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United States Senate
Committee on Health, Education, Labor & Pensions
"Crossing the Quality Chasm in Health Reform"
January 29, 2009

Good morning. Thank you, Mr. Chairman and members of the Committee, for the opportunity to testify before you. My name is Nancy Davenport-Ennis, and I am the Founder of the National Patient Advocate Foundation and the Patient Advocate Foundation. National Patient Advocate Foundation is a policy organization based in Washington, D.C. that is dedicated to providing the patient's voice in order to improve access to health care at the federal and state levels. Patient Advocate Foundation is a direct patient services organization which provides case management services to patients throughout the country seeking information and assistance for access to care issues resulting from a diagnosis of a chronic, debilitating or life-threatening disease. My testimony is grounded in more than 12 years of documentation across 300,000 closed patient cases reporting the concrete gaps and failures in our current healthcare delivery and financing systems.

When the Institute of Medicine published their report, *"Crossing the Quality Chasm: A New Health System for the 21st Century"*, back in March 2001, the hope was that doctors, elected officials and patients would demand that we fix our payment policies which have been reimbursing for unnecessary and ineffective care, adopt electronic medical records to help coordinate care in our complex healthcare system, and provide doctors with independent clinical research to help guide them when prescribing a treatment protocol. Unfortunately, almost eight years have passed and progress is moving very slowly. In health information technology, only 10-30 percent of primary care providers utilize

electronic medical records (EMRs). In other countries, such as the United Kingdom and Australia, adoption is around 75 percent.[1] In terms of treatment guidelines, while we have very specific and notable guidelines in cancer that is not the case for many other chronic diseases in the country where we still lack good scientific and evidence-based research to guide many clinical diagnoses. There are gaps in the utilization of treatment guidelines and in the availability of guidelines for specific patient and/or disease populations, such as the pediatric population. These gaps impact all healthcare stakeholders, including the patients I am here to represent.

Even though the United States spends 16 percent of GDP on healthcare, which is more than any other industrialized country, there is significant evidence that the quality of medical care trails other developed nations. The U.S. continues to fall behind other industrialized countries when comparing various dimensions of health system performance including: healthy lives, quality, access, efficiency, and equity. In The Commonwealth Fund's National Scorecard on U.S. Health System Performance, the U.S. achieved an overall score of 65 out of 100. Compared to 19 countries, the U.S. now ranks last on a measure of mortality amenable to medical care. However, the report did show that hospitals are showing "measureable improvement on basic treatment guidelines for which data are collected and reported nationally on federal web sites."[2]

Our system often reimburses for services independent of quality measurements. Currently, many providers lack incentive to promote and prescribe preventive care for their patients. Addressing these systemic reimbursement issues could greatly improve the quality of medical care patients receive. NPAF recommends we undertake reimbursement reform and include direct processes to incent providers to provide quality care.

[1] R Atkinson, D Castro & S Ezell. The Digital Road to Recovery: A Stimulus Plan to Create Jobs, Boost Productivity and Revitalize America. The Information Technology & Innovation Foundation, January 2009.
[2] Why Not the Best? Results from the National Scorecard on U.S. Health System Performance. The Commonwealth Fund Commission on a High Performance Health System, July 2008.

In 2006, a study by The Commonwealth Fund found that one-third of patients reported a medical, medication or laboratory error during the previous two years.[3] These errors result in the unnecessary deaths of nearly 100,000 patients annually.[4] In addition to the deaths that medical errors impose, the total financial cost of preventable adverse events, including lost income, lost household functioning, disability etc, are estimated to be $35 billion a year.[5]

The Agency for Healthcare Research and Quality (AHRQ) estimates that treating the nation's 10 most expensive medical conditions cost nearly $500 billion in 2005. The conditions beginning with the least expensive include: normal childbirth, back problems, osteoarthritis and other joint diseases, diabetes (type 1 & 2), hypertension, asthma and chronic obstructive pulmonary disease (COPD), mental disorders including depression, cancer, trauma disorders, and heart disease. Many of them, including cancer, heart disease and diabetes, are common, chronic conditions that may be reduced and in some instances prevented. Promoting and rewarding high-quality health care will help reduce unnecessary healthcare spending as we move away from acute, episodic care needs and towards disease prevention and management.

Transforming our healthcare system into a system that incents high-quality healthcare services is a long-term initiative, but there are steps we can take now to improve the care patients receive throughout the country. In the last two years, the World Health Organization's (WHO) Safe Surgery Saves Lives program implemented a 19-item surgical safety checklist in eight countries to improve patient care and reduce complications and death associated with surgery. Similar to the checklist a pilot runs through before takeoff, surgeons and nurses participating in the study completed a series of basic safety checks before and after each operation. The study found that the checklist cut surgical deaths and complications by a third. Study authors say that work is already

[3] The Commonwealth Fund Commission on a High Performance Health System, Why Not the Best? Results from a National Scorecard on U.S. Health System Performance. The Commonwealth Fund, September 2006.
[4] J Corrigan, L Kohn, M Donaldson, eds. To Err is Human: Building a Safer Health System. Committee on Quality of Health Care in America, Institute of Medicine, The National Academies Press, 1999.
[5] J Corrigan, L Kohn, M Donaldson, eds. To Err is Human: Building a Safer Health System. Committee on Quality of Health Care in America, Institute of Medicine, The National Academies Press, 1999.

underway to develop additional checklists for maternity and childbirth, heart disease, pneumonia, HIV and mental health. This WHO study illustrates that something as simple as a checklist can improve quality and safety in our healthcare system in ways that will be of enormous benefit to patients. Study authors assert that few U.S. hospitals currently use these surgical safety checklists. While various hospitals and physicians have developed checklists, utilization needs to be more widespread in our health care system.

National Patient Advocate Foundation believes our healthcare system should incent quality and promote transparency to encourage patients to be better purchasers of health care. The use of quality measures, comparative effectiveness research, medical guidelines and evidence-based medicine are tools that should be utilized to help improve the level of quality care patients receive in our healthcare system.

Quality healthcare coverage leads to improved outcomes and better coordinated care for patients. One tool that has proven valuable to patients and providers is health information technology. In the United States, the Veterans Administration (VA) leads in complete adoption of health information technology (HIT). In addition, institutions such as the Cleveland Clinic have universally adopted HIT. The American Health Information Community, a federally chartered advisory committee, officially certified HIT systems and developed interoperability standards so that with financial support, such as the funding included in the economic stimulus, providers can adopt and use HIT thus reducing medical errors.

The parents of a 13-year-old patient sought the assistance of Patient Advocate Foundation after their daughter began experiencing severe headaches that caused extreme pain and vomiting. Even after her pediatrician ordered X-rays and other tests, no diagnosis was reached. The family remained concerned, however, and after being provided a disc which contained all of the tests performed as well as radiology reports, the parents made an appointment with a pediatric neurologist. The neurologist and a pediatric radiologist, who specialize in neurological disorders, were able to review thoroughly the patient's electronic medical records and all of the tests included on the disc and to diagnose the girl

with Chiari Malformation, an abnormality in the lower part of the brain. The appointment with the specialists had been scheduled in very short order due to the immediate availability of the patient's health record in an electronic format. This example illustrates how health information technology allows instant access to medical records resulting in improved patient care.

The National Comprehensive Cancer Network (NCCN) is dedicated to improving the quality and effectiveness of care provided to cancer patients. Through the leadership and expertise of clinical professionals at their member institutions, NCCN develops clinical practice guidelines appropriate for use by patients, clinicians, and other healthcare decision makers. NCCN guidelines are considered "the gold standard" because they are developed by medical professionals adhering to strict standards on conflicts of interest. Our healthcare system should support and adhere to medical guidelines that are independently developed by skilled medical professionals and free from conflicts of interest. When assisting patients, case managers at Patient Advocate Foundation frequently cite medical guidelines when successfully appealing to insurance companies that have denied a particular treatment protocol.

NCCN guidelines are practical, up to date, easily accessible online at no charge, and relevant to a physicians' practice. These guidelines are developed by panels of unpaid, multidisciplinary experts including surgeons, nurses, patient representatives, radiation therapists, hematologists and clinical oncologists, who to date, have developed over 100 guidelines for therapeutic interventions covering 98% of all cancers. The guidelines specify best practices from a point of screening and diagnosis, through development of treatment plans, including all protocols selected, as well as maintenance and follow-up recommendations. NCCN guidelines also provide specific information concerning supportive care needed for patients to tolerate and respond favorably to therapeutic interventions. The American Society of Clinical Oncology (ASCO) has also developed guidelines specific to cancer that are focused on technology assessments, which evaluate the appropriate use of specific therapeutic interventions.

Other disease areas, including cardiology, also develop and utilize national guidelines. Guidelines are a tool routinely used in the field of cancer by treating physicians, patients, nurses, social workers and insurers. In addition, PAF case mangers use guidelines frequently when assisting patients with pre-authorizations or when negotiating appeals. Finally, the Centers for Medicare and Medicaid Services (CMS) uses NCCN guidelines to make coverage determinations about the use of off-label drugs and biologics in cancer care as well as in technology assessments.

Patient Advocate Foundation predominantly assists patients with healthcare access issues, but many patients also have underlying issues with the quality of care they are receiving. Approximately 78 percent of patients contacting Patient Advocate Foundation in 2007 had a cancer diagnosis.[6] After a serious diagnosis like cancer, many patients wish to seek a second opinion, but insurance companies are increasingly refusing to cover this important service. Research conducted by the University of Michigan Comprehensive Cancer Center found that more than half of breast cancer patients who sought second opinions received a change in their recommended treatment plan.[7] For some patients, a change in diagnosis and/or treatment results in less-invasive and higher-quality care.

Clinical research has improved the treatment of various diseases and has helped doctors make well-informed decisions about what particular therapy is best for their patients. In cancer, clinical trial research has vastly improved survival rates for many cancers and led to improved cancer care. However, according to the National Cancer Institute, less than 5 percent of adults diagnosed annually with cancer enroll in a clinical trial.[8] Broader enrollment in cancer clinical trials will enable researchers to discover new and better ways to treat and prevent cancer leading to higher-quality cancer care for patients. Unfortunately, access to clinical trials is decreasing here in the U.S. because many companies are moving their clinical trials abroad where it is not only less expensive, but where accrual rates are improved thus allowing trials to close earlier. While this may seem like a positive development because it may lower the cost of drug development and

[6] Patient Data Analysis Report. Patient Advocate Foundation, February 2008.
[7] University of Michigan Comprehensive Cancer Center, November 2006.
[8] Boosting Cancer Trial Participation. National Cancer Institute, February 2006.

reduce the clinical time to accrual completion, our nation must address disparities in outcomes from one population group to another. These very disparities may be extrapolated to the whole U.S. population who may ultimately engage in the treatment protocols resulting from the trial. NPAF encourages the federal agencies to work collaborative with manufacturers to address regulatory barriers that may contribute to the exodus in recent years of these clinical trials.

Patient Advocate Foundation assisted a 45 year old woman diagnosed with an adrenal tumor who was unable to locate treatment for her rare cancer. After accumulating nearly $10,000 in unpaid medical bills for out-of-network care, she was told she had 6 months to live and she should go home and prepare herself and her family. Immediately after contacting PAF, the patient's case manager began investigating clinical trials. PAF was successful in enrolling the patient in a clinical trial at the National Institutes of Health (NIH); the trial was successful, and the patient is cancer free today, three years after enrollment in the clinical trial. Unfortunately, many patients are unaware that clinical trials may be a good treatment option for them and seek less effective and/or lower-quality care as a result.

Patients seeking the assistance of Patient Advocate Foundation describe many reasons for not enrolling in clinical trials including: high costs and/or lack of insurance coverage; trial location; age restrictions; fear that the trial will reduce their quality of life; and fear they may receive a placebo. Patient Advocate Foundation assisted a 30 year old man diagnosed with stage IV olfactory neuroblastoma, a pediatric disease that is only seen in 1 percent of adults, who had difficulty enrolling in an appropriate clinical trial. The PAF case manager facilitated an agreement with the sponsors of a pediatric clinical trial at Duke University so that the clinical trial could be administered at the University of Alabama at Birmingham Hospital where the patient was located. Enrollment in this clinical trial ensured the greatest opportunity for control of disease for the longest period of time.

In 2005, cancer expenditures cost patients, insurers and the government $69 billion making it one of the top ten most expensive diseases. Clinical trials are critical in fighting cancer and improving the quality of care that cancer patients receive. We must strengthen our efforts to enroll patients in clinical trials if we wish to understand and effectively treat some of the most costly diseases.

The IOM report, *Crossing the Quality Chasm*, explains that redesigning the healthcare delivery system will require many changes. One of which, applying evidence to healthcare delivery, can be partially addressed with adoption of proven medical guidelines.

National Patient Advocate Foundation supports comparative effectiveness research to determine the comparative clinical effectiveness of various treatment options for patients with chronic and debilitating diseases. However, it is our belief that using comparative effectiveness research findings to limit access, deny treatment or reimbursement will not benefit patients or our healthcare system as a whole. A one-size-fits-all approach will not help us achieve a high-quality healthcare system since we know that patients can have very different reactions to certain medications or therapies. Moreover, denying access to some of the newer and/or more expensive treatments will only move us further away from personalized medicine which should be our ultimate goal. As we continue to learn more about genetics and gene profiles, science will enable us to further tailor medical care to an individual's needs which will benefit patients and payers by eliminating ineffective and sometimes costly treatments. Comparative effectiveness research should be used as a tool for doctors and patients to determine the best course of action for individual patients. Similar to clinical trials, comparative effectiveness research and medical guidelines must be sensitive to different patient populations since we know that ethnic populations react differently to medical treatments, as do patients with multiple co-morbidities.

In addition, National Patient Advocate Foundation strongly advocates that all relevant stakeholders, including patient and consumer groups, representatives from the public and

private sectors, such as government, physicians and other healthcare providers, medical specialists, insurers, and manufacturers of drugs and medical devices, should be involved in every step of the process, from setting the research agenda, and developing study methodology, to the translation and dissemination of findings.

National Patient Advocate Foundation strongly supports the goal stated in the IOM report:

> "narrowing the quality chasm will make it possible to bring the benefits of medical science and technology to all Americans in every community, and this in turn will mean less pain and suffering, less disability, greater longevity, and a more productive workforce."