TESTIMONY OF JOHN J. DONAHUE, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF NATIONAL IMAGING ASSOCIATES, BEFORE THE HOUSE COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH

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Chairman Deal, Ranking Member Brown, and Members of the Subcommittee, my name is John Donahue, and I am pleased to appear before you today to discuss the state of medical imaging in today's healthcare marketplace. As a fellow American, I am also deeply grateful to the commitment and contributions each of you Members have made to our Nation. I am the Founder, the President, and the Chief Executive Officer of National Imaging Associates, Inc. (NIA). NIA is the nation's largest radiology benefits management firm, covering nearly 18 million people through contracts with national and regional health plans. NIA is dedicated to improving the quality of patient care through clinically appropriate and cost-effective management of diagnostic imaging such as MRIs, CT and PET scans, and nuclear cardiology services. Robert LaGalia (who is with me today), Dr. Thomas Dehn and I , originally developed this company through a partnership with Quest Diagnostics. NIA became a separate entity in 1996, and is now a wholly owned subsidiary of Magellan Health Services. Headquartered in Avon, Connecticut, Magellan Health Services is the nation's leading specialty health care management organization.

NIA is the only radiology management organization to receive accreditation for our HIPAA privacy compliance program for all the Protected Health Information we receive in the course of our operations. NIA was also selected as an early adopter for the new URAC and

JCAHO/NCQA Privacy Certification Program for Business Associates. URAC awarded NIA HIPAA Privacy Accreditation for Business Associates in August 2003. Our Web based applications were also recognized by Computer World's Smithsonian Award for Healthcare Innovation.

Radiology benefits management involves evaluating diagnostic imaging to insure that services rendered are both clinically appropriate and cost effective. NIA currently partners with over 40 managed care organizations in 36 states to improve the quality and cost-efficiency of diagnostic imaging testing for health plan members and physicians. NIA's clients include the nation's leading managed care organizations, including Aetna and WellPoint, many other leading Blue Cross and Blue Shield Plans and regional leaders such as Harvard Pilgrim Health Care. In the government sector, we cover over 300,000 Medicare Advantage lives and over 1,200,000 Medicaid lives in multiple states. Given the scope of our role in our nation's health care, I believe our perspective on advanced medical imaging and the management of imaging costs can be useful to the Subcommittee.

The record on diagnostic imaging as one of the fastest growing cost areas in American health care, and the growth in advanced medical imaging as a major contributor to today's exploding Medicare spending, are both well documented. By most accounts, outpatient diagnostic imaging exceeds $100 billion and is growing at a rate in excess of 20 percent. It is interesting to note that we find almost axiomatically across the country, high tech imaging (MRI, CT, PET and nuclear cardiology exams), typically account for only roughly 15 percent of imaging volume, but over 50 percent of imaging cost (driven by their high relative fees) and over almost 80 percent of the

inflationary impact. Most health plans, State authorities or Center for Medicare and Medicaid Service (CMS) will report to you that diagnostic imaging represents upwards of over 15 percent of the overall health care spend in our country. While we understand the consternation with the MedPAC recommendations, the CMS Physician Fee Schedule changes for multiple procedures and nuclear medicine services, and the imaging provisions in the Deficit Reduction Act of 2005 (DRA), we fully endorse the concept of clinically based, safe and affordable imaging as sound public policy, and we are encouraged that the Subcommittee has held this hearing today.

I am often asked: What is causing this explosion in diagnostic imaging utilization, safety concern and financial stress on our health care system? There is no single simple answer. We are here today because a compendium of causal factors are forming *The Perfect Storm*, these dynamics include:

- The constant flow of remarkably innovative and therapeutically helpful new imaging technology that is flooding the market place. To the extent this helps patients, it is very positive.
- A lack of clinical consensus on the part of those who predominantly order diagnostic imaging. Well-intentioned primary care, family practice and internal medicine physicians, who endeavor to perform the best care for their patients but lack the time and acumen to master the nuances of every emerging technology, most often cast a wide, extraordinary costly and most often not clinically justified net of imaging prescriptions.
- There is a reflexive professional instinct to cast a broad net of multiple diagnostic imaging exams to protect a doctor from financially devastating and often unjustified instances of physician malpractice.
- And then there is the patient, who is bombarded with direct-to-consumer imaging advertisement, an enlightened sense of technological awareness, mixed with a smidgen of entitlement. He often requests specific imaging exams when thinking, "I twisted my knee this weekend playing hoops in the driveway, I want an MRI on a GE magnet just like my local sports star had last week."

Now, we turn to two of the most concerning issues this Committee will face:

- There is a proliferation of imaging capacity driven by entrepreneurial zeal and resulting in imaging orders, which is encouraged by aggressive marketing. They are not clinically warranted and are driven by return in investment decisions by the owner.
- World of self referral: We must find a solution to this gaping hole in the Stark legislation. A solution is necessary which affords patients access to highly skilled and convenient non-radiologist imaging care, while protecting our health care system from unsavory financially driven imaging utilization.

I have a solution for you to consider for both of these points. I will describe how diagnostic imaging is delivered in America. At NIA we organize this into three distinct areas: (1) ordering of imaging care; (2) delivery of imaging care; and (3) payment of imaging care.

Ordering, Delivery and Payment are the most quintessential elements of any capitalistic system whether it is widgets, or automobiles or diagnostic imaging. Scarcely anywhere is there more need in America for more governmental guidance on safety, clinical assurance and financial appropriateness than in the area of diagnostic imaging. It is also my firm belief that ordering, delivery and payment of imaging must be addressed holistically to achieve the goals of improved clinical care, patient safety and financial affordability. MedPAC and the DRA legislation have admirably addressed some of the delivery and payment issues – through highly justified pricing and billing solutions.

However, ordering of imaging tests, which predominantly drives volume and cost more than any factor has been, respectfully, somewhat under addressed. Let me zero in for a moment

on the ordering of imaging care. Remember, while self-referral is a justifiable concern, the vast majority of imaging exams in this country are ordered by physicians who will not render or economically benefit from their generation. As mentioned previously, these are the physicians who are, in every state in this nation, bombarded with a flow of innovative but confusing and costly new technology or applications of existing technology, patient demand and an uneasy concern over applying justifiable conservative ordering in the face of rampant malpractice litigation.

The appropriate ordering of imaging care requires evidence based support which tests clinical value. We find the most effective means to do this is through patient and physician education coupled with convenient physician decision support (founded in evidenced based medicine) at the point of ordering. Across this nation, we are providing physicians with clinically invaluable decision support (300,000 times per month) through 4 minute web and telephonic interaction and connection with board certified radiologists, while the patient is in the office. This service enlightens physicians, protects patients from clinically unwarranted and unsafe procedures and saves our managed care partners hundreds of millions of dollars per year by eliminating wasteful imaging exams. I strongly encourage this subcommittee to examine this methodology because we think it provides a solution transferable to the public health insurance programs. As you will hear, we feel this enlightened approach can unlock tens of billions in clinically warranted economic savings for our country.

NIA is confident that the empirical data demonstrates that clinically appropriate radiology benefits management is the responsible approach that offers the necessary cost reductions while ensuring the safety of the patients who require treatment. Our experience in radiology management has led us to three conclusions that I want to share with you. Congress should not shy away from a robust dialogue on the issue because:

1. Roughly One-Third of Advanced Imaging Tests Are Inappropriate or Do Not Contribute to Health Outcomes. We have first-hand experiences and successes managing imaging benefits for Medicare Advantage plans. We have found about one-third of advanced imaging tests are either inappropriate or do not contribute to the physician's diagnosis or ultimate health outcomes. For example, such tests could possibly be performed more efficiently and economically, and achieve the same clinical/diagnostic goal, with traditional technology. Applied to the nation as a whole, this data strongly suggests that efficient radiology benefit management could cut America's radiology expenditures by $20 billion to $30 billion annually.

2. There Are Inherent Risks In Radiation Exposure. There is no question that patient care is vastly improved when diagnostic imaging services are performed, but the inherent risks associated with radiation exposure should not be trivialized. The medical consequences that result when patients incur too much exposure to radiation may not be apparent to a physician when identifying what is in the best interest of the patient. This has the potential of trying to solve a problem by creating a brand new health risk to the patient.

3. There is a Substantial Incidence of Self-Referral for Nuclear Medicine Services. In our experience, self-referral is a driver of escalating imaging costs, despite nuclear medicine's approval as designated health service under the Stark Act. Since imaging services can be performed in referring physicians' offices under an exception, growth in self-referrals will undoubtedly continue to proliferate with little or no exceptions, despite the change in CMS rules. Our data shows that 68 percent of the encounters of nuclear cardiologists who made referrals for nuclear cardiology services within a major health plan in 2003 were self-referrals. When the data is stratified another way, virtually all providers whose self-referral rates were classified as "high" were nuclear cardiology referrals (1,045 out of 1,050). This practice must stop.

Taken together, the findings outlined above, and discussed in more detail below, suggest that the fiscal integrity of Medicare and Medicaid as well as the health and safety of beneficiaries are at risk with the explosive growth in imaging spending. We endorse the concept of cost controls and radiology benefits management and can demonstrate clinically appropriate and safe imaging management.

1. Roughly One-Third of Advanced Imaging Tests Are Inappropriate or Do Not Contribute to Health Outcomes.

In our experience, about one third of advanced imaging tests are either inappropriate or do not contribute to the physician's diagnosis or ultimate health outcomes. We maintain the nation's largest clinical and financial database that includes over 150 million imaging encounters. Among a variety of uses, the data enables us to provide the industry's most advanced algorithms to enhance the quality and efficiency of radiology modality choices, while providing doctors and plan partners with important information on radiology ordering practices.

NIA has drawn on its clinical and financial database from a sampling of pre-authorizations submitted through major managed care organizations for the period of September 1, 2004 through August 31, 2005. The data from our sample show that almost one-third of all requests for imaging services involved multiple procedures using the same modality for related body parts during a single clinical session. Specifically, there were more than 330,000 requests in our sample, and, of these, nearly 110,000 involved multiple procedures. In all, the data in our sample show a substantial incidence of requests for multiple procedures in a single session.

In another instance, NIA turned nearly 25 percent annual growth in Medicare Advantage imaging claims into a reduction of nearly 20 percent in the first year. This swing of nearly 45 percent exceeded NIA's management of the plan's commercial imaging benefit. Furthermore, this reduction helped the plan realize a savings of nearly $6.50 in its per-member per-month Medicare Advantage imaging rate, four times the per-member per-month savings realized on the non-Medicare side.

2. There Are Inherent Risks In Radiation Exposure.

As important as responsible cost management is, patient safety always comes first. We strive to help good doctors become better doctors. While patient care is vastly improved when diagnostic imaging services are performed, there are inherent risks associated with radiation exposure that should not be trivialized. We live in a society where an abundance of caution often supersedes what is an appropriate course of action. A doctor's assessment of the appropriateness of radiation exposure to a patient requires a subjective evaluation of the potential benefit to the patient in relation to the additional radiation risk resulting from the imaging test.

The medical consequences that result when patients incur too much exposure to radiation may not be top-of-mind for a physician when identifying what is in the best interest of the patient, which has the potential to cause a brand new health risk. For example, a July 2005 National Academy of Sciences report underscored the fact that ***any*** level of ionizing radiation may have carcinogenic effects[1]. NIA strives to mitigate overexposure to radiation by tracking patient dosages, through a combination of recent claim and pre-authorization data, and, through management techniques, preventing unnecessary and harmful exposure to clinically unnecessary and potentially dangerous radiation.

Radiology benefits management can reduce the dangers caused by too much radiation from too many procedures. We work with our clients to focus on patient exposure to radiation and the need to balance the risks and benefits of those procedures through utilization management.

3. There is a Substantial Incidence of Self-Referral for Nuclear Medicine Services.

Another driver of the cost boom is the ever-growing entrepreneurial physician network, comprised of doctors who have purchased imaging equipment and have a desire to see a return on their investment. Self-referral practices are emerging everywhere. Specialty and primary care practices are buying their own CT and MRI scanners, entering special lease agreements, and self-referring their patients while outsourcing the radiologists' interpretations. A May 3, 2005 article in the *Wall Street Journal* examined "increasingly common" arrangements in which physicians

[1] National Academy of Science Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, National Research Council 2005

contract with medical imaging centers to "structure referral deals as leases, under which physicians, each time they send over a patient, are renting the scan center's facilities and employees." Under the arrangements, the medical imaging centers charge physicians a flat rate per scan and physicians can bill health insurers for the scans at the reimbursement rate in their area.

Information drawn from NIA's clinical and financial database supports the view that there is substantial incidence of self-referral for nuclear medicine services and that self-referring providers are much more likely to order these types of services than those who do not self-refer and they do so with no concomitant clinical justification. Specifically, we reviewed data on nearly 1,000 providers who made referrals for nuclear cardiology services within a major health plan in the period June 2002 through May 2003. In all, 1,605 referrals for these services were recorded, of which 1,096 – 68 percent – were self-referrals.

We also stratified our data to identify groups of providers whose self-referral rates were classified as "high," "medium," and "low." In the "high" group of providers, virtually all nuclear cardiology referrals – 1,045 out of 1,500 – were self-referrals, while in the "low" group virtually none of the referrals were self-referrals. Using these classifications, we were able to determine that self-referring providers in the "high" group were four times more likely to make a nuclear cardiology referral *of any kind* than were providers in the "low" group.

It is clear that self-referring is a culprit for climbing imaging costs, despite nuclear medicine's approval as a designated health service under the Stark Act. Since imaging services can be performed in referring physicians' offices under an exception, growth in self-referrals will undoubtedly continue to proliferate with little or no exceptions, despite the change in CMS rules. This practice must stop. Self-referral is manipulating a loophole that must be closed in order to establish parity and allow the true intent of the Stark Act to properly police the imaging community.

CONCLUSION: A PROPOSED SOLUTION FOR MOVING FORWARD: PRIOR AUTHORIZATION AS A CHECK FOR IMAGING COSTS

NIA's safeguards ensure that patients receive clinically appropriate and safe imaging in an efficient and timely manner, but we recognize that pre-authorization programs are not always embraced by physicians. Therefore, we endeavor to expedite the pre-authorization process. Within minutes, referring physicians or their clinical staffs receive approval or are notified that the decision has been forwarded for clinical consultation by a Board-Certified Radiologist or physician. The best radiology professionals in medicine, including our over 60 board-certified radiologists and other specialists handle those cases that require further judgment on a peer-to-peer consultative basis. If a request is denied on a clinical basis, our reviewers always recommend an appropriate alternative procedure. No request is ever denied without a concerted effort by our physicians to discuss the matter with the referring physician in peer-to-peer dialogue.

Out safeguards ensure that patients receive clinically appropriate and safe imaging in an efficient and timely manner, but we recognize that pre-authorization programs are not always embraced by physicians. We endeavor to expedite the process. Within minutes, referring physicians or their clinical staff receive approval or are notified that the decision has been forwarded for clinical consultation by a board-certified radiologist or physician. Expert physicians, including over 60 board-certified radiologists and other specialists, handle those cases that require further judgment on a peer-2-peer consultative basis. If a request is denied on a clinical basis, our reviewers almost always recommend an appropriate alternative procedure. No request is ever denied without a concerted effort by our physicians to discuss the matter with the referring physician in peer-2-peer dialogue.

NIA also publishes up-to-date clinical guidelines covering the common reasons for requesting imaging tests. These guidelines have been developed from practice experience, literature reviews, specialty criteria sets, and empirical data from credible medical organizations such as the American College of Radiology, the American College of Cardiology, and other specialty doctor groups. Our proprietary algorithms are developed and updated using NIA's imaging database with reference to the latest medical literature. The algorithms are regularly reviewed and approved by state Imaging Advisory Committees, health plan Chief Medical Officers, state medical societies, and updated by our database of encounters which grows by 300,000 calls per month.

We believe that there are a number of options available to both Congress and the Administration as a means of identifying and deploying cost-cutting initiatives in imaging.

Congress could enact two of the 2005 MedPAC recommendations which require federal standards for physicians who perform diagnostic imaging procedures, as well as for those physicians who read and interpret the images. While the establishment of federal standards for medicine is admittedly a difficult and complex procedure, there is a precedent for setting these standards. For example, the Mammography Quality Standards Act (MQSA) that was first enacted in 1992 and reauthorized three times since could justify a legislative effort to set federal standards for other forms of diagnostic imaging. Furthermore, another law that demonstrates that the federal government does have a role, and responsibility, to set medical standards is the Clinical Laboratory Improvement Amendments (CLIA), which was enacted by Congress nearly 20 years ago in 1988. Just as MQSA established standards for mammography facility, CLIA did the same for laboratory testing.

We believe that these two laws illustrate a federal precedent for establishing medical standards and regulating the practice of medicine. Patient safety was the genesis behind both MQSA and CLIA, and we believe that the same argument can be applied more broadly across the spectrum of diagnostic imaging procedures. Clearly, patient safety is an issue in diagnostic imaging, e.g. exposure to excessive radiation, the improper handling of a patient, and the accuracy and reliability of tests.

Second, we believe that there are opportunities with Congress and CMS for the development of creative new techniques in the management of radiology services. For example, radiology benefits management could be a key enabler of "pay for performance" and other value-based purchasing systems planned for Medicaid, Medicare Advantage, and fee-for-service Medicare.

We have had some discussions with CMS officials on this topic, and we welcome any opportunity to broaden our dialogue on this issue. There is the potential of advancing this issue under a pay-for-performance proposal where payments to imaging providers are linked to quality and efficiency, which would address the issue of exploding costs. We look forward to the opportunity to collaborate with Congress, the Administration, and other stakeholders to develop an appropriate pilot program that strikes a balance between cost savings and patient safety. NIA recognizes that these are lofty goals being suggested at a time when the Congressional calendar is winding down. But, sound public policy initiatives require visionaries and forward thinkers, and the time is now to consider the framework for a pragmatic healthcare agenda for the 110th Congress and beyond.

Thank you for the opportunity to appear before you today. I would be delighted to answer any questions you may have.

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