Application of Default Rules to Address Financial Conflicts of Interest in Academic Medical Centers

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A recent report issued from the Institute of Medicine contains an extensive analysis of financial conflicts of interest (FCOIs) in biomedical science.[1] In brief, an FCOI exists when a profit-seeking motive either unduly influences or appears to influence an academic scientist's primary obligations.[2] The cornerstone of current policy to address FCOIs at academic medical centers (AMCs) is disclosure; however, disclosure does not appear to appropriately regulate, manage, or eliminate FCOIs.

Interestingly, the regulation of FCOIs for extramural scientists (those who conduct research at AMCs) is quite different than the rules that apply to intramural scientists (those who conduct research within the National Institutes of Health (NIH)). Policies that regulate extramural scientists tend to focus on disclosure, either to the university or to the granting agency that is funding the research in a particular laboratory. The policies that govern intramural scientists contain defined restrictions on the types of relationships that the government scientists can have with the private sector. Although extramural and intramural scientists exist in somewhat different environments, an analysis of the impact of the NIH guidelines for intramural scientists over the past several years may provide valuable information for the types of rules that could be applied to extramural scientists to address FCOIs at medical schools. Medical schools struggle to regulate this area, and the application of a set of default rules applied to all AMCs may assist in decreasing or eliminating the detrimental impact of FCOIs.[3]

Intramural scientists are employees of the federal government and they conduct research at the NIH. Intramural scientists receive government funding to support

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1. COMM. ON CONFLICT OF INTEREST IN MED. RESEARCH, EDUC., AND PRACTICE, INST. OF MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (Bernard Lo & Marilyn J. Field eds., 2009).

2. *See, e.g.*, *Conflict of Interest*, NAT'L INSTS. HEALTH ETHICS PROGRAM (April 10, 2010), http://ethics.od.nih.gov/topics/coi.htm; *see also* Joanna K. Sax and Neal Doran, *Evaluation of Academic Scientists' Responses to Situations that Pose a Conflict of Interest*, 12 CANCER BIOLOGY & THERAPY 4, 4–5 (2011) (See also references therein.).

3. Joanna K. Sax, *Financial Conflicts of Interest in Science*, 21 ANNALS HEALTH L. 291, 318 (2012); *see also* Sax & Doran, *supra* note 2, at 5 (citing the Institute of Medicine Report).

their laboratories. They do not apply for grants to obtain funding, but they do undergo a review process.[4] Extramural scientists are employed by AMCs, usually within a larger university. Extramural scientists apply for grants to fund their laboratories. Although multiple sources of funding may exist, the NIH is the largest agency that supports biomedical research.[5]

Intramural scientists interact with the private sector in a number of ways. For example, intramural scientists may be asked to serve as advisors to a private company. Intramural scientists may be asked to give presentations by outside companies or researchers in exchange for compensation.[6] This interaction with the private sector may create an FCOI if, for example, a private company applies to work with the NIH on a particular project. If an intramural scientist has a relationship with a private company and that intramural scientist is in a decision-making position with respect to the private company's request, the scientist may favor the company's request.

Extramural scientists interact with the private sector in ways that may be the same or different than intramural scientists. An extramural scientist may obtain funding from a private company to support their research. This type of interaction is increasing for a number of reasons including: (1) a decrease in the amount of government support and (2) incentives for public-private relationships created through the Bayh-Dole Act of 1980.[7] The extramural scientist may face an FCOI created by terms in the contract with the private company, such as delay of publication of results, or the extramural scientist may yield to pressure by a private funding source to present data in a favorable light in order to continue receiving funding from the private company.[8]

Although the relationships between intramural scientists and industry and extramural scientists and industry may be structurally different, they both can lead to FCOIs that threaten scientific integrity. Overall, the NIH policies governing FCOIs for intramural scientists are much stricter than those applied in AMCs. This Essay proposes that the NIH policies for intramural scientists can be used as a template to create default rules in AMCs that govern the extramural scientist-private company relationship.

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4. NIH INTRAMURAL RESEARCH AT THE THRESHOLD OF A NEW ERA: THE MISSION, VISION AND SCOPE OF THE NATIONAL INSTITUTES OF HEALTH INTRAMURAL RESEARCH PROGRAM 16 (2009), *available at* http://sourcebook.od.nih.gov/oir/IRP_transition.pdf [hereinafter NIH INTRAMURAL RESEARCH]; *see also* Renee Twombly, *Conflict-of-Interest Rules Worry Some Scientists*, 99 J. NAT'L CANCER INST. 6, 9 (2007) (quoting one institute director as saying, "We have relatively stable funding for our labs, but if you go into academia, you will have to compete for research grants, and the success rate is not high.").

5. *See* Hamilton Moses III, E. Ray Dorsey, David H. M. Matheson & Samuel O. Thier, *Financial Anatomy of Biomedical Research*, 294 JAMA 1333, 1336 & tbl.1 (2005).

6. *See generally* David B. Resnik, *Conflicts of Interest at the NIH: No Easy Solution*, HASTINGS CENTER REP., Jan.–Feb. 2005, at 18, 18–20.

7. *See* Sax, *supra* note 3, at 293–94.

8. *Id.* at 298, 300–02 (See references therein.).

I. SIMILARITIES AND DIFFERENCES BETWEEN INTRAMURAL AND EXTRAMURAL SCIENTISTS

Intramural and extramural scientists share many similarities including exercising intellectual freedom, receiving government support, researching issues in basic science, and conducting clinical trials. Both intramural and extramural scientists have the same objectives to relieve pain and suffering and to contribute research that benefits the public. Many scientists who choose to enter academics or take a position at the NIH could work in the private sector (for more money), but choose academics or the NIH because of the freedom of intellectual curiosity and personal ambitions. Both intramural and extramural scientists tend to have nontangible goals including enhancement of reputation and career advancement that come as a result of their hard work and accomplishments.[9]

The funding structure for intramural and extramural scientists is different. Intramural scientists are allocated resources for research and undergo a review every four years.[10] Extramural scientists apply to the NIH through a grant system.[11] The NIH has a limited amount of money that it can use to fund grant applications; thus, the grant process is highly competitive.

Other differences include the types of employment packages. For example, intramural scientists are federal employees, and they receive federal benefits. Extramural scientists are employees of AMCs and receive benefits from the university—although grant money is often used to pay for their benefits.[12]

Some might say that the research conducted at the NIH is riskier (i.e., it has a low likelihood of success), but if successful, the pay-off is high.[13] This may be because of the resources available to intramural scientists on the NIH campus as well as the goals of the NIH. Extramural scientists might be less likely to conduct high-risk research because it is harder for them to obtain grant money and because resources at their home campuses may be limited. Although there may be some truth to this assertion, many great discoveries come from academic laboratories, so it is difficult to determine the validity of this argument.

The overall characteristics between intramural and extramural scientists are quite similar. Many scientists move between academics and the NIH. Both

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9. *See* David Korn, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234, 2234 (2000).

10. NIH INTRAMURAL RESEARCH, *supra* note 4, at 16 ("As a result of these reviews, recommendations for altering allocated resources are made to the Scientific Director, the Institute or Center Director, the NIH Deputy Director for Intramural Research, and the Institute or Center National Advisory Council or Board.").

11. *Grant Review Process*, NAT'L INSTS. HEALTH (Mar. 20, 2008), http://grants.nih.gov/grants/grants_process.htm.

12. *See, e.g.*, *NIH Research Project Grant Program (R01)*, NAT'L INSTS. HEALTH (Jan. 25, 2010), http://grants.nih.gov/grants/funding/r01.htm (describing allowable costs).

13. NIH INTRAMURAL RESEARCH, *supra* note 4, at Preface ("The most important aspect of the Intramural Research Program, as delineated in this document, is its emphasis on high-risk, high-reward research. This takes place in an environment conducive to research that cannot be readily funded or accomplished in traditional academia, made possible through a vast and advanced technology infrastructure . . . .").

scientists face circumstances that allow them to interact with the private sector, yet these interactions are regulated quite differently depending on whether the scientist is intramural or extramural. Because both types of scientists receive federal grant money to conduct research and have the same goal of understanding and treating diseases, a goal that benefits the public, these two sets of scientists should be subject to the same FCOI rules. Intramural scientists have strict rules regarding holdings of securities and financial compensation for consulting, lectures, and awards. Extramural scientists, on the other hand, are largely governed by rules that focus on disclosure.

II. FINANCIAL CONFLICT OF INTEREST RULES WITHIN THE NIH

In 2005, the NIH instituted a set of rules that changed the financial relationships of its intramural scientists with the private sector. Under these rules, intramural scientists were required to divest, file disclosures on, and eliminate employment with substantially affected organizations (SAOs), and limit compensation through awards or gifts.[14]

A. History of Conflict of Interest Rules at the NIH

The changes instituted in 2005 marked a clear departure from the previous set of rules. In 1995, under the leadership of Harold Varmus, the NIH instituted polices allowing many types of relationships between intramural scientists and the private sector.[15] For example, intramural scientists could engage with the private sector and be paid any amount for their services including the receipt of stock (and stock options).[16] The intramural scientists went through an approval process, but in many ways this review process was perfunctory.[17] One of the reasons for the open nature of the 1995 rules may have been so that the NIH could attract and retain top scientists who would have otherwise gone elsewhere if they could make more money at another institution or in the private sector. Dr. Varmus is credited with recruiting top scientists and with convincing Congress to increase the NIH budget.[18]

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14. *Summary of NIH-Specific Amendments to Conflict of Interest Ethics Regulations*, NAT'L INSTS. HEALTH (Mar. 4, 2011), http://www.nih.gov/about/ethics/summary_amendments_08252005.htm.

15. *See Testimony Before the S. Appropriations Subcomm. on Labor, HHS, and Educ.*, 108th Cong., Sess. 2 (2004) (testimony of Ruth Kirschstein, Senior Advisor to the Director, National Institutes of Health), *available at* http://olpa.od.nih.gov/hearings/108/session2/testimonies/conflict2.asp (describing the 1995 rules) [hereinafter *Kirschstein Testimony*]; *see also* Twombly, *supra* note 4, at 7 (describing how Varmus relaxed the conflict of interest rules to attract top scientists).

16. *Kirschstein Testimony*, *supra* note 15.

17. *Id.*; *see also* Twombly, *supra* note 4, at 7 (quoting Zerhouni: "I think 99.5% of all requests were approved.").

18. Robert Steinbrook, *Financial Conflicts of Interest and the NIH*, 350 NEW ENG. J. MED. 327, 329 (2004) ("Varmus is credited with improving the NIH, recruiting and retaining top scientists, and helping to convince Congress to double the NIH budget.").

In late 2003, the *L.A. Times* published an exposé suggesting that the financial relationships between NIH scientists and the private sector created conflicts that negatively impacted subjects and studies.[19] The article, *Stealth Merger: Drug Companies and Government Medical Research*, named individual NIH scientists and indicated the amount of money these scientists received from the private sector.[20]

Congress responded to the news regarding the relationships between NIH scientists and the private sector by holding hearings in January 2004.[21] At these hearings, the then-NIH Director, Elias Zerhouni, testified before the Congressional Subcommittee.[22] In his comments, Dr. Zerhouni denied allegations that any patient was harmed as a result of a financial arrangement between an NIH scientist and the private sector.[23] Dr. Zerhouni acknowledged that there is a "perception of widespread conflicts that needs to be corrected as soon as possible."[24] To address these concerns, Dr. Zerhouni created a Blue Ribbon Task Force to review the NIH policies and make recommendations on reforms.[25]

On June 22, 2004, the Blue Ribbon Panel on Conflict of Interest Policies released its report.[26] The report contained eighteen recommendations that included such actions as restricting consulting arrangements, restricting financial interests for scientists engaged in research involving human subjects, limitations on compensation from outside activities, and greater oversight.[27]

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19. David Willman, *Stealth Merger: Drug Companies and Government Medical Research*, L.A. TIMES, Dec. 7, 2003, at A1, *available at* http://articles.latimes.com/print/2003/dec/07/nation/na-nih7 ("Katz and his institute staff could have responded to the death by stopping the study immediately. They also could have moved swiftly to warn doctors outside the NIH who were prescribing the drug for similar disorders. Either step might have threatened the market potential for Schering AG's drug. They did neither.").

20. *Id.*

21. *Senate Appropriations Subcommittee Holds Hearing on Conflict of Interest*, OFF. LEGIS. POL'Y & ANALYSIS, http://olpa.od.nih.gov/hearings/108/session2/summaries/conflict.asp ("On January 22, 2004, the Senate Appropriations Subcommittee on Labor, HHS, Education (Senator Arlen Spector [R-PA], Chairman) held a hearing on 'Avoiding Conflicts of Interest at NIH.'").

22. *Testimony Before the S. Appropriations Subcomm. on Labor, HHS, and Educ.*, 108th Cong., Sess. 2 (2004) (testimony of Elias A. Zerhouni, Director, National Institutes of Health), *available at* http://olpa.od.nih.gov/hearings/108/session2/testimonies/conflict1.asp.

23. *Id.* ("I want to inform you that, thus far, we have not identified any situations where patients were harmed as the result of financial arrangements NIH employees had with outside parties.").

24. *Id.*

25. *Id.* ("This is why I have asked that a Blue Ribbon Task Force, as an adjunct to the existing independent Advisory Committee to the Director of the NIH, review all NIH ethics practices, ponder what types of collaborations with non-government organizations are necessary and appropriate, and make recommendations to me on reforms of our policies and procedures within 90 days of its formation.").

26. BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES, REPORT OF THE NATIONAL INSTITUTES OF HEALTH BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES (Kathi Hanna ed., 2004), *available at* http://www.nih.gov/about/ethics_COI_panelreport.pdf.

27. *See id.* at 2–5 (summarizing recommendations).

In early 2005, Dr. Zerhouni announced a new set of rules, some of which were more restrictive than the recommendations proposed by the Blue Ribbon Panel.[28] The new rules include a prohibition on outside consulting with SAOs, divestiture of stock holdings above a specific threshold, prior approval for receipts of monetary awards, disclosure reports, review and prior approval for activities with professional and scientific organizations, and prior approval for compensated academic outside activities.[29] In sum, the 2005 rules were much more restrictive than the previous rules.

B. Impact of 2005 Rules on Retention and Recruitment of Scientists

FCOI rules try to strike a delicate balance between allowing a positive public-private interaction to exist without creating situations in which harms may occur. One concern that the NIH may have is how to attract and retain top scientists to the NIH knowing that these top scientists can make much more money in other capacities. Some may believe that restrictions on outside pay (e.g., from the private sector), may mean that top scientists will not want to work for a government salary.[30] And, although this may be a concern, others argue that the type of research and the freedom of research offered at the NIH will more than compensate for the lower salary.[31]

Due to concern over recruitment and retention of scientists from the increased restrictions of the 2005 rules, the NIH conducted a survey to evaluate the impact of the new ethics rules.[32] The NIH consulted with an outside independent research organization, ORC Macro, to conduct an assessment of the impact of the 2005 rules.[33] The survey found that the vast majority of NIH employees were satisfied

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28. *Taking a Hard Line on Conflicts*, 433 NATURE 557, 557 (2005) ("On February 1, Elias Zerhouni, the director of the National Institutes of Health (NIH), announced new rules that are clearly intended to put an end to one of the more embarrassing episodes in the agency's recent history."); *see also NIH Announces Sweeping Ethics Reform*, NAT'L INSTS. HEALTH (Feb. 1, 2005), http://www.nih.gov/news/pr/feb2005/od-01.htm; *Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services*, 70 Fed. Reg. 51,559 (proposed Aug. 31, 2005) (to be codified at 5 C.F.R. pt. 5501–02).

29. Memorandum from Elias A. Zerhouni, Director, National Institutes of Health, on Ethics Rules (Aug. 25, 2005), *available at* http://www.nih.gov/about/ethics/coipolicymemo_08252005.htm (summarizing features of the final rules).

30. Resnik, *supra* note 6, at 19 ("Since the NIH cannot afford to offer its top researchers competitive salaries, according to this argument, it should allow them to supplement their income with payments from outside agencies."); *see generally* Jennifer L. Gold, *Conflict over Conflicts of Interest: An Analysis of the New NIH Rules*, 34 J. L., MED. & ETHICS 105, 105–07 (2006).

31. Resnik, *supra* note 6, at 20 ("The NIH offers researchers non-economic benefits: job satisfaction, public service, and the opportunity to conduct cutting-edge research on human health. Scientists more interested in money can look elsewhere [for employment].").

32. *Evaluation of the Impact of the New NIH Ethics Rules on Recruitment and Retention*, NAT'L INSTS. HEALTH (Oct. 26, 2006), http://www.nih.gov/about/ethics/evaluationslides.pdf; *see also*, Twombly, *supra* note 4, at 8.

33. *Evaluation of the Impact of the New NIH Ethics Rules on Recruitment and*

with their jobs (78.6%) and they intended to be working at the NIH next year (85.6%).[34] More than one-third of respondents did not have a strong or basic understanding of the new ethics rules, despite that almost all the NIH employees completed the annual ethics training.[35] More than half of those surveyed felt that there was a need for the NIH to address the rules governing conflicts of interest, but it was almost evenly split among that group as to whether that could be addressed by improved enforcement of the 1995 rules or whether new rules were needed.[36] Many respondents felt that the 2005 rules may impact the overall ability of the NIH to complete its mission (37.5%), to keep its status as a leader in scientific research (16.5%), and to recruit and retain staff (56.2% and 54.7%, respectively). Respondents felt that the restrictions on outside activities were most likely to negatively impact the NIH in the long term (37.8%) compared to restrictions on financial holdings, restrictions on awards, and no restrictions.[37] More than half the employees responded that the new rules would have no impact on them personally.[38]

A different study analyzed the impact of the 2005 ethics rules on patenting, publishing, collaborations, and internal perceptions.[39] This study, conducted by Darren Zimmer and colleagues, employed a survey that was administered to a group of people within the NIH.[40] Some respondents answered that they had concerns about validity of the work of an intramural scientist who had a relationship with industry.[41] A larger number of respondents answered that they thought there would be an increase in bias and secrecy if the ethics rules were relaxed (32% and 42.4%, respectively).[42] Interestingly, 84.3% of respondents believed that new research that was not currently being done could be done if the ethics rules were relaxed.[43] In addition, almost half of the respondents believed that the NIH ethics rules should apply to extramural scientists in AMCs.[44] This survey also demonstrated that there has been a decline in government-industry relationships since the implementation of the 2005 ethics rules.[45] Furthermore, the study found that intramural scientists with industry relationships publish at nearly twice the rate as their peers (6.7 versus 3.8 articles per year).[46] The underlying reason for this is unclear. It could be that the most productive scientists are those sought out by industry, or that the most productive scientists are more likely to

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Retention, *supra* note 32, at 2–3.

34. *Id.* at 7.

35. *Id.* at 9–10.

36. *Id.* at 12.

37. *Id.* at 16.

38. *Id.* at 18.

39. Darren E. Zimmer, Catherine M. DesRoches, Steffanie J. Bristol, Brian Clarridge & Eric G. Campbell, *Tightening Conflict-of-Interest Policies: The Impact of 2005 Ethics Rules at the NIH*, 85 ACAD. MED. 1685, 1686 (2010).

40. *Id.* at 1685–86.

41. *Id.* at 1688 tbl.2.

42. *Id.*

43. *Id.*

44. *See id.*; *see also* Twombly, *supra* note 4, at 8.

45. *See* Zimmer et al., *supra* note 39, at 1688 tbl.2.

46. *Id.* at 1690.

engage in multiple types of collaborations.[47] Importantly, the overall rate of publication did not appear to decline after the implementation of the 2005 ethics rules.[48]

These studies suggest a lot about the impact of the 2005 ethics rules, but they do not establish that the rules do not have the desired effects. For example, these studies suggest that overall employee retention may not be greatly impacted because most respondents answered that they intended to remain working at the NIH.[49] This does not, however, address select big-name scientists. For example, the loss of five highly productive and creative scientists can have a much greater impact than the loss of twenty mediocre scientists.[50] It is difficult to test for these types of selective losses; rather, that information is most often noted anecdotally. But, the studies do show that the 2005 ethics rules are not causing a mass exodus and that intramural scientists continue to publish at the same rate as before the implementation of the rules.

The 2005 ethics rules can be analogized to a set of default rules. That is, the 2005 rules apply to all intramural scientist-industry relationships. The application of a set of default rules to intramural scientists is different than the types of rules that apply to extramural scientists, and this Essay urges that both intramural and extramural scientists should be subject to the same set of rules.

III. APPLICATION OF DEFAULT RULES TO EXTRAMURAL SCIENTISTS

AMCs struggle to properly regulate the area of FCOIs.[51] The cornerstone of current policies is disclosure.[52]

Why should intramural scientists be subject to one set of rules while extramural scientists are subject to another set of rules? One answer is that they should not. Another answer is that the rules that apply to intramural scientists should apply to extramural scientists. For example, the strict rules that limit personal financial gain through relationships with industry as applied to intramural scientists should extend to extramural scientists. Studies show that even small token gifts can have an influence over faculty.[53]

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47. *See id.* ("Unfortunately, the cross-sectional nature of this study does not allow us to test whether industry relationships make scientists more productive or whether industry seeks out the most productive scientists with whom to collaborate.").

48. *Id.* at 1691 ("However, our analysis of average publication rates before and after the implementation of the ethics rules did not detect a significant decline in scientists' productivity.").

49. *See Evaluation of the Impact of the New NIH Ethics Rules on Recruitment and Retention*, *supra* note 32, at 7.

50. *See* Gold, *supra* note 30, at 107.

51. *See* Sax & Doran, *supra* note 2, at 5.

52. Sax, *supra* note 3, at 307–09.

53. Troyen A. Brennan, David J. Rothman, Linda Blank, David Blumenthal, Susan C. Chimonas, Jordan J. Cohen, Janlori Goldman, Jerome P. Kassirer, Harry Kimball, James Naughton & Neil Smelser, *Health Industry Practices that Create Conflicts of Interest*, 295 JAMA 429, 430–31 (2006).

Some AMCs and faculty will likely oppose the application of the NIH guidelines. One argument they could make is that the survey results, described above, demonstrate some negative impacts since the implementation of the rules. One response to this is that while there may be some collateral damage, the surveys indicate that employee retention remains strong and publishing rates appear steady. Another argument against imposing the NIH guidelines on extramural scientists could be that it limits the amount of income that extramural scientists stand to make. Most scientists, however, enter academics to enjoy the intellectual freedom and the ability to work with smart colleagues, and it seems unlikely that the academy will fall apart with strict rules that govern FCOIs.

To address the concerns by opponents of applying the NIH rules to extramural scientists, the NIH could issue a call for grant applications for investigators that would like to study the impact of the application of the NIH guidelines to extramural investigators. Over a five-year period, a study could analyze what effect, if any, stricter rules have on retention, recruitment, publications, and morale. This study would be similar to the one conducted within the NIH to understand the impact of the NIH guidelines on intramural scientists.

The NIH guidelines may not adequately address all of the areas in extramural research that are impacted by FCOIs. To address the areas that differ, the NIH can give special awards to AMCs that produce innovative ways to address areas that are not included in the NIH guidelines.

The overall goal here is to protect scientific integrity and the public's trust in scientific research. To do this, it is necessary to ensure that the profit-seeking motive of private industry does not unduly influence the work of intramural and extramural scientists. For these reasons, the strict rules that apply to intramural scientists should extend to extramural scientists.

CONCLUSION

The legal and medical scholarship is in large agreement that something needs to be done to address FCOIs at AMCs. Many argue that the current policy of disclosure is inadequate. This Essay proposes that extramural scientists, who receive NIH grant money, should be subject to the same FCOI rules that apply to intramural scientists. The NIH guidelines are more restrictive than current rules that apply to extramural scientists. Although there may be some pushback to the application of strict rules, it is worth taking the time to apply these rules and then study the impact to AMCs.