The New York Times
David Shipley, Op-Ed Editor
Cc: Bill Keller, Executive Editor
Cc: Clark Hoyt, Ombudsman
Cc: Alex Berenson, Reporter
Cc: Reed Abelson, Reporter
620 8th Avenue
New York, NY 10018

July 1, 2008

Dear Mr. Shipley, Mr. Keller, Mr. Hoyt, Mr. Berenson and Ms. Abelson:

We respectfully request the opportunity to write an Op-Ed article about an important public health issue regarding Cardiac CT Angiography.

We read with great disappointment your recent article in the New York Times, entitled "Weighing the Costs of a CT Scan's Look Inside the Heart." Prior to the article's release, we each spoke to Ms. Abelson at length regarding the body of scientific evidence that has examined the clinical and cost-effectiveness of cardiac CT angiography. We point to numerous statements in your article which, based upon the scientific data and prevailing expert opinion, are undeniably inaccurate, misleading or untrue:

1) In your article, you indicated that cardiac CT scans "have never been proved in large medical studies to be better than older or cheaper test."

This statement is incorrect. CT scans have, in fact, been proven in large medical studies to be better than older tests. Two major prospective multicenter studies that have been recently presented at the late-breaking trials sessions of the 2007 American Heart Association and Radiologic Society of North America Scientific Sessions definitively demonstrate that cardiac CT angiography possesses higher diagnostic accuracy for the detection and exclusion of obstructive coronary artery disease than any other non-invasive cardiac test to date (Miller et al, AHA 2007; Min et al, RSNA 2007). Indeed, no clinical trials were cited nor were any of the ongoing multicenter trials listed on the Federal website, clinicaltrials.gov, which is expressly designed to make research-in-progress publicly available.

2) In your article, you indicated that cardiac CT scans "were given to more than 150,000 people in this country last year at a cost exceeding $100 million" and that "when doctors request a CT angiogram for a patient, they also frequently ask for a nuclear stress test."

This statement is incorrect. After extensive discussion with us, you ignored the totality of scientific data to date that has impartially examined the use of cardiac computed tomography, including the following:

- In a study encompassing >10 million insured lives, clinical outcomes for patients without known coronary artery disease undergoing cardiac CT were similar to those undergoing nuclear stress testing. Health care costs were lower for patients undergoing cardiac CT by almost $500 per patient in a 9-month follow-up (Am J Cardiol 2008, *in press*).
- In a similar study encompassing >6 million insured lives, clinical outcomes for patients without known coronary artery disease undergoing cardiac computed tomography were actually slightly *better* than those undergoing nuclear stress testing.

- Health care costs were lower for patients undergoing cardiac CT, by over $1000 per patient in a 12-month follow-up (Radiology 2008, *in press*)

- In the study we discussed with you, only 7.5% of patients undergoing cardiac CT required additional downstream testing by nuclear stress tests (Am J Cardiol 2008, *in press*)

3) In your article, you mentioned in certain patient populations, that one cannot "justify using the scans routinely, given their cost and radiation risks."

This statement is misleading and inaccurate. The Prospective Multicentre Study on Radiation Dose Estimates of Cardiac CT Angiography in Daily Practice, or PROTECTION 1 study, recently presented during the late-breaking abstracts session at the 2008 American College of Cardiology Scientific Sessions, found that the median dose exposure for cardiac CT is 15.4 mSv (Hausleiter et al., ACC 2007), similar to and often less than that of nuclear stress testing, the most common non-invasive diagnostic cardiac imaging test, whose radiation doses range between 10-20 mSv. The PROTECTION 1 study also examined three separate methods of radiation dose reduction with cardiac CT—automatic exposure control, electrocardiographic pulsing and 100-kV tube voltage—which significantly reduced overall radiation. Furthermore, the introduction of a novel technological development called "step-and-shoot" now reduces the radiation of cardiac CT by >80% to approximately 2 mSv of radiation (Radiology 2008; 246:742-53). In context, this equates to ambient radiation doses received from living in New York City for 8 months.

Even if cardiac CT radiation doses were not reduced by these novel technological developments, the hypothetical risks of future cancer for a 60-year old woman and a 60-year old man would be approximately 1 in 715 and 1 in 1911, respectively (JAMA 2007, 298:317-23).

We believe it irresponsible for you to neglect to mention that the risk of dying from cardiovascular disease for all persons in the United States is approximately 1 in 3 (www.americanheart.org). For symptomatic individuals with suspected coronary artery disease, the risk of dying from cardiovascular disease is much higher.

4) In your article, all patients undergoing cardiac CT angiography were asymptomatic.

This is irresponsible. All professional and governing societies related to the practice of cardiac CT have unconditionally stated that the performance of cardiac CT scans in asymptomatic patient is categorically *inappropriate*, and have published these guidelines for widespread dissemination (J Am Coll Cardiol 2006; 48:1475-97). These organizations include the American College of Cardiology, American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance Imaging, American Society of Nuclear Cardiology, North American Society of Cardiac Imaging, Society for Cardiovascular Angiography and Interventions and Society of Interventional Radiology.

We find it regrettable that you chose to neglect this widely known document and instead, focus your article on cardiac CT performance in an inappropriate patient cohort.

5) In your article, you indicate that the Society of Cardiovascular Computed Tomography, an organization with almost 5,000 professional cardiologist and radiologist members, has only "one purpose—to promote CT angiograms."

This statement is untrue. As representatives of the SCCT, we spoke to you at length in order to educate you on the mission of our organization, which can be easily viewed on the SCCT website (www.scct.org). Our mission is to:

- Foster optimal clinical effectiveness of cardiovascular CT through professional education, establishment of standards for quality assurance and professional training, and development of evidence-based guidelines for its use to enhance patient care and improve the quality of cardiovascular medical practice
- Ensure state-of-the-art application of cardiovascular CT through training and accreditation

- Support coordinated research efforts to promote further development and applications of cardiovascular CT, and to investigate accuracy, effectiveness, and cost-effectiveness in cardiovascular diagnosis
- Serve as an advocate for cardiovascular CT in all interactions with the health care industry, medical policy development and reimbursement organizations
- Cultivate close working relationships with other societies in the fields of Cardiology, Radiology, Vascular Surgery and Vascular Disease.
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6) In your article, you state that makers of CT scanners "do not have to conduct studies to prove that their products benefit patients, as drug makers do."

This statement is inaccurate and flawed. Cardiac CT is a diagnostic test, while drugs are therapeutic interventions. Owing to their inherent properties, diagnostic tests—which possess no intrinsic therapeutic value—cannot directly impact upon incident clinical outcomes (as a drug may be able to). Instead, the clinician employing a non-invasive cardiac diagnostic test for a symptomatic individual expects that test meet several criteria that include high diagnostic accuracy, effective risk stratification of patients at risk for future heart attack or death, safety and cost-effectiveness. The cornerstone of a diagnostic test's worth has resided in its diagnostic performance.

Cardiac CT has been demonstrated to have higher diagnostic accuracy for detection and exclusion of coronary artery disease than any other non-invasive cardiac test, to effectively risk stratify patients at higher risk of adverse cardiovascular events, and to be safe and cost-effective.

Since the introduction of 64-slice CT scanners in 2005, the professional and scientific community has made great efforts to evaluate the clinical utility of cardiac CT in symptomatic patient populations. Despite our informing you of these studies, you instead chose to focus your article on the use of cardiac CT in patients for whom performance is considered inappropriate. We discussed with Ms. Abelson the multiple situations in which the test results eliminate the need for invasive coronary angiography as well as the need for other unnecessary tests. Avoidance of unnecessary invasive procedures is the most common reason for performing coronary CT angiography. This provides an important contribution to the health care that is undermined by the inaccurate reporting.

Sincerely yours,

James K. Min, MD, FACC
Director, Cardiac Computed Tomography
New York Presbyterian Hospital

Daniel Berman, MD, FACC
President-Elect, Society of Cardiovascular Computed Tomography

Michael Poon, MD, FACC
President, Society of Cardiovascular Computed Tomography