tiveness and cost-effectiveness of chemotherapy for metastatic colon, gastric, and pancreatic cancers, and second- or third-line therapy for breast cancer. Those are all things that cancer doctors frequently do, and in the aggregate, they’re big-ticket items. But they’re completely unevaluated.”

Another major issue is the generalizability of clinical trial results to the larger community. Patients treated outside trials tend to be older and have more comorbidity than those in trials, and the state-of-the-art care given to trial participants is not matched everywhere. Costs, too, may differ in trials versus community practice.

Different Populations

“There is very little work on how the results found in clinical trials generalize once they get into community practice,” Brown said.

Smith agreed. “To my knowledge, there are no data showing that any adjuvant treatment can duplicate its efficacy when applied to a much more heterogeneous, older population with competing causes of death,” he said. “If the average age of patients in clinical trials is 67, but the average age of patients in the community is 74, you’re not going to have the same bang for the buck with adjuvant chemotherapy in the older age group.”

Smith suggested several ways to approach the problem, including making trials more representative of the general patient population.

“I think the CCOP [NCI’s Community Clinical Oncology Program] has helped with that, and the North Central Oncology Group has tried very hard to get real people with real disease on trials,” he said. “Another thing we can do — which we have not done — is community effectiveness studies: through insurers or Medicare, identify patients treated in the community, and ask [oncologists] if we can track their data to see what the incidence of benefits and side effects really is, and what the cost is.”

Bad Rap

Smith believes oncologists have taken undeserved hits in the medical community “because we make people sick, make them throw up and lose their hair, and many of our patients die anyway.”

But in reality, he said, oncology’s cost-effectiveness compares reasonably well, and in some cases favorably, with such ballyhooed medical advances as hypertension medications or thrombolytic therapy for heart attacks. These treatments are not without side effects, and in terms of survival benefit they have modest success rates, comparable to those encountered in oncology, he said.

Researchers agreed that the burgeoning field of cost-effectiveness research is spurring efforts to nail down better efficacy data, which will help patients make informed decisions about their own treatment. But many practitioners resist the notion of practicing medicine by algorithm and simulation model.

“There’s a real reluctance among doctors in general to quantify their results,” Smith said. “They think it takes away from the art of medicine and makes it a computer-jock science. That’s not what we’re trying to do at all . . . we’re trying to figure out what are the important concerns for a patient, and how do you measure them.”

— Tom Reynolds

Farming Tobacco Overseas: International Trade Of U.S. Tobacco

As smokers snuff out their cigarettes in growing numbers in developed countries, large multinational tobacco companies — many based in the United States — are aggressively peddling their wares in the newly opened and potentially hugely profitable markets of less developed countries in Asia and Eastern Europe.

Although the Clinton Administration hopes to make it more difficult for the multinationals to pitch their glitzy advertising campaigns in these countries, tobacco control activists say that such ads, combined with a dearth of legislation directed at tobacco control, continue to impede efforts to slow the rate of tobacco use in these countries.

Open Markets

Until recently, cigarettes in Asia and Eastern Europe were produced primarily by state-run monopolies. Pressured by the office of the United States Trade Representative (USTR), Asian countries began opening their markets to the international tobacco trade in 1985.

When the Berlin Wall fell, the multinational tobacco corporations were among the first to rush in and exploit the new Eastern European markets, said Ronald Davis, M.D., chief medical officer with the Michigan Department of Public Health, Lansing, and former head of the Office on Smoking and Health.

When the markets opened up, tobacco companies went in with advertisements “claiming that the products
are safe, and that the users are sexy and sophisticated,” Davis said. In contrast, “the monopolies usually had very drab marketing campaigns.”

In addition to print and broadcast advertising, multinational companies frequently advertise indirectly, sponsoring rock concerts, sporting events, and other social and cultural events that are successful, said Davis, in part because they capitalize on the American image. “In Japan, you see heavy TV advertising of Virginia Slims — using Western models. Why is this? It must be that people aspire to be like Americans.”

According to Donald R. Shopland, coordinator of the National Cancer Institute’s Smoking and Tobacco Control Program, anti-tobacco activists’ problems in overcoming these highly successful advertising campaigns are exacerbated by the fact that in many developing nations, there are no laws to control the use or promotion of tobacco products. “In a lot of places, they don’t even have minimal legislation,” he said.

Circumvent Laws

For example, in Poland there is no legal age of purchase requirement, and it is not unusual to see children as young as 10 years old smoking cigarettes, he said. In countries with legislation that bans direct advertising, tobacco companies often find ways to circumvent the laws. For instance, in China, which will not open its markets to American cigarettes until 1995, the display or mention of a cigarette is prohibited by law. However, the mention of a cigarette brand name is not, and American tobacco companies are promoting their brand names there with large advertisements on the sides of telephone booths, kiosks, and storefronts.

In some countries, including Russia, existing laws are simply ignored. The Russian Parliament has banned cigarette advertising; however, Gregory Connolly, D.M.D., director of the Massachusetts Tobacco Control Program, said that due to the political turmoil in the former Soviet Union, the government has had little opportunity to enforce the law. On Moscow MTV, he said, “cigarette ads run all the time.”

Heavy tobacco promotions overseas continue despite a shift in U.S. trade policy aimed at making it easier for other countries to resist advertising by U.S. tobacco companies. Anti-smoking forces won a major battle in 1990 involving Thailand’s ban on cigarette imports and advertising. American tobacco companies challenged the ban. The case was investigated by the USTR, who turned part of it over to the General Agreement on Tariffs and Trade.

GATT ruled that Thailand had to permit cigarette imports, but could prohibit advertising, mark the cigarette packages with strong warning labels, and require ingredient disclosures, as long as these laws applied equally to foreign and domestic tobacco products.

The Thailand case has important implications, said Shopland. “The GATT agreement will hold true for other countries as well in terms of how aggressively U.S. tobacco can be marketed,” he said. “What the GATT agreement said was that the tobacco companies must abide by the laws of the country they’re marketing tobacco in.”

Policy Shift

Backed by the Clinton Administration, the USTR has continued its shift in trade policy.

In July 1993, Secretary of Health and Human Services Donna Shalala, Ph.D., and U.S. trade representative Mickey Kantor formed an interagency task force to review export policy with respect to health considerations. The task force, which met for the first time in December 1993, will review trade policy, but its decisions will not abrogate existing agreements, said Gregory Schneider of the USTR.

“The USTR’s mandate is to expand the U.S. market and increase exports,” explained Schneider, “and traditionally tobacco has been viewed as ‘just another export.’ However, it’s certainly no mystery that this administration looks at tobacco somewhat differently than other administrations have, and Secretary Shalala and Ambassador Kantor are concerned about viewing tobacco as an innocuous export.”

Schneider explained the stance of the USTR: “If a country has a scientifically based judgment or health concern about tobacco, and they choose to ban advertising, I don’t think the U.S. Administration is going to object. It’s fine with us, as long as they ban advertising for their own products, as well.”

— Kate Nagy