Dear Colleagues:

In this age of discovery, where scientific developments are occurring at breakneck speed, our HMS faculty are deeply engaged in extending their discoveries so that they may eventually be translated into therapies. As we meet the challenges presented by this accelerated pace of innovation and the associated opportunities, we must also maintain the public's trust by managing potential risks associated with our research efforts.

As we pursue our research and advance our mission, it is necessary that we work in partnership with fellow academics, government agencies and the companies that commercialize innovations. At the same time, to ensure the integrity of our scientific endeavors, it is imperative that we identify and appropriately manage any potential conflicts that may arise.

This past January, I asked the faculty of medicine's Standing Committee on Conflicts of Interest and Commitment, in consultation with colleagues across our HMS community, to review our policy on conflicts of interest and commitment, focusing particularly on the restrictions defined by what we refer to as the Research Support Rule and the Clinical Research Rule. The HMS COI policy, adopted in 1990, is periodically evaluated and revised to ensure that it strikes the appropriate balance between risk and benefit for our faculty, and for society at large.

The Standing Committee has recommended, after a thorough review, that certain previously prohibited conflicts may, in fact, be allowed and managed, if appropriate safeguards are established. Based on this assessment, I have accepted interim recommendations from the Standing Committee that relate specifically to the Research Support Rule.

This change represents a small but meaningful revision to the HMS COI policy. I believe it strikes the right balance between risk and benefit as they relate to basic research carried out in our community.

Specifically, the Standing Committee found that the existing Research Support Rule is overly restrictive and does not address the risk analysis that ideally should be conducted independently for each situation. Therefore, I am authorizing the Research Support Rule to be changed as follows:

- A faculty member who holds equity in a *privately held business* is *presumed to be prohibited* from receiving sponsored research support from that business. *However*, the HMS Standing Committee, working with the COI committees at our affiliated institutions, *may consider a petition by a faculty member that rebuts this presumption*. The Standing Committee, or its designee, will approve such a petition if (a) the faculty member sets forth compelling circumstances to demonstrate how the potential benefits of allowing the proposed sponsored research will outweigh the potential risks of the conflict and (b) if reasonable safeguards can be implemented to manage the potential conflict.
- A faculty member who holds equity in a *publicly traded business* will *not be prohibited from receiving sponsored research support from that business unless the faculty member owns equity valued at more than 1% of the total equity of that business,* at which point the faculty member may petition the Standing Committee for approval consistent with the process criteria described above.

• As the Standing Committee's review of the HMS COI policy continues, the existing Clinical Research Rule will remain unchanged. This rule prohibits faculty who own equity in a business from receiving sponsored *clinical* research support from that business.

The Standing Committee's review of the policy is ongoing, and we invite your thoughts as the committee members continue to make a critical assessment of the standards and rules that guide our interactions with industry. I look forward to sharing with you any additional recommendations as they may be proposed in the coming months.

If you have any questions or would like to learn more about the Research Support Rule and the petition process, please visit the website of the <u>Office for Academic and Research Integrity</u>. You may also contact Gretchen Brodnicki, dean for faculty and research integrity, or Jennifer Ryan, director of research integrity, at <u>outsideactivites@hms.harvard.edu</u>.

Sincerely,

Jeffrey S. Flier Dean of the Faculty of Medicine Harvard University