With the regulatory changes, FDA can require drug companies to conduct additional clinical trials to provide prescribing information specifically for children. In exchange, the drug company would receive an additional 6 months of marketing exclusivity.

For drugs that are already off-patent, there is little incentive for drug companies to invest in additional pediatric research. Into that gap steps the National Institute of Child Health and Human Development, which will use a grant from the American Medical Association for pediatric pharmacology research. According to Alexander, only five of the 80 drugs used most frequently in newborns and infants have pediatric use instructions. NICHD's research will focus on drugs that are off-patent and frequently prescribed without specific pediatric labeling.

**Rules for Diagnostic Drugs**

Under the new regulations, diagnostic radiopharmaceuticals will have more specific safety and effectiveness requirements for FDA marketing approval. They had been treated the same as therapeutic drugs despite their different characteristics. The new regulations allow broader indications for FDA approval and should make the approval process more relevant to radiopharmaceuticals, thereby allowing them to reach medical practice sooner.

According to David Nichols, director of government relations for the Society of Nuclear Medicine and the American College of Nuclear Physicians, "the most significant change [in the regulations] is the recognition that diagnostic radiopharmaceuticals need to be treated separately from other pharmaceuticals because of their inherent safety and because the criteria for evaluating them are so different."

**Clearer Expectations**

The proposed FDA regulations allow indications that may be more appropriate for evaluating diagnostic radiopharmaceuticals: visualizing an organ, assessing its function or biochemical properties, as well as the more traditional disease-specific indications. Under the old regulations, the FDA had the flexibility to review diagnostic drugs differently than therapeutic drugs, if necessary, according to Jane Axelrad, J.D., associate director for policy, Center for Drug Evaluation and Research, FDA.

"With the new regulations, we hope to clarify what our expectations are. This should make it easier for radiopharmaceutical manufacturers to design trials, not do unnecessary research, and get products to market sooner," Axelrad said. The changes to the regulations were initiated by the radiopharmaceutical industry and Congress, she said, "but in the end, the provisions represent a consensus by the FDA and industry."


— Maggie Reh

**Middle East Cancer Consortium Stays on Track to Collect Data**

The Middle East peace process fluctuates like a patient in a fever, so it may be no accident that one little-noticed sign of progress comes from a regional effort in medical research.

The Middle East Cancer Consortium (MECC), formed in May 1996 and operational by January 1997, is a project of the health ministers of Cyprus, Egypt, Israel, Jordan, and the Palestinian National Authority and has strong support from the United States. The consortium seeks to improve cancer surveillance in the region, share information about the disease, and train people to study and combat it.

"The political process serves as an umbrella for medical cooperation," said Khamis El-Najjar, M.D., a hematologist and director general of the Ministry of Health for the Palestinian National Authority in the Gaza Strip. "Doctors can play a good role in the peace process."

Cancer rates are lower in the Middle East than in developed countries largely because cancer is a disease of old age, while half the population in the Middle East is under age 20. But as health care in the region improves and people live longer, cancer rates will rise.

There are good scientific reasons for getting cancer specialists in the region together. Researchers want to look more closely at regional patterns of disease, said Michael Silbermann, D.M.D., Ph.D., an oral surgeon on the faculty of medicine at the Technion-Israel Institute of Technology.
Technology in Haifa, Israel, who is the executive director of the MECC.

For instance, bladder cancer is unusually prevalent in Egypt, accounting for more than 40% of cancer cases in men. The disease is linked to schistosomiasis (a water-borne parasitic disease), said Amal Samy Ibrahim, M.D., an epidemiologist at Cairo University. In addition, those tumors are harder to treat because cancer patients harboring the parasites cannot tolerate normal doses of chemotherapy.

Even once the water supply is made safe, said Ibrahim, it will take 20 years before there is an impact on bladder cancer.

Similar diseases may manifest themselves differently in different countries. In Israel, for example, Jewish women of eastern European ancestry show a higher incidence of inherited breast cancer. In Egypt breast cancer seems to occur in younger women and is diagnosed at more advanced stages, said Silbermann.

This raises a number of questions, he said: To what extent is the disease based on genetics versus environmental factors? What role do nutrition, age at marriage, childbearing, nursing, and contraception play?

**Cultural Differences**

In fact, cultural practices specific to the region may influence the incidence of cancer, said Federico Welsch, M.D., Ph.D., associate director for International Affairs at the U.S. National Cancer Institute. For instance, the Middle East has more cousin-to-cousin marriages than elsewhere in the world and so sees higher rates of genetic diseases than anywhere else, including lymphomas and childhood cancers.

Despite these intriguing epidemiological patterns, the lack of good data hampers policymaking regarding cancer. To remedy that deficiency, consortium members began a regional cancer registry last January. Information from the registry — on incidence, staging, survival and mortality — will help everyone make better public health decisions, said Silbermann.

The MECC registry will start life as a virtual project, not centralized but linked electronically to all members. Support comes from participants and from the United States. The NIH/NCI is contributing $500,000 a year for 5 years and the U.S. Agency for International Development has just approved a grant totaling $1.05 million for 5 years. The cancer registry will cost $400,000 a year.

Another $300,000 will support small grants (up to $15,000 each) to help ongoing research or initiate pilot projects. Research proposals will be selected by scientific peer-review panels, and the evaluation board will place special value on proposals that include collaboration across borders in ranking grant applications.

**Beyond Politics**

Not unexpectedly, the larger political setting of the Middle East hovers behind the organization’s activities. On one hand, the ups and downs of the peace process can advance or retard attempts to build bridges. At the same time, progress in non-political arenas (like the MECC) may pave the way for wider political success. The scientists who met in Washington, D.C., in May seem remarkably hopeful, whatever the message of the day’s headlines.

“MECC is an example of how people who want to achieve something can work together,” said Egypt’s Ibrahim. But he also cautioned that MECC can only succeed “if there is equal opportunity among the parties and no desire to dominate” the organization.

“I see the work of the Consortium ideally,” said Bracha Rager, Ph.D., chief scientist at Israel’s Ministry of Health in Jerusalem. “We can look at the same problems of people living in the same area. This is what’s most important.”

So, slow as they might be, steps toward cooperation in the Middle East move ahead against the common enemy for a change.

“Bringing people together is better than bringing governments together,” said Samir Al-Kayed, M.D., a radiation oncologist with Jordan’s Ministry of Health. “The peace process goes up and down but the MECC plows straight ahead. It reflects the real needs of the area because it is humanitarian rather than political.”

— Aaron Levin