inappropriate means of regulating PET radiotracers, which are usually made as needed by a licensed radiopharmacist for the on-site treatment of a small number of patients. Moreover, they argue that they are impractical. The positron-emitting isotopes used in the production of PET radiotracers have very short half-lives (minutes to just hours as in the case of [^{18}F]FDG, which has a half-life of 2 hours).

"It's compounding a drug," says R. Edward Coleman of the Duke University Medical Center in Durham, North Carolina, who also heads up the Society of Nuclear Medicine's PET committee. "We're not Burroughs Wellcome or Glaxo and yet we're going to be held to the same standards of producing drugs." Coleman does admit, however, that there is some variability in the quality of oversight currently provided by State Boards of Pharmacy.

FDA regulators, however, are sticking to their guns. The agency's position was clearly outlined in a 27 February 1995 Federal Register notice: "The agency believes that there are fundamental principles of the CGMP regulations that need to be applied to drug manufacturing processes, including those for PET radiopharmaceuticals, to ensure the safety and efficacy of the finished products."

It is not necessary to gaze into a crystal ball to see how the new regulatory mechanism for regulating PET radiotracers might work in practice. While some members of the PET community have preferred to keep FDA at arm's length, a group at the Methodist Medical Center in Peoria, Illinois, chose to work with the agency in an effort to develop a workable model of how PET centres could operate under FDA regulation. The Peoria centre first filed an NDA for [^{18}F]FDG in late 1991.

"A lot of people said it shouldn't be done," says Steven S. Zigler, who, at the time, was operational director of the PET centre at Methodist Medical Center. Zigler, now at CTI Inc. in Knoxville, Tennessee, one of a handful of US-based manufacturers of PET equipment, says "people like us felt it was better to work with them [FDA] than it was to bury our heads in the sand and let them go off and regulate us in a vacuum."

The clinical data were not part of the Peoria NDA submission but were put together as a separate drug master file by ICP and a number of physicians, with the intention that institutions and companies could then use those data to support an NDA submission at a specific site. Although FDA's own medical imaging drugs advisory committee recommended in 1992 that the drug master file be accepted, when the Peoria site received NDA approval last August, the only approved indication for [^{18}F]FDG was for the identification of epileptic foci — one of its more minor uses.

Although Zigler says concessions were made on both sides (FDA waived the licensing fees for the Peoria NDA but has since stated that there will be no blanket waiver of fees), the process proved costly in time and money, the outcome was disappointing and did little to quiet the critics who saw it as a failed experiment. No PET centre has subsequently opted to run the NDA gauntlet.

Organizations representing the PET community (including ICP and the Society of Nuclear Medicine) say that, although it may look like a done deal, they are still reviewing their options and will discuss the issue of PET regulation at the society's upcoming meeting to be held later this month in Minnesota, Minneapolis.

Moreover, Duke's Coleman says that given the fact that reimbursement for medical services is increasingly subject to pricing caps, it is all the more important to document what PET can do from a clinical and a cost-effectiveness standpoint.

ICP is doing just that. Working with Methodist Medical Center, ICP is hoping to amass sufficient clinical data to expand the indications of the Peoria NDA beyond epilepsy. If successful, then other PET centres will be able to short-circuit the review process by filing an 'abbreviated' new drug application with the FDA so long as they follow the same procedures for making [^{18}F]FDG as at the Peoria site.

ICP is also undertaking two retrospective cost-effectiveness studies for the use of PET in the detection of colorectal cancer and breast cancer; one prospective study has just been completed for solitary pulmonary nodules, the results of which will be presented at the society's upcoming meeting. A retrospective study on the staging of lung cancer is expected to be completed in the next few months.

Although these studies may help to bolster the case for reimbursement for PET, if nothing else changes, clinical PET centres may still find themselves in a Catch-22 situation, where the cost of complying with FDA regulations turns out to be more than the cost of reimbursement by third-party payors.

DIANE GERSHON

DID YOU KNOW... ?

Klausner at NCI

If everything goes according to plan as *Nature Medicine* goes to press, Richard D. Klausner will soon be named director of the US National Cancer Institute (NCI), a highly political job that offers its incumbent more responsibility than authority. He succeeds Samuel Broder who has taken a job in the biotechnology industry.

Others on the list for the NCI post but who declined were J. Michael Bishop of the University of California at San Francisco, and Mary-Claire King who has just agreed to leave the University of California at Berkeley for the University of Washington in Seattle.

Klausner comes to the NCI directorship from the National Institute of Child Health and Human Development where he has been chief of cell biology and metabolism. B.J.C.

. . . and Gallo leaves NCI

Even as the new regime begins, some established investigators depart. Robert C. Gallo and William A. Blattner of NCI are joining forces with Robert Redfield of the Walter Reed Army Institute of Research to form the 'Institute of Human Virology' at the University of Maryland at Baltimore. Though emphazing HIV, the Institute's research program will include all human viruses.

The Maryland site was chosen by the scientists over several competing sites, largely because of public support. This includes US$9 to 12 million in start up funding from the State of Maryland and another US$3 million from the city of Baltimore. In addition, the University of Maryland has donated most of a newly renovated 200,000 square foot warehouse on its Baltimore campus to house a projected 300 employees. F.R.S.

Shroud shrouded in biofilm

The Shroud of Turin, which is reputed to be the burial cloth of Jesus Christ, is encased in a biofilm produced by microbes.

Researchers from the University of Texas Health Sciences Center at San Antonio report that salt-tolerant, alkali-resistant microbes have also been isolated from the shroud which, on the basis of carbon-14 dating, has been thought to come from the 13th or 14th century.

The new data may lead to a reevaluation of its historical origin. For instance, natron (sodium carbonate) was used in Palestine during the first century AD to bleach linen and as an ingredient in the perfumes and resins used in burials. The mystery continues. B.J.C.