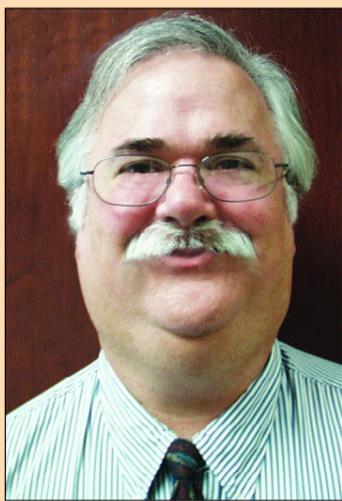


Self-Referral

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screening is not an approved use in Kansas.

"It was a complete administrative misunderstanding," says CATScan 2000 CEO Gina Johnson. "Kansas has a requirement of a physical examination by a doctor before a preventive CT scan can be performed; and our protocol was not set up in such a way that we could make that happen in a cost-effective manner."



Thomas A. Conley, RRPT, CHP

Despite the Kansas incident, and the skeptical view of leading medical groups, Ms. Johnson's faith is unshaken

that her mobile CT screening improves the health and increases the longevity of customers.

"Absolutely and without question," she said in an interview. But she added that the CATScan 2000 screening trucks and promotional materials claiming "New Technology Could Save Your Life!" won't roll into states that require on-site physicians or otherwise restrict self-referrals.

Each State Has Own Regulations

National statistics regarding self-referred CT screening are difficult to come by. Each state has its own regulations, ranging from those like Kansas that act to restrict CT scanning to diagnosis and treatment to a handful of states that have no rules prohibiting self-referred screening. (In general, the Food and Drug Administration regulates only the manufacturers of CT scanners.)

A draft statement from the Conference of Radiation Control Program Directors (CRCPD) urges, "Until large-scale clinical trials have been performed and analyzed thoroughly and effectively, insufficient scientific evidence exists for the efficacy and safety of the self-referral whole-body CT process. Unnecessary radiation exposure during medical procedures should be avoided at all costs."

Ron Fraass, Executive Director of CRCPD, which is an association of the 50 state directors of radiation use, says a resolution calling on members to

JAMA Study: Little Value for Lung Cancer CT Screens

CT scans do not appear to be useful for mass screening for lung cancer, according to a study by Johns Hopkins researchers published in the Jan. 5 issue of the *Journal of the American Medical Association*.

"Direct-to-consumer marketing and media coverage has encouraged demand for lung cancer screening despite a lack of evidence for its efficacy," lead author Parthiv J. Mahadevia, MD, MPH, said in a news release.

"These scans are not risk-free.

There is a downside, including high costs and possible harm to individuals who may unnecessarily get invasive procedures if the scan detects a benign lung nodule."

The NCI has begun an eight-year trial comparing CT scans with chest x-rays in the diagnosis of lung cancer.

"We're not down on the technology--just its injudicious use," said coauthor Neil R. Powe, MD, MPH. "CT can be a very useful tool, but only when recommended by a physician for a specific clinical purpose."

actively discourage self-referral CT screening was one of the few such measures to pass unanimously.

Scanning center operators in Oregon say that state's self-referral ban does reduce the number of people who request a whole-body CT screen. However, radiologist James Borgstede, MD, Chair of the Patient Safety Task Force of the American College of Radiology, has doubts about the effectiveness of self-referral bans.

"A lot of those laws are really paper tigers, because there are a lot of ways to circumvent the intent of that law; so I'm not really sure that it really protects the patient," he said.

For instance, a radiologist at a scanning center can write a prescription for

a scan, as long as it doesn't run afoul of the Medicare and Medicaid bans against physicians referring patients to scanning centers they have an interest in.

Dr. Borgstede predicts conclusive research into the pros and cons of CT screening will ultimately have more influence than regulations.

For now, he urges people to be skeptical about marketing claims for CT screening. "Have a 'buyer beware,' 'caveat emptor' type of approach and let people know what they are getting into here. It's a free country and people can do what they want, but I think they should understand what the potential consequences are of getting one of these scans," he says.

CT Screening Exams: Official Statements

ACR Statement on CT Screening Exams: www.aacr.org

"The American College of Radiology recognizes that an increasing number of computed tomography screening examinations are being performed in the United States. Much CT screening is targeted at specific diseases, such as lung scanning for cancer in current and former smokers, coronary artery calcium scoring as a predictor of cardiac events, and CT colonography (virtual colonoscopy) for colon cancer.

"Early data suggest that these targeted examinations may be clinically valid. Large, prospective, multicenter trials are currently under way or in the planning phase to evaluate whether these screening exams reduce the rate of mortality.

"The ACR, at this time, does not believe there is sufficient evidence to justify recommending total-body CT screening for patients with no symptoms or a family history suggesting disease. To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life.

"In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings

that will not ultimately affect patients' health but will result in unnecessary follow-up examinations and treatments and significant wasted expense.

"The ACR will continue to monitor scientific studies concerning these procedures."

American Association of Physicists in Medicine: www.aapm.org

"The use of computed tomography for total body screening of asymptomatic patients has not currently been found to be scientifically justifiable or clinically efficacious.

"The greatest concerns surrounding this procedure are: (1) that the procedure will lead to the discovery of minor anomalies that have no influence on patient health, but their identification will lead to added medical examinations with associated risks and unnecessary medical expenses, and (2) the wide-scale use of significant radiation exposures from total body screening CT for a yet unproven screening procedure.

"Total body CT screening should not be confused with the scientific CT studies of screening for lung cancer in

high-risk patients or cardiac scoring to identify calcification in coronary vessels. Scientists in the AAPM will continuously assess the scientific literature as to the efficacy of total body CT screening and make revisions to this policy statement when appropriate."

Food and Drug Administration: www.fda.gov/cdrh/ct

"At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause.

"Statements by CT imaging facilities that imply FDA 'approval,' 'clearance,' or 'certification' of CT for screening procedures misrepresent the actual situation. FDA has never approved or cleared or certified any

CT system specifically for use in screening (i.e., of individuals without symptoms), because no manufacturer has ever demonstrated to the FDA that their CT scanner is effective for screening for any disease or condition."

Conference of Radiation Control Program Directors: www.crcpd.org

"No scientific studies have demonstrated that CT screening of individuals without symptoms provides a greater probability of benefit than harm.

"The main risks of CT screening scans for an individual are: (1) abnormal test results for a benign or incidental finding, leading to unneeded and possibly invasive follow-up tests that may present additional risks; (2) normal findings that carry the possibility of inaccuracy and false reassurance which may lead the patient to conclude that further routine screening tests such as for breast cancer, cervical cancer, colon cancer, hypertension, diabetes, etc. are unnecessary; and (3) the increased possibility of cancer induction from x-ray radiation exposure."