



2016 MAY 19 AM 11: 53

NIH EXECUTIVE SECRETARIAT

MemorandumCritical Care Medicine Dept.
Building 10, Room 2C145
TEL (301) 496-9320
FAX (301) 402-1213

May 16, 2016

TO: Director, NIH

FROM: Senior Clinical Center Department Heads and
Distinguished Senior Scientist

SUBJECT: Red Team Report

As senior Department Heads and a distinguished senior scientist at the NIH-Clinical Center, we are writing to express our disagreement with the overall message communicated in the recent Red Team report and associated news coverage about patient safety at the NIH-Clinical Center, and our dismay with the process and decisions regarding Clinical Center leadership.

While the Red Team did identify some important safety related issues at the Clinical Center, the implication that these indicate a culture that overlooks patient safety and/or reflects a general attitude of putting research considerations ahead of patient care and safety is, quite simply, incorrect. Research participants receive excellent care at the Clinical Center and safety is a top priority. The Clinical Center is a unique clinical research institution, seen by many as a model of clinical care in a research setting.

The Red Team would have had a fuller picture of patient care and safety and might have focused their recommendations differently if they had systematically:

- Reviewed the extant metrics assessing the quality of care in the NIH Clinical Center, many of which have been collected for decades
- Acknowledged the laudatory in depth reviews by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), College of American Pathology (CAP), the Accreditation Council for Graduate Medical Education (ACGME), American Association of Blood Banks (AABB) and numerous quadrennial Operational Reviews of the various clinical departments within the Clinical Center
- Met with NIH Clinical Center Department Heads and with Institute/Center Clinical Directors to review quality assurance and quality improvement programs, which are foundations for programmatic quality of patient care
- Met with patients or representatives of the Patient Advisory Committee and reviewed patient satisfaction surveys

- Spent sufficient time in the hospital with clinical, administrative, and regulatory staff to appreciate the singular culture of an institution in which clinical investigators and research participants are truly partners.

In reviewing an organization that is driven by science and data, the Red Team concluded that the Clinical Center lacked a “culture of safety” without indicating in their report what data they had reviewed.

It is unfortunate that the Red Team, seems to have conflated deficiencies in certain Clinical Center operations such as the problems with the Pharmacy as indicative of the quality of care that individual patients receive. This conflation has confused the general public and provides a distorted impression of the quality of care delivered at the Clinical Center. The report and subsequent news coverage has also demonized CC leadership, demoralized highly effective employees who perform admirably and professionally within the constraints of an acknowledged under-resourced medical system, and alarmed our patients. Rather than hoping that the Clinical Center will function the way that other hospitals do, as noted in your *Washington Post* interview, we believe that future leaders should recognize the uniqueness of the Clinical Center and direct their efforts to ensure that it continues to surpass other hospitals in quality of patient care, safety, and clinical research.

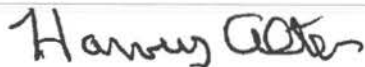
The Red Team did acknowledge critical structural problems with Clinical Center governance that we agree need to be addressed, including:

- NIH-Clinical Center leadership is tasked with supervising and regulating stakeholders who also control CC resources
- NIH-Clinical Center leadership reports to a confusing and overlapping array of committees and stakeholders some of which have considerable priority conflicts
- NIH-Clinical Center is inadequately funded to provide the needed physical plant, equipment, maintenance, and personnel
- NIH-CC Director is neither empowered nor expected to hold Institute employees accountable for conduct or performance.
- NIH-CC Director does not have authority over the hospital physical plant and there is inadequate expertise at NIH to address facility needs.

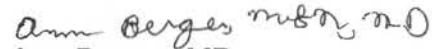
We acknowledge that certain recommended changes are attempts to correct some of these structural problems. However, any plan must address the following stark reality: the majority of physicians and researchers that conduct patient based research in the Clinical Center report to an NIH Institute or Center and not to the Clinical Center. This places certain limits on the authority of the CC that will not change by replacing leadership, but only by changing the governance structure and funding mechanisms. Further, none of these points speak to mismanagement by the Clinical Center Director or his staff.

We support your efforts to maintain and improve the quality of care in the Clinical Center and welcome the opportunity to assist you to attain this goal. In this regard, we suggest the following:

- NIH CC Department Heads and IC Clinical Directors could present to you, any relevant committees, and future leadership applicants, the robust quality assurance and quality improvement programs that have been in place for many years
- NIH-Clinical Center leadership could work with NIH leadership to develop management structures and budget reassessments to address identified problems
- NIH CC Department Heads and Clinical Directors could provide an important perspective in the selection process for new Clinical Center leadership



Harvey Alter, MD
Distinguished Senior Scientist



Ann Berger, MD
Chief, Pain and Palliative Care



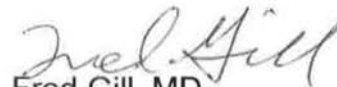
Thomas Fleisher, MD
Chief, Laboratory Medicine



Tara Palmore, MD
Chief, Epidemiology



Christine Grady, RN, PhD
Chief, Bioethics



Fred Gill, MD
Chief, Internal Medicine
Consult Service

Harvey G. Klein -S

Digitally signed by Harvey G. Klein -S
DN: c=US, ou=U.S. Government, ou=NIH, ou=People, o=2342.15000000.100.1.1=0010035894,
cn=Harvey G. Klein -S
Date: 2016.05.16 13:18:28 -0400

Harvey Klein, MD
Chief, Transfusion Medicine



Henry Masur, MD
Chief, Critical Care Medicine