

recommending the clinical use of Laetrile. . . . The experimental results reported by Dr. Burk, while of interest, have no implications in respect to the advantages, disadvantages or desirability of the clinical use of Laetrile."

In addition to his toxicity studies, Dr. Burk reports work showing that Laetrile, which is a combination of cyanide, benzaldehyde and sugar, selectively kills cancer cells of virtually all types, possibly because those cells lack an unspecified enzyme that protects normal cells from the effects of cyanide. Laetrile itself, he says, is broken down in the body by the enzyme betaglucoisidase.

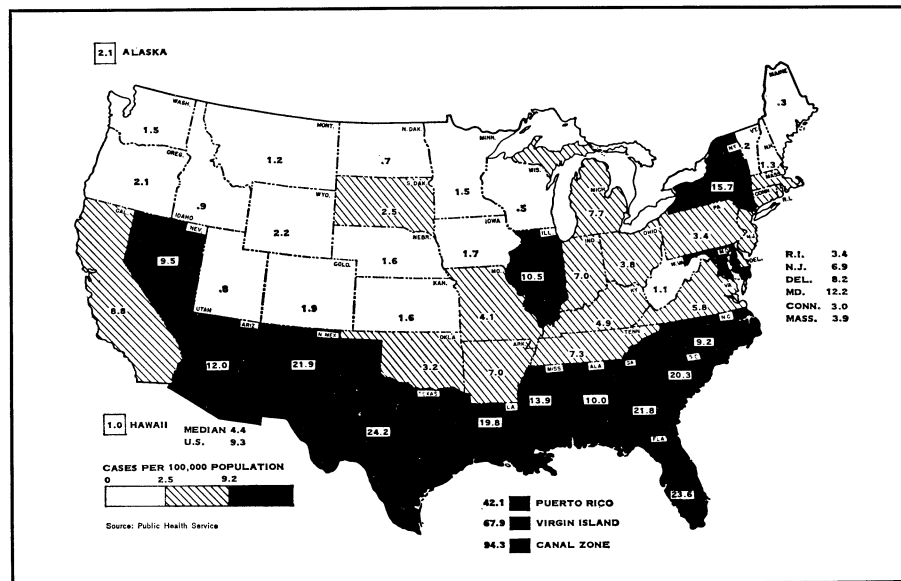
According to Dr. Burk, the existence of enzymatic differences between normal and cancerous cells is theory, not a phenomenon he puts forward as fact. Charging the FDA with being unfair in its handling of the Laetrile application, he cites the fact that the agency declared IND 6734 deficient in part because the theory of mechanism is inadequately documented. Conceding that mechanism is not proved, Dr. Burk rightly points out that FDA frequently approves drugs whose mechanism of action is not precisely known. Aspirin, penicillin and tranquilizers are among compounds approved without prior specific knowledge of their mechanism of action.

While the arguments are being weighed by the FDA, Laetrile is, at present, in limbo. Its use now is illegal, but until the agency brings forth a verdict on the supplementary data submitted in May, its proponents continue to hope for approval. Says Dr. Henry Simmons, director of FDA's Bureau of Drugs, "In this country Laetrile has not had its day in court and I intend to see that it gets it if the evidence justifies it. That is the law."

By way of explanation of FDA's initial granting of an IND number, Dr. Simmons says that the application first submitted by the McNaughton Foundation looked acceptable; that is, it followed the prescribed form and appeared to contain data covering the essential scientific questions and protocols for human trials. On second glance, FDA changed its mind.

In the past, when a scientist received an IND number for his application for a new drug study, he was automatically free to begin work. Partly as a result of the Laetrile fiasco, FDA is altering that policy and a new regulation has been promulgated. In the future, assignment of an IND number will carry with it a 30-day hold, giving the FDA time to scrutinize applications for clear deficiencies before work begins. After that time, when the agency undertakes a serious and careful review of the application, INDs can still be terminated if defects are uncovered. □

In epidemic proportions



The incidence of syphilis in the United States is rising dramatically.

The advent of penicillin in the 1940's lulled many authorities into a complacent state regarding venereal disease. For the first time, syphilis and gonorrhea could be cured; gonorrhea, in some circles, even acquired a reputation for being no worse than a bad cold. Clearly, this is untrue. Both syphilis and gonorrhea, transmitted by sexual contact, have serious, even fatal effects. And the incidence of both of these infectious diseases is on the rise.

According to a study released by the American Social Health Association, the incidence of syphilis in the United States in June of this year was 27.3 percent higher than it was in June 1969. In a year's time, the syphilis rate in New Jersey rose 55.3 percent; in Georgia it was up 28.5 percent; in California, up 20.5 percent, giving those three states the dubious distinction of having the highest increase-rates in the country. Nationwide, the incidence of reported cases of gonorrhea has jumped 15 percent in the last year. As with syphilis, epidemiologists agree that the actual incidence of venereal disease is even higher because many cases go either undetected or unreported by practicing physicians.

According to Dr. James McKenzie-Pollock, venereal disease director of the ASHA, "During the last months of the fiscal year, the increase of syphilis has been so dramatic that national emergency action is needed." Such action, he declares, could be provided if Congress passes legislation slated to go up for a vote within the next few weeks. Sponsored by Rep. Paul Rogers (D-Fla.), it would give cities and states funds to be used specifically for com-

municable disease programs—\$75 million in fiscal 1971 and \$90 million in fiscal 1972. Chances of passage are estimated to be 50-50.

In its VD report, the ASHA, with the backing of the American Public Health Association and the American Venereal Disease Association, called on the Secretary of the Department of Health, Education and Welfare to appoint a group to develop a national program for the control of venereal disease, emphasizing prevention through education and improved efforts at diagnosis and treatment.

Though transmitted in the same way, syphilis and gonorrhea are distinct diseases. Syphilis, caused by a spiral-shaped organism, *Treponema pallidum*, first manifests itself, between 10 days and 10 weeks after infection, by sores which disappear slowly even if the patient is untreated. The organism, however, remains in the body, causing, after 10 years or more, damage to blood vessels, the brain, heart, eyes and other organs.

Gonorrhea's symptoms include burning at urination and a discharge of pus, usually apparent in males but sometimes undetected in females. Ultimately the infection can lead to sterility, arthritis and heart disease, among other disorders. Both syphilis and gonorrhea can be passed from a mother to her unborn child.

The ever-increasing mobility of the population and relaxed sexual mores are cited by public health officials as the causes of the epidemic of venereal diseases. These same factors, Dr. McKenzie-Pollock says make control extremely difficult. □