



Lurking Legal Issues for AMCs in Faculty-Led Consulting for Industry via Institutional Contracts

Rebecca Schaefer, K&L Gates LLP


Faculty physicians at academic medical centers (AMCs) are regionally, nationally, and internationally renowned for their expertise in various disciplines. As a result, industry often seeks to engage these physicians in a variety of consulting activities that rely upon their specialized professional knowledge, experience, and abilities. The consulting services most frequently sought tend to include (1) speaking engagements, (2) consulting on clinical trial design, (3) advice in support of Food and Drug Administration (FDA) applications, (4) advice regarding pharmaceutical or medical device product development, (5) serving on advisory boards or steering committees, (6) providing educational presentations or training to pharmaceutical or medical device company employees regarding certain diseases, (7) product evaluations, and (8) serving on data monitoring committees or data safety monitoring boards.

At many AMC institutions, current policies allow for these activities to be performed either as external professional activities of the faculty member or pursuant to institutional contracts that the faculty member staffs. The latter requires institutional resources to support and entails the institution bearing certain

legal risk. Discussions on AMC, teaching hospital, and university association listserves show a growing trend in faculty requesting that opportunities first presented to them personally be structured as agreements between their institution and the industry partner and treated as part of the faculty member's institutional responsibilities, with the contractual income paid to the entity instead of them individually. Institutions report struggling with where to draw the line. When current policy permits the faculty member to drive the choice of an institutional contracting approach without guardrails defining appropriate and worthwhile consulting, and absent AMC measures to locally align risk/burden with the faculty member's unit, these externalities can accrue undue liability for the AMC. This article discusses various legal, policy, and operational considerations with enabling an open-ended institutional contracting approach to industry consulting.

Why an Institutional Contract?

There are a number of reasons faculty may wish to structure the consulting activity as an institutional contract versus performing the service in their personal capacity. The predominant reason



When current policy permits the faculty member to drive the choice of an institutional contracting approach without guardrails defining appropriate and worthwhile consulting, and absent AMC measures to locally align risk/burden with the faculty member's unit, these externalities can accrue undue liability for the AMC

relates to conflict-of-interest (COI) implications if the faculty were to receive payment for the services directly and the notion that by being a step removed, the financial payment is not as directly attributed to the individual or attribution is avoided entirely. Individually receiving payment for personal consulting typically requires disclosure of the financial interest and may, depending on the amount, preclude the faculty member under the institution's COI policies from certain roles in AMC research sponsored by the same industry partner or from serving in advisory roles for national societies or federal research committees under the COI policies of those entities. Faculty also may believe that Sunshine Act reporting is avoided if the compensation is paid to their institution versus to them personally, though with institutional agreements that require a specific faculty member's performance, applicable manufacturers are still likely to list the faculty on the Centers for Medicare & Medicaid Services Open Payments portal as recipients of direct or indirect payments.¹

Faculty may fear that being conflicted on an individual basis or listed on Open Payments will degrade their reputation and ability to be perceived and pursued as key opinion leaders in their fields. The argument continues that this perception will correspondingly impair their institution's prominence and academic reputation. Similarly, faculty may believe that these types of consulting activities are consistent with their employment responsibilities, whether as secondary duties or otherwise, and that there is an institutional interest in the acclaim these opportunities may garner for their institution, as well as the professional development they may afford.

Directing the compensation to the institution also avoids a personal income tax obligation to the extent the funds are not passed through as additional compensation. Performing the services pursuant to an institutional agreement also avails the faculty member of the institution's infrastructure support, including legal review and negotiation of the contract and departmental processing of the invoice, thereby obviating the need for the faculty member to obtain those resources or perform those functions individually. However, unless the institutional contracts include an overhead amount (beyond the rate the company originally offered to the individual faculty), this institutional support may go uncompensated. Lastly, faculty may be interested in limiting personal liability by substituting the institution as the party in interest responsible for adherence to the contract terms and in this approach availing her of institutional liability coverage or defenses, as well as institutional representation, in the event of a dispute.

Considered from a personal perspective, these are compelling reasons to want an institutional contract for industry consulting. From the AMC's perspective, limiting an institutional approach and forcing more consulting to personal contracts may decrease the overall number of opportunities that faculty deem worthwhile to pursue, thereby limiting the potential for these activities to bring reputational acclaim to the faculty member (and by extension the AMC), as well as their potential to foster professional development and innovation. Further, an institution as compared to an individual faculty member, may be better positioned to identify and comply with regulatory and contractual

To the extent a faculty member's interest in the contract and payment going to the institution is motivated by a desire to avoid a direct and reportable financial interest with the company, the institution should be careful not to create or enable a COI circumvention scheme.

obligations and may appreciate the opportunity to counsel and structure consulting engagements appropriately.

Why Not an Institutional Contract? Legal, Policy, and Operational Considerations

The foregoing interests should be balanced with the resource burden and liability implications of an institutional contracting approach. Entering into and implementing an institutional agreement for faculty-led industry consulting often requires substantial time on the part of the AMC's legal and contracting departments and the faculty member's departmental administrators. When the speaking engagement, for example, is paid by a \$500 honorarium without any overhead, it is likely the institutional cost of negotiating and performing the contract is not covered. The mission-based rationale for this type of internal cost sharing or subsidization is less clear in the case of these consulting activities (often performed for private, for-profit industry entities) than it may be in the case of performing research, teaching, or public service duties.

Enabling activities through an institutional contract that could otherwise be performed by the faculty member in her personal capacity additionally introduces some level of institutional liability. As a practical matter, the AMC bears the contractual liability for performance. Also, performing the services as part of the faculty member's institutional responsibilities typically introduces the AMC's professional liability coverage (to the extent available) and the associated expense that may arise from a covered event. An institutional contracting approach also means institutional involvement in the case of a dispute.

Additional legal and regulatory considerations include:

Health Care Fraud and Abuse Laws. Laws like the Anti-Kickback Statute prohibit entities that provide or supply items or services billable to governmental programs (e.g., Medicare/Medicaid) from inducing or rewarding the referral or purchase of those items or services.² The Anti-Kickback Statute is implicated and compliance with it must be assured where, for

example, a drug manufacturer compensates consulting services provided by a physician or his health care employer who order and bill for the company's drugs. Whether the AMC or the individual faculty member are contracting with a drug or device manufacturer, each is responsible for ensuring that the arrangement involves fair market value payment for identifiable services, does not contemplate impermissible marketing, and otherwise complies with applicable regulatory requirements. Making the AMC versus the faculty member the party to the arrangement introduces direct regulatory obligations for the institution, as well as additional complexity, because elevating the arrangement to the AMC level requires understanding the totality of arrangements with the particular industry partner as compared to just those of the individual faculty member with the same company.

COI/Sunshine Act. Rules on COI seek to minimize bias in research due to the personal financial interests of researchers. Structuring consulting activities through institutional agreements could be perceived by regulators or other stakeholders as a circumvention of these rules if the faculty member otherwise directs the use of such funds to her benefit or the benefit of her laboratory or programs. To the extent a faculty member's interest in the contract and payment going to the institution is motivated by a desire to avoid a direct and reportable financial interest with the company, the institution should be careful not to create or enable a COI circumvention scheme. As the Dr. Baselga story from Memorial Sloan Kettering taught us, it is easy for the media and other interested parties to cross-check Open Payments listings against a physician's disclosures in publications and presentations. In the fall of 2018, Dr. José Baselga resigned from his position as the chief medical officer at Memorial Sloan Kettering Cancer Center after it was revealed that he failed to disclose significant financial interests he had with pharmaceutical manufacturers to the editorial boards of medical journals when publishing scholarly articles, a fact that the media discovered after reviewing information available on the Open Payments portal and comparing it with his journal article statements.³ If applicable manufacturers are attributing payments to physicians that a physician is not disclosing because the consulting was via institutional contract, the resulting gap may be difficult to explain. Institutions could be accused of complicity in thwarting the transparency and bias management that COI rules were designed to ensure, giving rise to legal and reputational liability.

Effort Reporting. Federal grant rules require that faculty members engaged in federally sponsored research activities certify to the level of effort expended on sponsored activities versus other institutional activities.⁴ Absent systems that coordinate counting effort assigned to institutional consulting contracts with research effort, it creates the risk that a faculty member who is otherwise heavily externally funded for research may be overcommitted when the consulting agreements are factored into his or her available effort. Personal contracts avoid this issue, since the faculty member would be conducting the consulting on his own time as an outside activity.

Public Records. For public AMCs subject to Freedom of Information Act-type open records laws, conducting the consulting activities through institutional contracts may render the materials received from the third party and prepared by the faculty member in furtherance of the scope of work public records that are subject to disclosure. At a minimum, responding and objecting to public records requests requires institutional resources. Of potential greater concern are the reputational impacts to the AMC and the faculty member, and to the relationship with the industry partner, that media or other requestors' interest in the records may present.

Export Controls. Many AMCs in the research space carry out what is termed "fundamental research" under the export control regulations.⁵ When a project qualifies for fundamental research, the results of the research are not subject to export control rules. To qualify as fundamental research, there can be no restrictions on publication. Often for consulting type agreements there are tight controls around sharing of information generated under the agreement. Such restrictions make the work subject to export control rules and require associated institutional review.⁶ This not only creates a burden on AMC resources but exposes the institution to potential civil and criminal penalties should export control rules be violated.⁷

Intellectual Property Considerations. Most consulting arrangements begin with form contracts required by the outside drug or device company. These templates often include broad transfer of valuable intellectual property rights to the industry party. Where the AMC is the named party, these broad provisions must be eliminated or substantially curtailed to avoid undue or impermissible encroachment on the institution's intellectual property interests. The industry party, by default, approaches these contracts as "works for hire" by individual faculty (not institutional contracts with academic partners); therefore, these provisions are often difficult to negotiate, even in circumstances where intellectual property transfer is substantially irrelevant for the company's purposes.

Tax/UBIT. In certain circumstances depending on the AMC's organization and tax status, the provision of a non-research service to a third party could create an obligation on the part of the AMC to identify and pay unrelated business income tax (UBIT) on the compensation received for those services. If the consulting activity gives rise to UBIT, it creates a tax liability for the institution and a reporting obligation requiring an administrative mechanism for review and tracking.

Other. As noted, conducting consulting activities pursuant to institutional contracts has the effect of creating institutional responsibility for compliance with applicable laws in the performance of the work (e.g., international activity that involves disclosure of data from the European Union (EU) may trigger the need for compliance with the EU General Data Protection Regulation).⁸ Areas of consideration for industry consulting that are outside of the legal and regulatory framework include

preservation of institutional academic integrity and scholarly dissemination (e.g., publication rights).

Current Policy Landscape

An author-conducted survey of policies revealed that most AMCs and universities have policies defining institutional duties versus outside activities (e.g., COI and commitment policies, industry relations policies). The distinction is frequently a prelude to requiring that faculty disclose external consulting for COI tracking and other reasons. However, these policies often do not declare a position on when an institutional approach will be permitted or a personal contracting approach required. A handful of policies directly address the choice between external consulting versus institution-facilitated engagements, with those that do tending to substantially limit an institutional option for consulting with for-profit industry partners. Overall, the policies we identified take a variety of approaches, from outright requiring consulting be conducted in the faculty member's personal capacity to more freely enabling industry consulting through institutional agreements, but most simply contemplate both options (an institutional or a personal contract) as available pathways.

Recommendations/Conclusion


AMCs often acknowledge that, when conducted ethically and transparently, faculty consulting for industry can result in advancements and training activities that benefit the public through, for example, sound drug and device development strategies and dissemination of best practices. Also frequently acknowledged is the potential for consulting activities to provide professional development opportunities and bring reputational acclaim to AMC faculty, which in turn can boost institutional visibility. However, the counterpoints of legal liability, risk, and institutional burden associated with institutional consulting, especially that which does not fall within the traditional framework of patient care, research, or teaching activities and in which scholarly benefits are a secondary aspect of the activity, elevates the importance of bringing smart intentionality to the choice between an institutional versus personal contracting approach.

In light of the legal, policy, and operational considerations outlined above, AMCs should develop or tighten policies to delineate the potentially narrow set of circumstances under which an institutional contracting approach for industry consulting is appropriate. Some factors AMCs may consider to delineate activities properly conducted pursuant to institutional agreements include where the arrangement is (1) not associated with undue professional liability, regulatory, or contractual risk; (2) is compensated at a rate that covers the cost of providing the services, the overhead associated with institutional processing, and the resulting tax liability; and (3) aligns with the institution's academic priorities; has scholarly value, without undue constraints on academic freedom; and provides an institutional or public benefit consistent with the institution's mission and nonprofit status.

As a counterpart, institutions also should create a short rider for the personal contracts their faculty enter into in

Many academic institutions are actively debating the factors for determining an appropriate institutional nexus [for consulting], and some have implemented policies delineating appropriate institutional involvement, mindful of the resources required and potential liability that attaches when an activity that could be conducted by a faculty member individually is performed as an institutional contract.

connection with industry consulting, which puts fences around institutional liability, intellectual property, conflict of commitment, and implied endorsement. These contract riders could double as the representation that drug and device manufacturers often require faculty to produce from their institutions demonstrating that they are not prohibited under institutional policy from performing the outside activity.

More and more, AMCs are considering how to handle consulting opportunities first presented by industry to faculty based on their individual expertise and that the faculty, for a variety of reasons, wish to structure as institutional contracts. Many academic institutions are actively debating the factors for determining an appropriate institutional nexus, and some have implemented policies delineating appropriate institutional involvement, mindful of the resources required and potential liability that attaches when an activity that could be conducted by a faculty member individually is performed as an institutional contract. There are a range of options AMCs could develop or refine within their policies to address these considerations. The policy choices are many along a spectrum of continuing to enable faculty-led choices between institutional and personal contracting, to outlining the criteria for institutional priority and assumption of risk, to foreclosing an institutional contracting option altogether. Whatever the approach a particular institution ultimately decides to take, this article presents a case for institutions making intentional policy choices to define consulting parameters that are informed by the considerations outlined above. 



Rebecca Schaefer is a partner in K&L Gates' health care and FDA practice group, focusing her practice on health care regulatory and transactional matters. Ms. Schaefer has specialized knowledge of issues affecting academic medical centers, including those

related to faculty physician practices, clinical research, mission support, and privacy and she presently advises hospital, health system, academic medicine, pharmacy, and other health care clients on myriad compliance matters and strategic initiatives. Prior to joining K&L Gates, Ms. Schaefer served as associate university counsel at The University of North Carolina at Chapel Hill, where she was the senior health care attorney for the UNC School of Medicine and UNC Faculty Physicians. In this capacity, Ms. Schaefer advised campus and school-based leadership on various regulatory, transactional, institutional policy, and governance matters, including in the areas of health care fraud and abuse, privacy, human subjects research, and life sciences regulation. Her transactional experience includes hospital acquisitions, strategic affiliations, joint ventures and physician practice acquisitions, as well as professional service, data use, and other types of agreements. Ms. Schaefer has also counseled on faculty physician employment matters, including physician compensation plans, employment agreements, and restrictive covenants. Prior to UNC-Chapel Hill, Ms. Schaefer was in private practice in Washington, D.C. advising clients from various sectors of the health care industry on matters such as clinical trial agreements, FDA regulatory compliance counseling, health care transactional due diligence, and the research, analysis, and compilation of legal and policy positions to comment on various agencies' rulemaking.

* Special thanks to Bruce W. Andrews, Assistant University Counsel at The University of North Carolina at Chapel Hill, for his contributions to the article.

Endnotes

- 1 The Sunshine Act generally requires certain "applicable manufacturers," which include pharmaceutical and medical device manufacturers, to report direct and indirect payments or transfers of value to a physician or physician's immediate family member. See 42 U.S.C. § 1320a-7h; 42 C.F.R. § 403.
- 2 42 U.S.C. § 1320a-7b(b).
- 3 See Katie Thomas, *Top Sloan Kettering Cancer Doctor Resigns After Failing to Disclose Industry Ties*, N.Y. TIMES, Sept. 13, 2018, <https://www.nytimes.com/2018/09/13/health/jose-baselga-cancer-memorial-sloan-kettering.html>.
- 4 2 C.F.R. § 200.430.
- 5 15 C.F.R. § 734.8.
- 6 *Id.* § 734.8(c).
- 7 15 C.F.R. § 764.3.
- 8 *European Union General Data Protection Regulation*, OJ L 119, 4.5.2016, pages 1-88.