OTA Peers into Cancer Therapy Fog

The most controversial project ever undertaken by Congress's think tank slips quietly into the mail this week

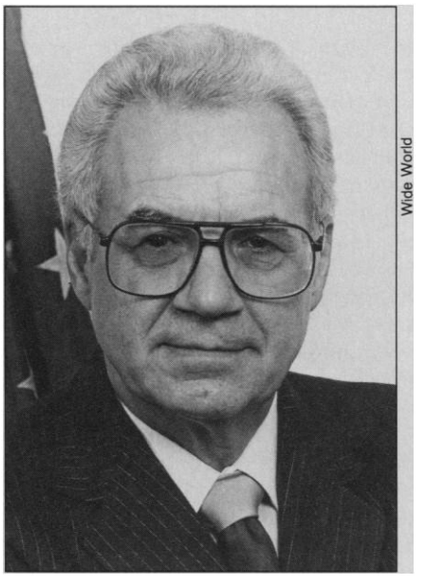
A 4-YEAR BATTLE over unapproved cancer therapies comes to an end this week as the U.S. Office of Technology Assessment (OTA) mails out its 300-page, $500,000 review of the topic.* The report has been a lightning rod for criticism: "Alternative" therapists seized on it at first as a means to gain respect, then later blasted the final product as biased against them. But the cancer research establishment has been critical, too, claiming that OTA is giving too much credence to questionable therapies.

Written for Congress, the report delves into the murky world of coffee enemas, laetrile, and other remedies that fall outside accepted medical practice. In some cases, these are available because they have been approved for some other use or are considered so benign that they are not restricted by the Food and Drug Administration. But in other cases, practitioners had to move outside the United States to avoid government regulations.

The problem with evaluating these therapies, according to OTA, is that no clinical trials have been done that would give a statistically valid thumbs-up or thumbs-down decision on any of them. Even using less rigorous methods of evaluating alternative therapies, the OTA report concludes that, "for none of the treatments reviewed in this report did the evidence support a finding of obvious, dramatic benefit."

Despite its skepticism, OTA did find that a few unconventional techniques—such as certain psychological and dietary regimens—may deserve additional study. It also levels a few criticisms at the orthodox cancer world, noting that radiation and chemotherapy may be overused or applied in cases where there is no evidence that they do much good. But OTA comes down firmly in support of "formal clinical trials"—meaning double-blind, randomized, peer-reviewed tests—to evaluate new ideas before they are recommended to the public.

This is the most controversial study OTA has ever produced—"by a long shot," says Roger Herdman, OTA's assistant director for health and life sciences. Herdman insists the report's authors did everything possible to sift out the best information and present it fairly. But there was trouble "right at the start," Herdman recalls, when proponents of unorthodox methods decided the study was going to be too critical. They denounced project director Hellen Gelband as biased, tried to get her removed, and lobbied to block publication. They are still battling. Alternative health journals printed tear-out protest forms for readers to mail to Congress, and legislators received thousands of them. "We have received letters or phone calls from about half the members of Congress," Gelband says.



Instigator. *Former U.S. congressman Guy Molinari sought OTA report.*

Meanwhile, OTA started getting flak from the other side—hardened "quack-busters" and members of the cancer establishment—who thought OTA was being soft on fraud. Officials of the National Cancer Institute and members of the National Cancer Advisory Board, for example, spoke out against the report.

The record of protests and responses is laid out in an appendix to the report and in a public memo from Gelband to OTA director John Gibbons. They reveal that well-placed promoters of one particular therapy had a lot to do with getting the OTA study started and, later on, they were involved in attempts to kill it.

The central characters in this drama are Lawrence Burton, a doctor in the Bahamas who treats cancer patients with a regimen of his own invention (called Immuno-Augmentative Therapy or IAT) and Guy Molinari, until 1990 a Republican congressman from New York.

It was Molinari who got the ball rolling in 1986 when he held an unofficial hearing to air complaints from Burton and his patients. Burton's clinic had been shut down by Bahamian health authorities after a sample of the serum he injects into patients was found to be contaminated with both the AIDS virus and a hepatitis virus.

Patients claimed that the U.S. medical establishment was discriminating against Burton, and they appealed to Molinari. He in turn persuaded 41 other members of Congress to petition for an OTA review of Burton's IAT therapy. Representative John Dingell (D–MI), as chairman of a full committee, commissioned the study, but converted it to a broad review of all unconventional cancer therapies. With this mandate, OTA set out to cover a wide spectrum, ranging from psychotherapy to special diets and herbal medicines, and the nonlicensed use of drugs and biologic compounds.

Burton's IAT therapy comes in for some strong criticism. In early research, Burton claimed to have discovered natural substances that inhibit tumor formation in fruit flies and mice. He moved on to human experimentation and soon began treating patients with a serum derived from pooled blood.

"There is no record of Burton's carrying out biochemical analyses of these materials to identify their components," the OTA report states, "nor has independent analysis of IAT materials been reported from samples provided directly by Burton." In fact, Burton has made little or no effort to publish any analysis of his work in peer-reviewed scientific journals since the early 1970s, according to OTA and others. Yet he now operates three clinics—on Grand Bahama Island, in Mexico, and in West Germany.

Although representatives from OTA and the Food and Drug Administration met twice with Burton in the Bahamas to negotiate a clinical trial protocol, they were unable to reach agreement. Burton and his supporters say they could not accept unfavorable conditions that were designed to produce negative results, and the OTA staff says they couldn't devise any valid approach that would satisfy Burton.

Thus, despite all the efforts to resolve the issue, the kindest adjective one can use to describe IAT is "unproved," an adjective that found frequent use throughout the OTA report. ■ ELIOT MARSHALL

**Unconventional Cancer Treatments* (U.S. Government Printing Office, Washington D.C., 1990).