



A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

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March 31, 2005

**Via Regular Mail and Electronically Filed**

Office of the General Counsel  
Ethics Division  
Department of Health & Human Services  
200 Independence Ave., S.W.  
Room 700-E – HHH Bldg.  
Washington, DC 20201  
Attention: Linda L. Conte

RE: Interim Final HHS Supplemental Ethics Rule [RIN 3209-AA15]

Dear Ms. Conte:

The Cancer Leadership Council (CLC) is an informal forum of national organizations dedicated to advancing sound public policy to benefit people with cancer and their caregivers. The undersigned organizations are fervent advocates for government-sponsored research and feel compelled to comment on the overly broad restrictions placed on employees of the National Institutes of Health (NIH) by the interim final rule published February 3, 2005 (70 Fed. Reg. 5543). If the revised ethics standards, which were made effective immediately and without benefit of notice and comment, remain unchanged, the public interest will suffer. Specifically, the ability of NIH to recruit and retain qualified scientists will be further eroded, and we, as non-profit organizations supporting high quality cancer research and care, will be deprived of the valuable contributions made on an uncompensated basis by the many NIH employees who volunteer their time and talent to our efforts.

**Impact of the Interim Final Rule on NIH**

NIH currently faces difficulty in recruiting and retaining the best scientists because their government compensation and benefits cannot match those available in the private sector. We believe the new ethics standards will contribute to the disincentives for NIH employment, not just because they seem to sweep more broadly than necessary to achieve the desired result, but also because the manner in which they were imposed—without

consultation or consideration of less burdensome alternatives—will contribute to an already flagging morale at NIH.

The nation's substantial investment in federally funded research can best be optimized if it is carried out by scientists of the highest caliber, and the interim final rule will make that result less likely. While it is entirely appropriate and expected that NIH would address individual abuses and maintain an ethical climate among federal employees, rules governing conduct outside of federal employment should be balanced and narrowly tailored to meet a specific public policy imperative. In this instance, NIH employees are subjected to restrictions that are, in certain ways, more severe than those applied to employees of the Food & Drug Administration (FDA), despite the fact that NIH exercises few of the direct regulatory authorities over commercial interests that are the routine business of FDA employees. The interim final rule should be amended to target restrictions to those NIH employees who are in a position to influence decisions that can truly affect commercial interests involved in the biomedical research enterprise.

#### *Impact on Non-Profit Organizations*

The interim final rule would appear to prohibit volunteer activity by NIH employees with many, and perhaps all, of the member organizations of the CLC. This result is reached because NIH employees are prohibited from "employment" (which federal regulations apparently define to include uncompensated volunteer activity) with "substantially affected organizations," meaning virtually every entity involved in biomedical research, or with related trade, professional, or similar associations, including advocacy groups "significantly involved in advancing the interest of persons or entities engaged in activities related to or affected by the health, scientific, or health care research conducted or funded by the NIH."

This broad restriction essentially treats large multinational pharmaceutical or biotechnology corporations no differently from small non-profit groups, many with limited resources and staff. The mission of such groups, which can range from advocacy on important public health issues to sponsoring of small but significant clinical trials, will inevitably suffer if they are deprived of the human capital represented by the frequent volunteer contributions of time and energy from NIH employees. If the recently announced rules remain in place without change, one of the consequences would be harm to non-profit groups that work successfully with already constrained resources in an effort to advance the interests of patients with life-threatening diseases like cancer. Furthermore, such restrictions would significantly impair the ability of NIH to participate in the important dialogue among patients, academics and others to effectively translate and disseminate research findings.

Some have suggested that such volunteer activity can continue pursuant to a waiver, but the preamble to the interim final rule indicates waivers are to be granted in unusual circumstances, such as "where the prohibition unduly causes personal or family hardship"

(70 Fed. Reg. at 5546). Given such language, NIH employees will be dissuaded from applying for waiver, regardless of the intent of NIH officials. In addition, the process for applying for waivers has been made significantly more burdensome and less predictable, which also will discourage NIH employees from seeking them.

### *Lack of Notice and Comment*

In order to avoid the otherwise applicable notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553, the preamble relies on two exceptions: for the employees themselves, the exception for “agency rules of organization, practice or procedure,” and for everyone else who may be affected, the “good cause” exception where notice and comment procedures are “impracticable, unnecessary or contrary to the public interest.” In addition, the statutory requirement of a 30-day delayed effective date was “dispens[ed] with” by a “good cause” assertion that the revisions “are critically necessary to preserve the integrity of NIH programs and operations” such that a delay in the effective date “would be contrary to the public interest.”

Contrary to the contention that “external entities” are only affected “marginally” by the interim final rule (70 Fed. Reg. at 5557), the impact on the activities of non-profit advocacy or research organizations may be substantial. Moreover, there is no showing that applying to these non-profit organizations the same restrictions that are applied to commercial entities would be necessary or useful. There is thus no basis for concluding that notice and comment under such circumstances would be either “unnecessary” or “contrary to the public interest.” It is therefore inconsistent with the terms of the APA to assert these “good cause exceptions” here.

The problem with publishing the interim final rule with legally insufficient public notice and opportunity for comment is amply demonstrated by the front-page February 23, 2005, **Washington Post** article entitled “NIH Clears Most Researchers in Conflict-of-Interest Probe.” This article disclosed that the reported 100 or more NIH scientists undergoing ethics investigations were in fact perhaps no more than 20, with the excess attributable to various errors in the review process. Since the allegation of widespread abuse formed a significant part of the justification for an “emergency” exception to the otherwise applicable notice-and-comment requirement, this report would seem to confirm that there has been a rush to judgment, at least in not adhering to the APA and probably in the substance of the interim final rule as well.

### CONCLUSION

The undersigned non-profit organizations wholeheartedly support ethics standards for NIH and other government employees that specifically target potential abuses and provide appropriate protections against financial interests in regulated commercial entities in a manner that does not needlessly discourage qualified individuals from

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government service. The interim final rule is too severe and risks a negative impact on recruitment and retention at NIH. In addition, the extension of the restrictions to non-profit advocacy and research organizations should be abandoned. A new proposed rule should be drafted and made subject to the public notice and opportunity to comment mandated by the APA.

Sincerely,

**Cancer Leadership Council**

American Psychosocial Oncology Society  
American Society of Clinical Oncology  
American Society for Therapeutic  
Radiology & Oncology  
Cancer Care, Inc.  
Cancer Research and Prevention Foundation  
The Children's Cause for Cancer Advocacy  
Coalition of National Cancer Cooperative  
Groups  
Fertile Hope  
International Myeloma Foundation  
Kidney Cancer Association  
Lance Armstrong Foundation

The Leukemia & Lymphoma Society  
Lymphoma Research Foundation  
Marti Nelson Cancer Foundation  
National Coalition for Cancer Survivorship  
North American Brain Tumor Coalition  
Sarcoma Foundation of America  
The Susan G. Komen Breast Cancer  
Foundation  
Us TOO International Prostate Cancer  
Education and Support Network  
The Wellness Community  
Y-ME National Breast Cancer Organization

cc: Elias Zerhouni, M.D., Director, NIH  
Raynard Kington, M.D., Ph.D., Deputy Director, NIH