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Joan Claybrook, President

**Testimony of Frank Clemente
Director, Public Citizen's Congress Watch
On the "Medical Malpractice Reform Act of 2005 (Title II)," B16-418
Committee on Health of the Council of the District of Columbia
November 21, 2005**

Chairman Catania, thank you for this opportunity to testify on the important issue of improving patient safety in the District. Let me begin by publicly thanking you for asking me to serve on the Health Committee Task Force on Medical Malpractice that you created earlier this year. I appreciate your efforts to bring both sides together on these issues and actually get something done that will benefit District residents, of which I am one.

I will confine my remarks to Title II of your legislation, which would establish a mandatory adverse event reporting system for the District. Sid Wolfe, director of Public Citizen Health Research Group, will testify about Title I of the legislation on the later panel.

Public Citizen believes passage of an adverse event reporting system is a very important step on the way to improving patient safety of local residents. There is a growing trend by state governments in this direction. As of September 2005, 24 states had already passed legislation or regulations related to reporting of adverse events. This is documented in a new report prepared by the National Academy for State Health Policy, which I strongly urge you and your staff to review, as it provides an excellent analysis of adverse event reporting systems that currently exist in the states.¹

One very clear conclusion emerges from all the research on medical malpractice by the Institute of Medicine (IOM) and others: medical malpractice is a major health and social problem. It is a tragedy that *preventable* medical errors kill more people in the United States every year than automobile and workplace accidents combined. The IOM has estimated that medical errors and negligence in *hospitals* alone kill as many as 98,000 patients a year, compared with 44,509 highway deaths and 5,559 workplace deaths.² The cost of these in-hospital preventable medical errors to the American economy is estimated to be as much as \$29 billion annually.³ Preventable medical *injuries* – as opposed to deaths – affect even more people and cost even more money.

Why should District residents be concerned? Extrapolation of IOM data to the District means that nearly 200 patients are killed in District hospitals each year by preventable medical errors, and cost the District up to \$59 million. The human tragedy caused by these unnecessary deaths and the social and economic consequences for their families and our community, require Council action.

It's against this stark background that the Task Force you established wisely proposed the creation of a modest adverse event reporting system as one of its key recommendations. My testimony will focus on how to build on this initial proposal and hopefully strengthen it.

Interestingly, just one day after the Task Force completed its report on July 28, 2005, the bipartisan Patient Safety and Quality Improvement Act of 2005 became federal law.⁴ The Patient Safety Act (PSA) encourages providers to report medical errors by creating a secure environment, in which patient safety organizations are established and operated to collect, analyze and make recommendations about adverse events that will improve patient safety. The federal Agency for Healthcare Research and Quality (AHRQ) is now developing guidelines to implement the PSA.

We recently engaged some of their top officials in a conversation about the adverse event reporting system proposed in your legislation. We also asked them if they would be willing to assist you and all of the stakeholders in developing a first-rate adverse event reporting system. The recommendations in this testimony for strengthening the adverse event reporting proposal are based, in part, on their recommendations. I am also happy to say that their initial reaction to assisting the District in this effort was very favorable. I would like to work with you and your staff to take that discussion to the next level with the relevant stakeholders.

AHRQ officials believe the PSA creates a foundation in certain areas that state and local organizations should use when developing their own reporting systems. Public Citizen also believes that the District should look beyond the PSA and consider adopting several practical measures modeled after the Pennsylvania system, which will assist in reaching our mutual goal of improving patient safety.

In the Appendix, we have included a side-by-side comparison of your legislation with the Pennsylvania patient safety system, which Public Citizen considers to be a very good model. For reference, we have also included Mayor Williams' proposed adverse event reporting system.

Public Citizen is making suggestions that go well beyond those put forward by the Task Force and in your legislation. We don't do that lightly. We are looking to promote further dialogue about and deeper understanding of the complexity of these issues with all the stakeholders in the hope that we can do better than our original product. The bottom line for Public Citizen is that we want to do what is best for the patients of the District. It would be a shame to adopt a system that does not take full advantage of the protections and opportunities presented by the Patient Safety Act and the experience of other states. (Who was it who correctly said, "If a thing is worth doing, then it is worth doing well!")

Briefly, here are our suggestions on how this Committee should modify and strengthen the proposed adverse event reporting system.

1. The District should create an independent patient safety organization whose activities meet all the requirements of the Patient Safety Act.

Section 203 of your bill envisions the creation of a centralized reporting system, headed by a system administrator, within the Health Professional Licensing Administration (HPLA). As you know, the HPLA helps protect public health and safety by providing staff support to the

professional boards and advisory committees that regulate and discipline the practitioners of the respective health professions in the District. Establishing the adverse event reporting system within the HPLA would represent a co-mingling of disciplinary and learning functions that presents a potential conflict of interest that should be avoided.

The PSA establishes the criteria necessary for a state patient safety organization to be certified. If the patient safety entity is a component of another organization (i.e., the HPLA), federal criteria for certification requires that (a) the entity maintains patient safety work product separately from the rest of the organization and establishes appropriate security measures to maintain confidentiality of the work product; (b) the entity does not make unauthorized disclosure to the rest of the organization; and (c) the mission of the entity does not create a conflict of interest with the rest of the organization.⁵

We believe the better course is to create a separate and independent patient safety organization (PSO) outside the HPLA that eliminates all concerns about security and conflict of interest. The HPLA serves health professionals first. Patient safety organizations are intended to serve patients first. Given the primary goal of patient safety, AHRQ officials strongly recommend creation of a separate and independent patient safety entity. Incidentally, Pennsylvania and Maryland both have created independent patient safety boards.

Another requirement of the PSA is that the patient safety organization must have an appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals. Your bill is silent as to qualifications for the system administrator and how the administrator will provide or obtain the expertise to carry out the tasks assigned. We believe the District PSO should be empowered to employ or contract with a paid director and other staff as needed to execute the duties of the PSO.

Nor does the bill provide for membership or participation in the PSO by patient and consumer representatives. Pennsylvania and Maryland have provided their independent board with membership drawn from the medical and patient communities, which we think is crucial. Of course, both the mayor and the city council should appoint members to the PSO, and those members should serve without compensation.

Finally, we believe the PSO should be required to publish an annual report using aggregate data that summarizes the information contained in annual incident reports, such as the number of incidents, the number of incidents by category, trends in reporting over time etc. Such information would enable policymakers and the public to track the progress of implementation of the law. It would also help identify specific areas of frequent safety problems that could be dealt with, all without violating the confidentiality of the reporting hospital. Several states are now doing this – Florida, Maine, Maryland, Minnesota, Nevada, New York, Oregon, Pennsylvania, and Utah.

2. The District should adopt the privilege and confidentiality provisions of the Patient Safety Act.

One of the principal concerns of providers has been their reluctance to report mistakes because they feared doing so would lead to increased litigation. Section 206 of the bill attempts to address this concern by providing that information maintained within the system shall be

confidential and protected from use in civil or criminal proceedings. Virtually all patient safety systems whose main objective is to learn from past mistakes recognize the need to provide similar protection.

This is one of the main objectives of the Patient Safety Act. That statute carefully defines patient safety work product and provides a privilege against unauthorized disclosure of patient safety work product that supercedes any other provision of Federal, State or local law. Unfortunately, the definition used in your legislation does not use the same terminology as the PSA and may lead to confusion and create gaps.

More importantly, your legislation does not make it clear that a patient's medical record, billing and discharge information or other original patient or provider records are not included in the definition of patient safety work product. Nor does the definition make it clear that information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system is not included in the definition of patient safety work product.

The PSA also authorizes the Secretary of Health and Human Services to facilitate the creation of a network of patient safety databases as a resource for providers and patient safety organizations. The ultimate goal is to facilitate a national roll-up of adverse event data to improve patient safety on a broad scale.

In order to eliminate potential confusion, unnecessary litigation and promote the fullest exchange of patient safety information between certified systems, we recommend that the District adopt the definitions and privileges of the Patient Safety Act.

3. The District should provide specific guidance and incentives to local medical facilities regarding the adoption of internal adverse event reporting systems within their facilities.

Section 205 of the bill simply mandates that medical facilities in the District shall submit biannual reports on adverse events to the system administrator. The bill provides neither sanctions nor incentives to encourage participation. Nor does it outline a set of requirements that would revolutionize the commitment and focus on patient safety. The IOM's study of reporting systems concluded that their success depend on structure, training and education, and clear standards, definitions and tools. Feedback to reporting entities strongly influences participation levels.

The bill should provide that structure, since participation is mandatory, by outlining what is expected of the facility. Pennsylvania has implemented guidelines that are calculated to obtain maximum participation and benefits. In calendar year 2004, the Pennsylvania Patient Safety Authority received nearly 71,000 reports of serious events and incidents.⁶

Working from the Pennsylvania model, we believe each facility should develop and implement an internal patient safety system that includes, but is not limited to:

- (a) Designation of a patient safety officer;
- (b) Establishment of a patient safety committee within the facility;
- (c) A system for health care workers to report adverse events to the officer 24 hours per day;

- (d) Education of all facility employees on the existence of the patient safety system, encouragement to participate and the requirement that participation is a condition of employment;
- (e) Requirement that adverse events be reported within 24 hours of occurrence or discovery; and
- (f) A requirement that the patient or patient's family, as appropriate, be notified by the facility of adverse events that cause death or serious injury within seven days of the occurrence or discovery of the event.⁷

At first blush, this last requirement might seem controversial – but it shouldn't be. This was a major recommendation of the IOM in its groundbreaking report that breathed life into the patient safety movement. Moreover, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the private regulatory body for hospitals, requires this.

We recommend that each health facility's proposed system should be required to be submitted to the District's PSO within six months of the adoption of the District system. Unless the District PSO disapproves the system within 60 days of submission, it would be considered approved.⁸

The central purpose of this adverse event reporting system is to learn from past mistakes. The system should not be punitive in nature. Rather than provide sanctions for failure to participate, we believe the system should develop incentives to encourage participation. To measure that participation and the quality of that participation, we believe the District PSO or its representative should periodically audit each facility. Audits, for example, are used by JCAHO to measure compliance. This should be carried out in accordance with audit standards developed by the District PSO in consultation with District medical facilities. The audit should measure operation of the facility system, employee education, satisfaction and knowledge of the system, employee interviews concerning their experience with the system, and other relevant criteria. The audit should occur without advance notice to the facility.

4. An adverse event reporting system needs clear, inclusive and expanded definitions of reportable events, and it needs uniform reporting formats.

Section 202 of the bill defines adverse event as “an event, occurrence or situation involving the medical care of a patient by a healthcare provider that results in death or an unanticipated injury to the patient that is **substantial in nature.**” (emphasis added) This definition is clearly limited to “serious” events that cause death or substantial injury.

In order to obtain maximum benefit from the system, the reporting of incidents that do not cause injury but might have done so – the so-called “near-misses” – should be included in the definition of reportable events. This was a major recommendation in the 1999 IOM report, in addition to the reporting of serious adverse events, which forms the foundation for the development of reporting systems today.

Safety experts say that frequently as much is learned about how to improve the health care system from a near-miss as from a death or serious injury. Pennsylvania provides a good example. That system requires that “serious events” (those that cause death or compromise patient safety and result in unexpected injury requiring additional care) and “incidents” (an event which could have injured the patient but did not injure or require additional care, the so-called “near-miss”) be reported.⁹ Of the 70,851 reports received in 2004: 95 percent of all reports were

incidents (near-misses) in which the patient was not harmed; 5 percent of all reports were serious events involving some level of injury to the patient.¹⁰

Almost every state that has adopted a reporting system has its own list of reportable events with various definitions. This has limited the potential value from exchange and analysis of information between states and the ability to roll data up into a national system. Now, with passage of the Patient Safety Act, the HHS Secretary is working on determining common and consistent definitions, common formats for the reporting to and among PSOs, and a standardized computer interface for the analysis and processing of patient safety work product.

For example, one reporting format problem that stands out is Section 205 of the bill, which requires that every report of an adverse event contain “the patient’s full primary health record.” The requirement that the facility submit the complete medical record may be overkill. Hospital records frequently run to hundreds of pages. Can you imagine the human resources necessary to analyze mountains of medical records? A better alternative is to require submission of information on a standard secure electronic format.

The District should adopt a broad and flexible definition of adverse events and uniform reporting formats in order to take full advantage of the opportunities available under the Patient Safety Act.

5. The District should provide funding for the adverse event reporting system.

Your legislation includes no provision to fund the mandatory adverse event reporting system maintained by the patient safety organization. While the Patient Safety Act may provide federal technical assistance to PSOs, no direct funding appears to be available. Without a clearly defined source of funding that enables the PSO to have staff or hire consultants, it is unrealistic to expect much from this effort.

When one considers the current cost of medical errors to District residents, money spent to eliminate those errors is a wise and prudent investment. Pennsylvania’s system has begun to bear fruit in this regard. More than 30 percent of all hospitals responding to a survey indicated that they have implemented patient safety protocols as a result of specific advisories they received from the Patient Safety Authority.¹¹

The costs of reporting medical errors, in order to reduce them, should be borne by the medical facilities where the bulk of the errors occur. We recommend that each medical facility be assessed annually on a pro-rata basis for the cost of creating and operating the District PSO.¹² A portion of that assessment should be used to create a fund that will provide financial discounts to medical facilities that prove through the PSO audits mentioned previously that they have fully participated in the program.

I have included in the appendix the following:

1. A side-by-side comparison of the adverse event reporting systems from Pennsylvania, the Health Committee’s Medical Malpractice Task Force and the Mayor.
2. A copy of the Federal Patient Safety and Quality Improvement Act of 2005.

3. Executive Summary of the 2004 Annual Report of the Pennsylvania Patient Safety Authority.

Again, Mr. Chairman, I thank you for the opportunity to provide Public Citizen's views and I look forward to working with you and your staff as this legislation progresses to the next stage.

¹ Jill Rosenthal and Maureen Booth, "Maximizing the Use of State Adverse Event Data to Improve Patient Safety, National Academy for State Health Policy," October 2005.

² *To Err is Human*, Institute of Medicine, 1999; National Highway Traffic Safety Administration Report, 2004; and U.S. Bureau of Labor Statistics Report, 2004.

³ *To Err is Human*, Institute of Medicine, 1999.

⁴ 42 U.S.C.A. §299b et. seq.

⁵ 42 U.S.C.A. §299b-24.

⁶ 2004 Annual Report, Executive Summary, Pennsylvania Patient Safety Authority, April 29, 2005.

⁷ American College of Physicians "Ethics Manual" says: "Physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent or unethical behavior, but failure to disclose them may."

⁸ Pennsylvania Statutes, 40 P.S. §1303.307.

⁹ Pennsylvania Medical Care Availability and Reduction of Error Act (Mcare), §1303.302.

¹⁰ 2004 Annual Report, Executive Summary, Pennsylvania Patient Safety Authority, p. 2, April 29, 2005.

¹¹ 2004 Annual Report, Executive Summary, Pennsylvania Patient Safety Authority, p. 3, April 29, 2005.

¹² Although the Pennsylvania Act permits a total facility assessment of \$5 million in any one year, plus an increase for cost of living adjustment, for the second year in a row the Authority requested a partial assessment of 50%, reducing the potential financial burden on Pennsylvania's healthcare facilities. 2004 Annual Report, Executive Summary, Pennsylvania Patient Safety Authority, April 29, 2005.