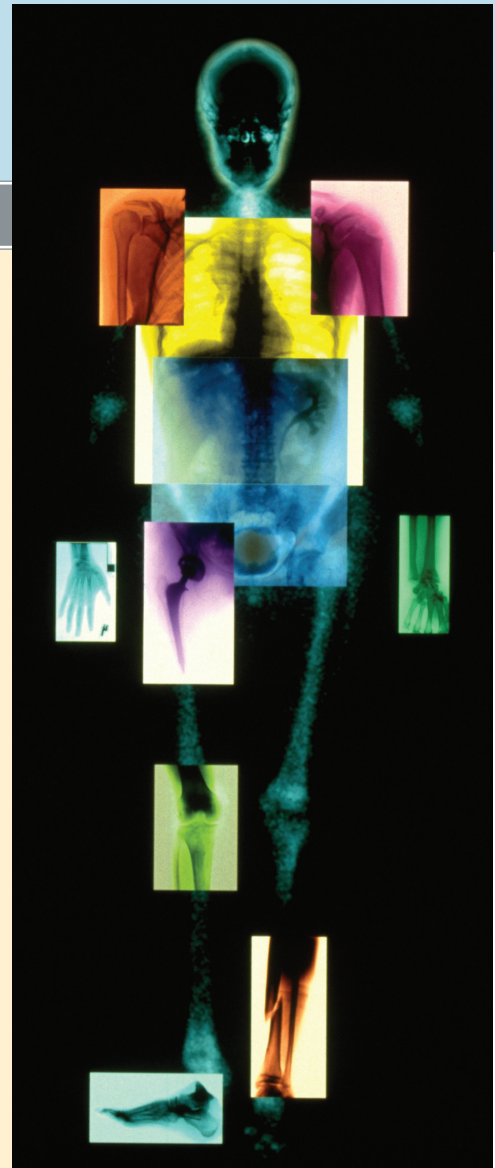


# ONCOLOGY TIMES

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### VIEWPOINT: The New Limitations on Resident Work Hours

The Director of NYU's Humanistic Aspects of Medical Education Program on the implications of the new national reduced work hours for residents, a change mandated by the ACGME that will go into effect in July, prohibiting residents from working more than 80 hours a week and more than 24 hours at a stretch. *Page 16*



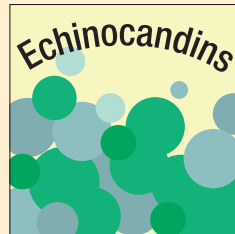
### ECRI Study Says No Proof of Clinical Utility for Ductal Lavage

A new analysis from the international health technology assessment safety agency concludes there is insufficient information to reach conclusions about the clinical utility of ductal lavage, and that there is no apparent clinical benefit to screening asymptomatic women with nipple aspiration. *Page 38*

## Whole-Body CT Screening: Scanning or Scamming?

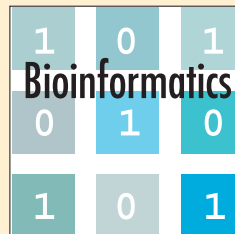
The opinions of expert groups are nearly unanimous that people without symptoms or a family history or other specific risk should not get whole-body CT screening scans, because there is no evidence any benefits would outweigh the risks and costs. Yet newspapers, TV, and radio are filled with upbeat ads encouraging their use. When patients heed marketing over expert consensus, what can and should clinicians do? *Page 5*

## Antifungal Echinocandins Improving Care of Immunocompromised Cancer Patients



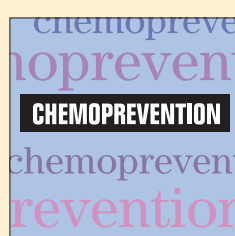
This new class of cyclic lipopeptide drugs have a novel mechanism of action against pathogenic fungi, making it easier to treat persistent fungal infections, which have proliferated in recent years. *Page 12*

## From Fuzzy Logic to Artificial Neural Networks...



A host of sophisticated bioinformatics tools are accelerating the development of cancer drugs & detection. An update from a recent NCI workshop. *Page 23*

## No. 3 in Our Chemoprevention Series: Skin & Colorectal Cancers as Research Models

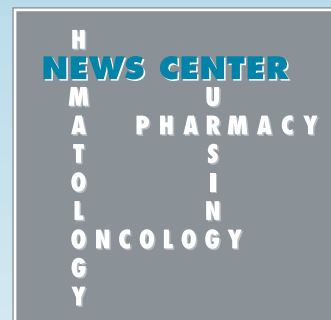


Chemoprevention aimed at intraepithelial neoplasia is an area of intense study, with much research in skin and colorectal cancers. Both have precursor lesions easy to survey, and each—actinic keratoses and adenomatous polyps—are separate from surrounding normal tissues, countable, and measurable. *Page 40*

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## Whole-Body CT Screening: Scanning or Scamming?

By Andrew Holtz, MPH

The opinions of expert bodies and medical societies are nearly unanimous: Individuals without symptoms or a family history or other specific risk factor should not get whole-body computed tomography screening scans, because there is no evidence there are any benefits that would outweigh the risks and costs. Yet newspapers, television and radio are filled with upbeat ads for CT screening.

When patients heed marketing over expert opinions, what can and should clinicians do?

### One Scan Leads to Another

"We'll get a request from a physician saying, 'Patient had screening study. They recommended further scans. Please do what they said,'" says radiologist Kendall Barker, MD, Section Head for CT scanning for Kaiser Permanente's Northwest Region.

He doesn't see much leeway at that point. "I feel like we are pretty much forced to do that," he explained. "I guess there could be an occasional case where we could look at the scan and say, 'Well, we just don't agree with their interpretation. We don't think it was anything to begin with.'

"But a lot of times the findings are in fact indeterminate. We don't know for certain what they are, and so you may have to do something more to disprove disease."

In Dr. Barker's experience, the suspicious findings in CT screening scans usually turn out to be benign cysts or hemangiomas.

"We've seen only a modest number of cases to date, but I have the impression that it is gradually picking up," he said. While he says the health conse-

*Increasingly the question for physicians is not whether CT screening is good or bad, but how to counsel curious patients, and then support and care for those patients who get screened...only to be given results that raise questions and fears.*

quences of CT screening for an individual are almost always of no consequence, the potential cost and burden for the system are daunting.

At the most recent Radiological Society of North America Scientific Assembly and Annual Meeting in December, Dr. Barker heard a presentation by Giovanna Casola, MD, of the University of California, San Diego, on the results of 1,200 whole-body CT screening scans at a for-profit facility in Southern California.

Three out of four of the individuals screens had referred themselves to the scanning center. There was at least one

finding in 87% of the scans. Recommendations for further testing or other follow-up work were entered in 32% of the records.

"You can imagine if your entire adult population in a health plan over a couple of years all went and got a screening study, and a third of them needed more work-up, then you'd be working-up a third of your population for mostly benign disease. There's a big cost to that," Dr. Barker notes.

### Proactive Approach

At the Be Well Body Scan facility in Chestnut Hill, MA, Medical Director Max Rosen, MD, urges physicians to take a proactive approach toward whole-body CT screening of individuals who do not have symptoms or other indications that might suggest disease.

Ideally, he says, physicians should communicate with radiologists at local facilities before patients undergo a screening scan.

"We have some doctors in the Boston area who are integrating this into their practice," Dr. Rosen said. "We had a couple come in, and their doctor happens to be across the street from me. He came over when I was ready to review the scan with them, sat with them for 10 or 15 minutes as we reviewed the scan, and was really part of the discussion and part of the process.

"Obviously that only works in certain situations, but I think it's very reasonable for patients to discuss with their doctors whether they should have the scan done, and then, with the patient's permission, have the radiologist call the primary care doctor."

Of course, everyday practice does not always match that ideal collaborative scenario. Dr. Rosen admits some

(continued on page 6)

### On the Cover:

Artistic rendering of medical imaging composite of body, with x-rays, MRI, CT, and bone scan. © Scott Camazine/Photo Researchers, Inc.

### Letters

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breast cancer, cardiac events, stroke, and clots among women who were assigned to the treatment group were small. They do not state that the risk, at least of breast cancer, was not statistically significant and was based on statistical assumptions that could render the conclusion invalid.

The piece in *Oncology Times* goes on to quote Dr. Robert Hoover, Director of NCI's Epidemiology and Biostatistics Program, who "noted that in 1989 a Swedish study suggested that combination HRT might not only not decrease the risk of breast cancer, but might in fact increase it."

That study, by Bergkvist et al, *The risk of breast cancer after estrogen and*

*estrogen-progestin replacement (N Engl J Med 1989;321:293-297)*, reported a relative risk of 4.4 among women who used the combination for more than six years.

Two months after this article appeared in the *New England Journal of Medicine*, it was reviewed in the *Harvard Medical School Health Letter (October 1989;14[12]:1-3)*.

The reviewers commented: "There is a very important reason not to take this figure [RR=4.4] literally. There were only 10 women in this group, too few to provide a statistically stable result. Indeed, on the basis of these 10 cases, the true value had a 95% chance of being 10% below the average, as high as 22.4 times average or somewhere in between."

They go on to write: "Earlier research has given us no reason to expect

a strong association between estrogen replacement and breast cancer."

I fear the article in *Oncology Times* will validate the premature conclusions of the Women's Health Initiative, which has already generated headlines around the world warning women away from hormone-replacement therapy. This warning, which is generating a great deal of anxiety (not good) and discussion (good), may be incorrect.

After the headline fever abates, a better and continuing analysis of this issue would be appropriate. For now, any specific change in practice on the part of physicians or patients with regards to HRT should not be based on the results of this study.

Avrum Bluming, MD  
Clinical Professor of Medicine  
University of Southern California

## Whole-Body CT

continued from page 5

physicians are less than pleased when they learn patients have been screened at his center.

"Sometimes when I've called doctors because one of their patients was here, the initial response has a bit of an edge to it," Dr. Rosen concedes.

"But I think because I am calling them and communicating with them directly, that edge disappears in about 10 seconds. And the conversation always finishes up with, 'Thank you very much for taking care of my patient, and thank you for calling me.' I can't stress enough how important that communication is."

*One resource oncologists cannot easily turn to are practice guidelines for investigating findings on CT screening scans.*

Be Well Body Scan is a not-for-profit operation affiliated with Beth Israel Deaconess Medical Center in Boston. "We feel that this is an extension of our academic department; so we would not do anything here that we would not feel comfortable doing at the hospital," Dr. Rosen said.

Unlike the marketing materials produced by some commercial, for-profit scanning centers, Be Well's Web

site emphasizes that CT screening is not for everyone.

Also, Dr. Rosen says there needs to be more awareness of the fact that "abnormalities" on a sophisticated scan image are indeed normal in healthy individuals.

### 'Something' is Almost Always Nothing

At Johns Hopkins Medical Institutions' Advanced Medical Imaging Laboratory, Elliot Fishman, MD, goes further to downplay the significance of "findings" on CT screening scans.

"Most of the time, and I mean 90% of the time, if there is 'something' seen on one of these studies, it is something that is of no significance or something that is not important," Dr. Fishman said.

Nevertheless, he strongly advocates CT as a useful tool in the context of a comprehensive medical care program. "If I do a study, and we do a great study, and we don't see anything, that's good. But realistically, if you are a male of a certain age, you need a PSA. If you are a woman, you need a mammogram. There are so many things you need that are part of the whole process."

However, self-referred whole-body CT screening scans lack the proper context, Dr. Fishman warns, urging physicians to be wary.

"My first word of advice is to proceed slowly, without going into the mega-work-up," he says. "Say a report comes back: 'possible metastasis in the liver or solitary mass right lobe.' Well, seven to 10 percent of women have lesions in the right lobe that are hemangiomas.

So before you start working up the



**James Borgstede, MD:**  
"Physicians need to reassure their patients that they are going to take care of the person, whether they agreed or disagreed with the decision to get the initial scan. I think there is some value in reassurance of the patient that a lot of these findings are false positives, in some situations up to 90% of the lung scan findings, for example, are false positives."

patient and running their bowel and doing x, y, and z to look for the primary tumor, say, 'Wait a second, there's a good chance this could be a hemangioma.' Do not put the pedal to the metal. You are not dealing with a biopsy. I'm very, very cautious."

Dr. Fishman says the first step by a physician should be to consult a radiologist he or she regularly works with, in order to get an independent review of images taken at a scanning center.

If it were up to the leading professional organizations of radiologists, whole-body CT screening of asymptomatic individuals would not be done outside of clinical trials.

As a policy statement of the American College of Radiology (ACR) puts it, "To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life."

James Borgstede, MD, Vice Chair of the ACR Board of Chancellors and the Chair of ACR's Patient Safety Task Force, says the college issued its cautionary statement in response to a rising number of questions from members.

Despite the skeptical approach to CT screening, he recognizes that once a screening study has been done, the situation is changed. "Now we are dealing with the reality of a finding on an

examination, and while we may not have recommended that evaluation to begin with, we are confronted with the finding and we have to take the next step," Dr. Borgstede says.

### The Scan Changes Everything

"Once you embark upon this course,

then you've got a commitment that you really have to evaluate, from an ethical point of view, from a medical-legal point of view, and from a purely health care point of view; you have to go ahead and find out what this abnormality is," Dr. Borgstede notes.

"First, physicians need to reassure their patient that they are going to take

## Who Pays?

When individuals decide to get a CT screening scan, they usually pay out of pocket. A scan of the chest, abdomen, and pelvis in a mobile CT scanner can be had for \$398. At the other end of the scale, a Hawaiian resort spa and scanning center offers airport pick-up, lei greeting, spa treatments, meals, and two nights lodging, in addition to five imaging tests and other exams, all for \$4,000.

That hit to the wallet does dampen public enthusiasm for CT screening. According to a market survey performed by Be Well Body Scan in the Boston area, cost was the most common reason people cited for not wanting a CT scan.

Recognizing that an initial test often raises new questions, Be Well includes a limited amount of follow-up testing in the basic package.

"If somebody has something, particularly in the liver or the kidney, sometimes in the CT scan it looks like a cyst, but you just can't be 100% sure; we will do an ultrasound to clarify that finding or the abnormality in

the liver or the kidney, as part of the exam without charging extra for it. We are doing it so people leave with as few loose ends as possible," Be Well's Medical Director, Max Rosen, MD, says. But he concedes that scanning centers cannot offer a full work-up after every scan that shows some sort of abnormality.

Radiologist Jim Borgstede, MD, Vice Chair of the ACR Board of Chancellors, says the initial scans are not the problem—"The real problem is the false positives that come out of that screening scan. Who pays for those?" he asks.

"You know, the patients will come in and pay the money for the scan, but then as soon as something is found in the scan, which is typically a false-positive finding, then their insurance kicks in. And if you have a health care plan, now suddenly somebody in your plan gets one of these scans, that changes the profile of your health care plan, and that, in effect, changes your premiums. So I think we have to think about this from an

epidemiologic and a population basis."

Some experts go even farther, arguing that until CT screening proves its worth, individuals who opt for CT scans in the absence of symptoms or clear risk factors should bear the full cost of the consequences.

Elliot Fishman, MD, Head of the Advanced Medical Imaging Laboratory at Johns Hopkins Medical Institutions, notes that a positive scan often leads to a steady stream of regular follow-up scans, a cash cow for scanners, but a drain on health plans.

"As far as I'm concerned, they ought to do this: If you self-refer, you are responsible for everything," he argues. While he supports coverage of screening ordered by a physician as part of comprehensive care, Dr. Fishman warns about the cost to society of uncontrolled CT screening.

"Truthfully, it could break the system. You start running up these costs chasing nonsensical things," he predicts. "I'm not here to have my insurance rates go up because people

decide on their own they are going to go for studies at second-rate places and then get more studies to follow something that's of no importance."

The potential price tag for self-referred CT screening is as uncertain as potential health benefits. In a plenary session debate on CT screening at December's Radiological Society of North America Scientific Assembly and Annual Meeting, Bruce Hillman, MD, Chair of Radiology at the University of Virginia, said yet-to-be-published results of a study of CT scanning indicated that screening healthy 50-year-old individuals for key cancers, aneurysms, and heart disease could cost \$150,000 per year of life saved.

On the other hand, Michael Brant-Zawadzki, MD, Medical Director of Radiology at Hoag Memorial Hospital in Newport Beach, CA, pointed to other analyses of more limited screening for lung cancers that predict CT scanning might cost less than \$50,000 per year of life saved.

—AH

care of the patient, whether they agreed or disagreed with the decision to get the initial scan. I think there is some value in reassurance of the patient that a lot of these findings are false positives, in some situations up to 90% of the lung scan findings, for example, are false positives."

He also suggests that physicians consult with radiologists within their medical group or hospital to decide what, if any, steps should be taken to answer questions raised by the CT screening scan.

### Guidelines Lacking

One resource oncologists cannot easily turn to are practice guidelines for investigating findings on CT screening scans.

At the American Society of Clinical Oncology, a spokesperson said that ASCO does not have a policy position or guidelines regarding body scans of asymptomatic individuals who do not have identifiable risk factors.

Meanwhile, some other specialty groups have taken steps to help their members navigate the aftermath of CT screening. In recently revised guidelines on the management of chronic stable angina, the American College of Cardiology and the American Heart Association included guidelines for workup of asymptomatic patients following CT screening, not as an endorsement of the screening, but merely acknowledgment of "the clinical reality that such patients often present for evaluation after such tests have been performed."

The guidelines go on to suggest which, if any, follow-up tests or procedures should be considered, based on the patient and the finding on the screening scan.

*If it were up to the leading professional organizations of radiologists, whole-body CT screening of asymptomatic individuals would not be done outside of clinical trials.*

For example, the updated guidelines point out in which circumstances a stress echocardiogram is preferable to an exercise electrocardiogram. That sort of specific consensus advice is not yet readily available to oncologists or other physicians faced with a mass on an abdominal CT image.

### Is Resistance Futile?

In the absence of practice guidelines, oncologists are left to pick and choose from the advice offered by individuals in the field. Dr. Rosen at Be Well Body

Scan suggests physicians become familiar with the scanning centers in their area.

"Find out who is doing screening in their area, call up the medical director or one of the radiologists at the site, and say, 'I'd like to come see what you are doing, I'd like to talk with you, and I'd like to maybe start thinking about how, for my patients who want the service, how I can integrate this into my practice.'

"It doesn't have to be for all their patients. They don't have to be recommending it to everybody. But for the

*The impact of screening CT on patient-physician relationship bears some similarity to issues relating to alternative or complementary medicine.*

patients who are interested in it, I think it can actually be a very useful tool for

the clinician," he says.

Dr. Borgstede of the American College of Radiology agrees that local research, including tours of local scanning centers, can be useful; in part to help build a persuasive argument against screening CT.

"It's always better to have knowledge. If that gives the primary care physician some knowledge so they can comment to their patient, that's probably better, I think it will give them more credibility. I think it will also give them credibility with their patients if they

*(continued on page 8)*

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Please refer to the accompanying brief summary of the Aranesp® prescribing information.  
Reference: 1. Byrne JJ, Bunn FC. Development and characterization of novel erythropoietin stimulating protein (EESP). *Br J Cancer*. 2001;84(suppl 1):14-16.



## Self-Referral

continued from page 8

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](http://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](http://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](http://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](http://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."