would not be feasible or desirable for insurance to usurp the volunteer element. Blue Cross-Blue Shield is attempting to sort out some of the issues in a number of experimental arrangements it has set up with individual providers of hospice services. But as a Blue Cross official says, "hospices can't rely on medical payments as the sole funding source."

Project Sleep

In light of the "explosion" of new knowledge about sleep, insomnia, and sleeping pills, the government is launching a 3-year educational campaign to reduce the use of sleeping pills.

Project Sleep is being conducted by the Alcohol, Drug Abuse, and Mental Health Administration in cooperation with the Food and Drug Administration. According to Charles Krauthammer, psychiatrist at ADAMHA, the early stages of the campaign will be aimed at health professionals. "Half the medical schools we surveyed didn't have a single course on sleep disorders or sleep pharmacology," he says. Working with various professional societies and insurance and drug companies, the government plans eventually to blanket the nation with public-service messages.

According to HEW, 50 million Americans have trouble sleeping in any given year and 10 million of these are unhappy enough about it to consult a doctor. Of these, 5 million get sleeping-pill prescriptions—33 million of them a year. There are three classes of sleeping pills: flurazepam, barbiturates (the kind it is easiest to commit suicide with), and nonbenzodiazepines. Tranquilizers, antidepressants, and antihistamines are also dispensed as sleep aids.

According to Krauthammer, part of Project Sleep will be an effort to stimulate research in areas where the answers are thin; there will also be a new emphasis on exploring alternatives to medication—that is, relaxation therapies and "stimulus control," in which the insomniac develops various routines and rituals associated with sleep.

Most sleep disorders are thought to be the result of other problems, such as pain or anxiety. However, Krauthammer says about 15 percent of the 5 million regular pill-takers are hard-core chronic insomniacs who suffer no underlying disorder and for whom sleeplessness is the primary problem.

Flurry over Venom

The idea of using snake venom as a therapeutic drug is one that holds great fascination for the public and the news media. And when the use of venom is proposed to treat diseases for which there is no known cure, it sounds like a prescription for another Laetrile-like situation.

On 16 December the television program "60 Minutes" aired a segment on a Florida doctor's use of a serum made from the venom of cobras and kraits to treat arthritis and multiple sclerosis. The publicity has brought to a head pressure on the Food and Drug Administration to sponsor clinical trials for the drug, labeled PROven, even though there is no hard evidence that it is efficacious and no definite scientific reason to suppose it should be.

The doctor in question is Ben Sheppard, a 77-year-old pediatrician who runs a private clinic in Miami. For the past couple of years he has been working with snake handler William Haast, who runs the Miami Serpentarium. Haast has been supplying venom, which Sheppard claims to have used to treat some 1500 patients, reportedly with positive lasting effects in 20 percent of them.

Harry Meyer, director of FDA's Bureau of Biologics, says the rush of publicity surrounding Sheppard and Haast's operation began with a story in the magazine put out by Delta Airlines early this year. The FDA received many inquiries in ensuing months and Meyer decided to hold a workshop to submit available knowledge to scientific evaluation. The upshot of the workshop according to Meyer is that there is "not much to go on," although there is "some dialog going on about whether it would be worthwhile to do a clinical trial."

Byron Waksman, research director of the National Multiple Sclerosis Society, says that MS, an inflammatory disease of the central nervous system, follows such an erratic path, with unpredictable attacks and remissions, that it is impossible to attribute improvements to any therapy without double-blind studies. He says that only two substances—ACTH and adrenocorticosteroids—have offered symptomatic relief in MS. "Ordinarily you wouldn't have a trial in absence of either a scientific rationale or evidence of actual cures," he says. The MS society supports research on 11 potential therapies, ranging from enzyme inhibitors to hyperbaric oxygen, but "venom wouldn't make the list as far as I'm concerned." Nonetheless, the MS society is looking for reputable investigators willing to work with venom.

Earlier this year another venom preparation, "modified neurotoxin," gave negative results in trials with patients suffering from amyotrophic lateral sclerosis, or Lou Gehrig's disease. Another Florida doctor, Murray Sanders of the Sanders Medical Research Foundation in Boca Raton, claims the potion has "partial efficacy" with sufferers from ALS, an incurable nervous disease that causes paralysis and death. However, two double-blind studies, at Harvard and Baylor universities, showed that it worked no better than placebos. Sanders is currently treating 200 patients with the drug but has been barred by the FDA from taking any new ones.

Snake venoms are broadly classified as hemotoxins and neurotoxins. They also have shown evidence of an ability to block the formation of immune responses, which may be relevant to theories about their effects on arthritis and MS, both of which may be autoimmune diseases. As neurotoxins, it has been hypothesized that they block neurotransmitters by occupying receptor sites, and thus could have various effects such as inhibiting pain or preventing the spread of viruses.

Although venoms offer a rich field for research, clinical applications are slow in coming. Several years ago the FDA banned two venom-based drugs, Cobroxin and Nyloxin, manufactured by the Baltimore firm of Hynson, Westcott and Dunning, as being ineffective for pain, arthritis, and a variety of other conditions for which they were advertised. In Europe, a venom-based drug has been in use for some years as an anticoagulant, but no such drugs are approved for any use in the United States.

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