions in those days."

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Technology, and Government. That calls for a major restructuring of the federal effort, says a task force cochaired by Robert Fri, president of Resources for the Future, and Carnegie commissioner Guyford Stever, former head of the National Science Foundation.

Some suggestions:

- Strengthen environmental leadership within the White House by merging the Council on Environmental Quality with the (little-known) White House

Office of Environmental Quality (OEQ). The director of the expanded OEQ would serve as "assistant to the president for the environment."

- Establish an Institute for Environmental Assessment to sponsor policy research, and an Environmental Research and Monitoring Initiative to set R&D goals as part of a broader National Environmental Strategy.
- Combine the National Oceanic and Atmospheric Administration (now in the Commerce Department) and the U.S. Geological Survey (now in Interior) in a new U.S. Environmental Monitoring Agency.

A similar reappraisal of the nation's environmental policy is currently under way at the National Academy of Sciences (NAS). At a 15 December press conference announcing the Carnegie study, Stever explained that the Carnegie effort is mainly concerned with "organization and process," while NAS is going "deeper into the substantive science."

Are the Clinton people listening? No one can say. But, said Stever of his group's effort, "if ever the time has come politically, this is it."

FDA Okays Surrogate Markers

The Food and Drug Administration (FDA) is about to revolutionize its approval process for some drugs, potentially lopping off years at one stroke. Music to the ears of the pharmaceutical industry (and patient advocacy groups) who lobbied hard for such changes? Perhaps not. The new rule, published in the 11 December *Federal Register*, contains dozens of restrictions that may create problems of a new kind.

The speedier process is based on the use of "surrogate markers"—such as CD4 cells in AIDS—of a disease's progression. The idea is that if a drug has shown signs of efficacy, holding off approval until clinical trials yield conclusive results could cost lives (*Science*, 16 October 1992, p. 388). So FDA will accept surrogate marker data

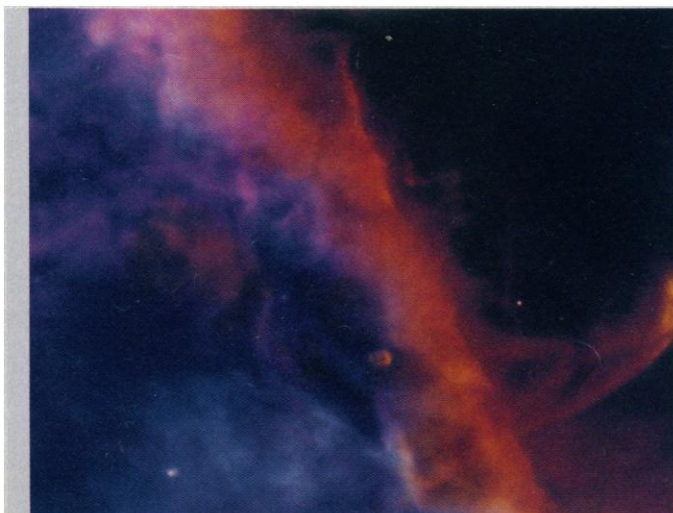
in lieu of clinical results for "serious or life-threatening" diseases.

Overall, drug companies favor the scheme, says Thomas Copmann of the Pharmaceutical Manufacturers Association. But when industry first lobbied for a surrogate marker-based approval track, what they sought was an explicit list of acceptable surrogates. As the rules came out, however, a drug company has to persuade FDA that the chosen marker is linked to clinical outcome. After having done that, a company still has to conduct trials to prove both that the marker is an appropriate one and that the drug is effective. And during that time the company will be, in effect, on probation. It has to submit all drug promotional material to FDA for review, sell the drug only to physicians with special training, and can lose approval for a variety of reasons.

All that could discourage companies from taking the accelerated route. Yet critics such as Sidney Wolfe of the Public Citizen Health Research Group still worry that drug companies could abuse the procedure by failing to do careful clinical trials once they get a marker approved. And, he warns, if clinical trials don't pan out, it might be very hard to ban the unapproved drug—or, as FDA commissioner David Kessler put it, "get the genie back in the bottle"—if there is an activist community clamoring for it.

EPA Prods Chip Makers to Clean Up

The U.S. semiconductor industry may have reclaimed some of the ground it lost in the international market in the 1980s, but environmentalists still think it has a long way to go to improve its image at home. The main complaint: Chip manufacturing sites have become so polluted that many have been designated as Superfund toxic waste sites. Now the Environmental Protection Agency (EPA) is trying to get things moving with a plan for an organization that will define the industry's cleanup priorities and



Another Hubble surprise. C. Robert O'Dell of Rice University in Houston has discovered big, dusty disks in a star-forming region in the Orion Nebula, which, he says, supply a "missing link" in scientists' understanding of how planets form. Labeled protoplanetary disks (or "proplyds"), their presence had been suggested by infrared studies, but this is the first visual identification, says NASA. Scientists now believe that most if not all newborn stars are surrounded by disks of the basic material (gas and dust) of planets for brief periods (tens of thousands of years). Over subsequent millions of years, the dust grains collide to form kilometer-sized bodies that in turn collide to make planets. The abundance of the disks, which—unlike most big Hubble findings to date—are only 1500 light-years away, suggests that many planetary systems remain to be discovered. The findings "confirm more than a century of speculation, conjecture, and theory about the genesis of the solar system," claims NASA. A proplyd can be seen in the lower middle of this image, which is almost as clear as it would be if Hubble didn't have a flawed main mirror, thanks to illumination from bright stars in the vicinity. At lower right is a hyper-sonic shock wave of material moving out from newly formed stars.

help pay for remediation.

The semiconductor mess stems from three decades of poor solvent handling practices, officials say. Studies in the mid-1980s at 11 Silicon Valley firms revealed that several solvents used to degrease, strip, and dry chips and electronic boards—including vinyl chloride, trichloroethane, liquid freon, xylene, and toluene—had leaked from underground waste tanks and in some cases had contaminated local groundwater. Since 1988, electronics firms—including big names such as National Semiconductor and Intel—have spent \$300 million on cleanup, says Gary Burke, president of the Santa Clara County Manufacturing Group, which represents 110 high-tech companies. But only one site—a Fairchild-owned plant in San Jose—has been

remediated to EPA's satisfaction.

That has prompted EPA's Technology Innovation Office (TIO) to lay the groundwork for the Remediation Technologies Development Forum, to bring companies together with representatives from states, universities, and federal agencies, so that those who need new remediation technologies can find them. "We have started a dialogue with American companies who want to collaborate to share the risks of technology development," says TIO director Walter Kovalick Jr.

Nice Guys Can Thank Their Genes

Research on heritability has lately suggested that genes and environment are about equally responsible for most personality traits. But psychologist Jim Stevenson of the

Institute of Child Health in London has found that when it comes to our "nasty" behavioral traits, genes seem to have less influence than they do over "nice" ones.

Stevenson, who presented his results at the annual London meeting of the British Psychological Society in mid-December, administered questionnaires on children's behavior to the parents of 160 pairs of identical twins and 213 pairs of fraternal twins aged 5 to 16. Each child was rated for sociability (the extent to which one seeks out company), "prosocial" behavior (the tendency to empathize with and help others), and antisocial behavior (destructive acts directed against people or objects). Stevenson found that genetic factors accounted for more than half the variance in scores rating prosocial behavior and sociability. But for antisocial behavior, genes could explain only about 20% of the variance.

What's more, although the most powerful aspect of nongenetic influences on behavior has usually been found to be the "non-shared" environment—experiences that are unique to an individual (*Science*, 10 July 1992, p. 165)—Stevenson found that most of the nongenetic influences on antisocial behavior could be attributed to the "shared" family environment. "Being nasty...is something you seem to learn with your brothers and sisters," he says.

Psychologist David Rowe of the University of Arizona adds that while parents may create a major part of the shared environment, other studies have suggested that when it comes to antisocial behavior, the influence exerted by peers ("shared" friends) is far more powerful than that by parents.

Stevenson says the jury is still out over the relative importance of bad parenting versus falling in with a bad crowd. But he notes that the argument isn't just academic, as a better understanding of the causes of antisocial behavior may lead to more effective therapy for childhood conduct disorders—which are notoriously resistant to treatment.