Kickbacks and Inducements: Guidance and Compliance Strategies

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Cautionary Notes

- Company-specific citations in slide and accompanying discussion based on public sources – no privileged or confidential information
- In any referenced civil settlement, the company denied wrongdoing and expressly disavowed any admission of liability
- The purpose of today's discussion is to describe and analyze theories of liability/risks (and potential defenses and mitigation strategies) – not to judge or criticize the conduct of any particular company

Compliance Controls for Consultants

- **PhRMA Code Provisions**
- **Orthopedic DPAs**
- **Past and Current CIAs**
- **Concluding Thoughts**

HHS OIG Guidance

2. Specific Risk Areas

This section is intended to help prudent pharmaceutical manufacturers identify areas of their operations that present potential risk of liability under several key federal fraud and abuse statutes and regulations.[6]

This section addresses the following areas of significant concern for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

HHS OIG Guidance (cont'd)

> Pharmaceutical manufacturers and their employees and agents should be aware that the anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.

PhRMA Code

6 Consultants

Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they produce and market are meeting the needs of patients. Decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.

Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

PhRMA Code (cont'd)

- a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- a legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues.

PhRMA Code (cont'd)

7 Speaker Programs and Speaker Training Meetings

Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code, and the requirements of Section 7 apply to company interactions with that healthcare professional in his or her capacity as a speaker. Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.

Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement should only be offered when (1) the participants receive extensive training on the company's drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications; (2) this training will result in the participants providing a valuable service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6 above). Speaker training sessions should

PhRMA Code (cont'd)

be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.

Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.

Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication.

While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines. Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.

AdvancePCS – Early Safeguards for Consulting Arrangements

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ADVANCEPCS

I. PREAMBLE

AdvancePCS hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, AdvancePCS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

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1. "Arrangements" shall mean every arrangement or transaction that:

   a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between AdvancePCS and any actual or potential source of health care business or referrals to AdvancePCS or any actual or potential recipient of health care business or referrals from AdvancePCS. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program. Such Arrangements shall include: (1) every arrangement or transaction whereby compensation or remuneration is received by AdvancePCS from or on behalf of a pharmaceutical manufacturer, including but not limited to, rebates, regardless of how categorized, market share incentives, commissions, fees under products and services agreements, fees received for sales of utilization data and administrative or management fees but specifically does not include purchase discounts based upon invoiced purchase terms; (2) every arrangement or transaction between AdvancePCS and a client where "client" shall mean any governmental entity, employer, insurer, union or other entity that contracts with AdvancePCS to provide or administer a pharmacy benefit for such plan and its members or participants (hereinafter referred to as "Client Plans"); and (3) every arrangement or transaction between AdvancePCS and a broker engaged by AdvancePCS to perform services on its behalf.

AdvancePCS (cont'd)

D. Compliance with the Anti-Kickback Statute and Stark Law.

1. ***Arrangements Procedures.*** Within 120 days after the Effective Date, AdvancePCS shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);

b. tracking remuneration to and from all parties to Arrangements;

c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);

AdvancePCS (cont'd)

e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;

f. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

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2. ***New or Renewed Arrangements.*** Prior to entering into new Arrangements or any amendment to an existing Arrangement in which new terms and conditions (other than pricing terms and renewal dates) are negotiated and documented, in addition to complying with the Arrangements Procedures set forth above, AdvancePCS shall comply with the following requirements (Arrangements Requirements):

a. ensure that each Arrangement is set forth in writing and signed by AdvancePCS and the other parties to the Arrangement;

b. include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with AdvancePCS' Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, AdvancePCS shall provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures or shall provide access to the Code and relevant policies via the Internet or intranet, as appropriate;

c. include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

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APPENDIX A

ARRANGEMENTS DATABASE

AdvancePCS shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certai information to assist AdvancePCS in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;

2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);

3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;

5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market valu of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between th parties;

7. Whether each party has fulfilled the requirements of Section III.D.2; and

8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

Medtronic CIA Applied Concepts to Manufacturer-Consultant Arrangements

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures*. Within 120 days after the Effective Date, MSD shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement, including Contractual Arrangements and Non-Contractual Arrangements, does not violate the Anti-Kickback Statute (taking into account the regulations, directives, and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, that shall contain the information specified in Appendix A (Arrangements Database);

b. tracking remuneration to and from MSD to all other parties to Arrangements;

c. tracking service and activity logs to ensure that parties to the Arrangement(s) are performing the services required under the applicable Arrangement(s) (if applicable);

MSD CIA (cont'd)

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s);

e. establishing and implementing a written review and prior approval process for all Contractual Arrangements, including but not limited to, a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all existing and new or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not

MSD CIA (cont'd)

limited to, an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

g. requiring the MSD Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to MSD's Compliance Committee; and

h. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Section III.I (Reporting).

DPA Consultant Provisions – Further Evolution

Definitions

12. "Consultant" is defined as any United States-based orthopedic surgeon, PhD, health care professional, non-physician practitioner, medical fellow, resident or student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for or in anticipation of personal or professional services relating to hip and knee reconstruction and replacement. The term Consultant shall not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or any other types of non-physician professionals or entities excluded from this definition by the Monitor upon recommendation by the Company.

13. "Consulting Agreement" includes all contracts with Consultants for services to be performed on behalf of the Company. This includes, but is not limited to, agreements for compensation, payments, remuneration, honoraria, fellowships, professional meetings, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research, and professional services agreements. The term "Consulting Agreement" also includes agreements to provide grants, donations, sponsorships and other forms of payment to medical educational organizations, medical societies and training institutions.

14. "Consulting Services" or "Services" include any and all professional services provided by a Consultant to or on behalf of the Company.

15. "Payment" shall include any and all compensation or remuneration paid to or for the benefit of Consultants, including but not limited to payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (e.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property. Unless otherwise approved by the Monitor, the Company shall only compensate or remunerate Consultants through direct Payments made pursuant to a Consulting Agreement. The Company shall not knowingly make any Payments to Consultants indirectly, such as through distributors.

DPA Consultant Provisions (cont'd)

Needs Assessment

27. The Company shall complete a Needs Assessment no later than December 31, 2007, and annually thereafter. The Needs Assessment may be modified if bona fide, commercially reasonable, unexpected business needs arise ("Modification"). The Needs Assessment must reflect the Company's expected, commercially reasonable needs for all Consulting Services to fulfill its medical, clinical, training, educational, and research and development needs. The Needs Assessment shall also contain a budget for the total amount of honoraria, fellowships, gifts, donations, charitable contributions, and any other payments contemplated to be made to Consultants for which no Consulting Services are provided. The Needs Assessment and any Modifications as defined herein shall be prepared in consultation with those areas of the Company that have bona fide needs for the services to be performed. The Needs Assessment and any Modifications must be approved by the Compliance Officer and the Monitor before they are finalized. As of January 1, 2008, the Needs Assessment and any Modifications shall be used as a basis for Consultant selection and all Consulting Agreements, Services and Payments. The Compliance Officer shall attest to the best of his or her knowledge, after conducting reasonable due diligence, that the Needs Assessment and any Modifications reflect the bona fide, commercially reasonable consulting needs of the Company.

28. The Needs Assessment shall establish or incorporate by reference detailed protocols or procedures that must be followed before a Consulting Agreement will be authorized. The Needs Assessment must identify and quantify the services needed within each discrete service category (e.g., operating room training, speaking engagements, clinical studies, product

DPA Consultant Provisions (cont'd)

development groups), and provide written support for the needs. The Needs Assessment must set forth the nature of the services needed, the range of hours or other quantitative measure needed to complete the services, the number of Consultants needed, and the maximum fair market value compensation to be paid for each consulting service. The Needs Assessment shall also identify the qualifications and expertise required to perform the services. The Needs Assessment shall ensure that Services are distributed appropriately to all regions of the country.

29. The Needs Assessment and any approved Modifications shall be used to define and limit all Consulting Services performed for the Company for the ensuing year. All Consulting Agreements entered into by the Company shall be for services specified and enumerated by the Needs Assessment and any approved Modifications. No Consulting Agreement shall be entered into with any Consultant for services outside those specified in the Needs Assessment and any approved Modifications, or for services exceeding the number of services specified in the Needs Assessment and any approved Modifications. For example, if the Needs Assessment specifies that the Company will require Consultants to conduct 50 speaking engagements on a particular topic, once the total number of contracted-for speaking engagements reaches 50, the Company may not engage any additional Consultants for such speaking engagements unless it obtains an approved Modification.

DPA Consultant Provisions (cont'd)

Consulting Agreements

31. All Consulting Agreements shall be in writing and executed by the Compliance Officer, the President, the General Counsel, the Director of Research & Development for product development and research agreements, and the Director of Clinical for clinical services agreements (including clinical trials, clinical studies, follow-up visits). On an annual basis, the Compliance Officer, the Director of Research & Development for product development and research agreements, and the Director of Clinical for clinical services agreements shall attest and certify in writing that, based on their reasonable inquiry and knowledge, all Consulting Agreements and all Consulting Services performed thereunder were bona fide, commercially reasonable, and compliant with all federal health care programs. The Company shall not enter into Consulting Agreements with Consultants through any third parties, including distributors.

32. All Consulting Agreements for Consulting Services to be rendered in 2008 and thereafter shall be for a term of the calendar year, with the exception of product development agreements that could result in the payment of royalties, clinical agreements, and external research agreements, which may be for a length appropriate to the type of Service being rendered, upon approval of the Monitor. All Consulting Agreements shall identify the specific Services to be provided as defined by the Needs Assessment and any Modification thereto, and specify the rate to be paid for each Service. The Company may not enter into Consulting Agreements for Services exceeding the total number of Services set forth in the Needs Assessment and any Modification thereto. Consultants shall be paid only for the actual time expended in providing Consulting Services, in hourly billing increments or other reasonable quantitative measure as identified in the Needs Assessment, without regard to the total amount of consulting services permissible under their Consulting Agreements.

DPA Consultant Provisions (cont'd)

Payments to Consultants

35. A Company employee or representative must be present for every Consulting Service, except that the Monitor, upon application by the Compliance Office, may exempt certain Services from this requirement (such as collection of clinical study data, travel or preparation time). Upon completion of the Consulting Service, both the Company employee (or representative) in attendance and the Consultant must independently verify in writing that the Service took place, identify the participants present and length of service, and summarize the Service provided. These verifications must be certified, made under penalty of perjury, and submitted to the Compliance Office within ninety (90) calendar days of the date of the Service and as a condition precedent to any Payments being issued under a Consulting Agreement.

36. For all Consulting Agreements entered into after the Effective Date of this DPA, the Company agrees to make Payments to Consultants at a fair market value hourly rate ("Hourly Rate") of no more than $500 per hour for time actually expended by a Consultant performing Consulting Services. In the event the Company wishes to make Payments to a Consultant at a higher Hourly Rate or at a different rate because of the Consultant's special expertise or the nature of the service (such as a per patient rate for clinical studies), the Company must obtain or have obtained a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the Monitor. Any changes to the Hourly Rate or Payments other than at the Hourly Rate must be approved by the Monitor.

PhRMA Code vs. DPA Requirements

PhRMA Code Requirements

- Written contract
- Legitimate need identified in advance
- Selection based on identified need
- # HCPs limited to meet need
- Documentation that services were received and used
- Venues should be appropriate
- Compensation based on FMV
- Provision of/reimbursement for travel, lodging, meals
- No recreation or entertainment
- Speakers:
  - Per-HCP annual cap on comp
  - Min, max # of programs per HCP
  - Disclosure of company role
  - Periodic monitoring

DPA Provisions*

- Annual needs assessment certified by senior management
- Individual agreements approved by senior management
- Written agreements of at least one year
- Compensation capped at $500/hour subject to exceptions process (supported by external analysis)
- Post-event report and certification

* Beyond PhRMA Code provisions

Pfizer CIA – New Consulting Controls

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PFIZER INC

I. PREAMBLE

Pfizer Inc (Pfizer) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Pfizer is entering into a Settlement Agreement with the United States. Pfizer will also enter into settlement agreements with various States (State Settlement Agreement and Release) and Pfizer's agreement to this CIA is a condition precedent to those agreements.

Consultants – General Requirements

1. *Consulting Arrangement Activities*. To the extent that Pfizer engages HCPs for services other than for speaker programs (e.g., as a member of an advisory board or to attend consultant meetings) that relate to Promotional and Product Related Functions, such HCPs shall be referred to herein as Consultants. Pfizer shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Pfizer. Prior to the retention of justify the retention of the consultant. The business rationale form shall include an identification of the business need for the information to be provided by the Consultant and provide specific details about the consulting arrangement (including, for example, information about the numbers and qualifications of the HCPs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated).

Consultants – Annual Plans

To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall establish a process to develop an annual Consultant budgeting plan that relates to the annual brand operating plans and that identifies the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Personnel from Pfizer's legal department shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. Within 120 days after the Effective Date, Pfizer shall also establish a process for the review by personnel from Pfizer's legal department of all business rationale forms associated with the retention of any Consultant prior to the retention of the Consultant. The purpose of this legal review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and that Consultant arrangements are consistent with the applicable approved Consultant budgeting plan. Any deviations from the Consultant budgeting plans shall be documented in the business rational form (or elsewhere, as appropriate) and shall be considered as part of the legal review. To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall amend its policies to require the collection, assessment, and retention of work product generated by Consultants.

Consultants – Monitoring and Auditing

Within 120 days after the Effective Date, Pfizer shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 50 consultant programs with HCPs during each Reporting Period. Of the Consultant Program Audits, at least 35 of the audits shall pertain to non-advisory board programs, and 15 shall pertain to advisory board programs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a random sampling approach. Personnel conducting the Consultant Program Audits shall review business rationale forms, consultant contracts, and materials relating to the program or work of the Consultant (including a verification that the work product resulting from any Consultant-related program or event or otherwise generated by the Consultant is consistent with the stated business need set forth on the business rationale form or elsewhere), in order to assess whether the programs and arrangements were conducted in a manner consistent with Pfizer's Policies and Procedures. Results from the Consultant Program Audits shall be compiled and reported to Pfizer headquarters for review and remediation as appropriate. Potential violations of Pfizer's Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity.

Concluding Thoughts

- PhRMA Code + DPA Controls + CIA Controls = virtual 360º safeguards for individual HCP engagements
- But disagreements likely between Gov't and Industry perspectives on overall consultant numbers …
  - This is important as Gov't increasingly focuses on overall "schemes" (based on numbers of consultants, selection criteria, ROI evidence, and lack of documentation on receipt/use of consulting services) -- not on "quid pro quo" evidence in individual arrangements
- ... and sunshine laws will ↑ scrutiny of use of HCPs
- Which puts premium on rigorous annual plan/needs assessments + proper execution on other HCP controls