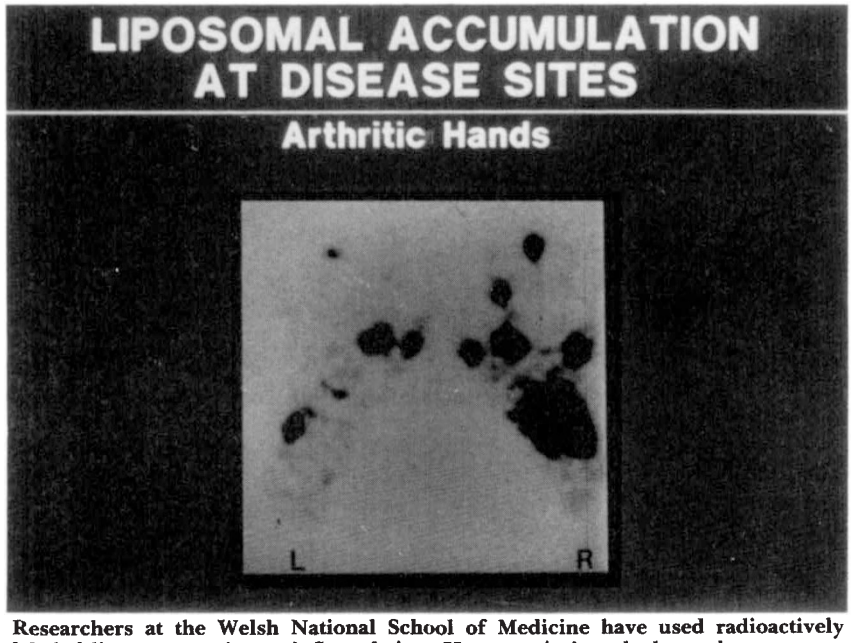
DRUG DELIVERY

LIPOSOMES CAPTURING INCREASED ATTENTION

SAN FRANCISCO—A year ago, only two companies focused on liposomes. Now some half-a-dozen start-ups concentrate on these phospholipid-based particles, according to Edgar T. Mertz's count, including The Liposome Company (TLC, Princeton, NJ) and Vestar (Pasadena, CA), both publicly traded, and privately held Liposome Technology Inc. (Menlo Park, CA).

Mertz, TLC's chairman and chief executive officer, was describing the liposome field in general—and his company in particular—to a packed audience at the 1987 Hambrecht & Quist Health Care Conference. He noted that although liposomes injected into the body normally accumulate in the liver and spleen, researchers have found that they congregate at sites of inflammation as well. This holds true for infections, for certain tumors, and even for rheumatoid arthritis (where liposomes gather at the specific joints that are giving the patient pain; see photo).



Researchers at the Welsh National School of Medicine have used radioactively labeled liposomes to image inflamed sites. Here, a scintigraph shows the congregation of liposomes in a patient's arthritic hands. The areas where the liposomes gather are the afflicted joints.

John Morgan and colleagues at the Welsh National School of Medicine (Cardiff, U.K.) have performed some of this targeting research on humans by using negatively charged liposomes labeled with ^{99}Technetium (*Brit. J. of Radiol.* **58**:25–39, 1985). Morgan believes that liposomes associate with serine proteases *in vivo* and are then taken up by macrophages and polymorphonuclear leukocytes. When an inflammation occurs, these cells travel to the affected site and carry the liposomes with them.

Mertz warns that liposome distribution is quite complicated, making it impossible to generalize about the behavior of liposomes of varying size or charge, or of those carrying different drugs. And he believes that two additional mechanisms could play a role in liposomes' targeting of inflammation. One possibility is that macrophages travel to the inflamed site first and then gobble up liposomes there. He points to a case, however, where liposome-encapsulated drug cleared up a serious eye infection in a person with low neutrophil levels. Here, he reasons, something else must have been occurring. Infections, inflammations, and tumors are all places where the body's plumbing is imperfect and its vasculature is broken up, he notes, so it is possible that liposome particles leak out of the circulation and become trapped in the surrounding tissue. It is at this point, Mertz postulates, that cells like macrophages dispose of them.

TLC's preliminary animal data using the anti-cancer agent doxorubicin (also called adriamycin) encapsulated within liposomes seem impressive. Mice with tumors can tolerate some 10 times the normal lethal level of this potent but dangerous drug, and they also live longer than those treated conventionally. The firm boasts the first pharmaceutically approved liposome manufacturing facility; it plans human clinical trials with a liposome-doxorubicin product in Canada later this year. If it turns out that liposomes really do allow larger and more therapeutic levels of drug to be administered, Mertz says, "That's called 'Bingo!' You win."—**Arthur Klausner**

WASHINGTON SCENE

BSCC REFINES AND LIMITS ITS REGULATORY ROLE

WASHINGTON, D.C.—In federal corridors, biotechnology discussions tend to be virtually bilingual, encompassing the dialects of both science and law. Because misunderstandings arise, much of the January meeting of the interagency Biotechnology Science Coordinating Committee (BSCC) was spent clarifying confusion about the committee's participation in federal biotechnology policymaking. In the end, BSCC re-emphasized its role as a scientific coordinating body only, albeit one that oversees a debate with many regulatory implications. Although this limited charter was set at BSCC's inception, it has become obscured by the recent flurry of documents, discussions, and lawsuits surrounding federal biotech policy proposals.

The decision by Judge Gerhard A. Gesell of the U.S. District Court of the District of Columbia late last year to dismiss two lawsuits brought by activist Jeremy Rifkin helped to prompt the BSCC review. In one suit, Rifkin sought to prevent BSCC and the President's Office of Science and Technology Policy (OSTP) from implementing the "Coordinated Framework for Regulation of Biotechnology," proposed in the *Federal Register* last June. In the other, Rifkin objected to the Environmental Protection Agency's (EPA) procedures for evaluating experiments involving deliberate release of genetically engineered organisms.

Judge Gesell concluded in both instances that the issues were "not ripe" for litigation and that Rifkin and his