Additional FCPA Compliance Points – Clinical Trials

The information provided herein is additional resource material to the training provided in the following EduNeering module: Foreign Corrupt Practices Act (referred to as the “Module”). The information provided herein is also additional resource material to the Nektar Compliance Manual for Interactions with Healthcare Professionals (the “Compliance Manual”).

The additional training information contained herein is applicable to the conduct of all phases of all human clinical trials conducted by (or funded by) Nektar inside or outside of the United States. As noted, this training information contained herein is in addition to the training information contained in the Module and the Compliance Manual. It is assumed that all readers of this additional training material have already read and understood the information contained in one or both of the Module and the Nektar corporate policy information contained in the Compliance Manual.

1. “Bribery” is generally defined as the act of offering anything of value to a “Foreign Official” to gain an improper advantage. As you learned from the Module, this concept of US law applies to activities outside the US by virtue of the Foreign Corrupt Practices Act (among other US laws).

2. The term “Foreign Official” has been construed very broadly by the US Department of Justice (the primary criminal prosecution arm of the US government) to include any or all of the following (which are in addition to all of the examples provided in the Module):

   (a) any direct or indirect government employee of any government (US or foreign country) at any level of government (local, state or federal), and includes executive agencies such as foreign counterparts to the US Food & Drug Administration and the US Centers for Medicare and Medicaid Services;

   (b) any physician in private practice who receives any compensation or reimbursement directly or indirectly from any government entity or agency (local, state or federal);

   (c) any physician, nurse, pharmacist, orderly, therapist, or clerical support person employed by any government hospital, medical school, or other healthcare training school (such as a nursing school);

   (d) any physician, nurse, pharmacist, orderly, therapist, or clerical support person employed by any private (non-governmental) hospital, medical school, other healthcare training school (such as a nursing school) that receives any compensation or reimbursement directly or indirectly from any government entity or agency (local, state or federal);

   (e) any physician, consultant or other person or entity involved in any way with any governmental decision to (i) authorize a clinical trial to be conducted in a particular country; (ii) authorize a drug or device to be commercialized in a particular country; or (iii) authorize direct or indirect governmental payment or reimbursement in connection with the commercialization of any drug or device in a particular country; or

   (f) any Investigator or Sub-Investigator involved in any clinical trial.
3. Any payment to or on behalf of any Foreign Official, such as an institution, physician, other healthcare professional or consultant to conduct or assist in conducting a clinical trial can be construed as an illegal bribe unless: (a) the payment is covered by a written contract between Nektar and the recipient of the payment that is in place (i.e., signed and delivered) by both parties prior to the payment being made; (b) the contract covers the services to be provided by or on behalf of the recipient in exchange for the payment; (c) the amount of the payment is consistent with fair market value for the services provided in the relevant market; (d) the fully-executed contract is maintained by the Nektar Legal Department in its contract files; and (e) all payments made under the contract are recorded by the Nektar Finance Department in Nektar’s financial books and records maintained by Nektar in the ordinary course of Nektar’s business.

4. Any payment to or on behalf of any Foreign Official, such as an institution, physician, other healthcare professional or consultant to provide services outside of conducting or assisting in the conduct of a clinical trial (such as consultation services involving presentation of data at medical meetings or to the financial community, consulting on future clinical programs and protocols, or participating in meetings with regulatory authorities) can be construed as an illegal bribe unless: (a) the payment is covered by a written contract between Nektar and the recipient of the payment that is in place (i.e., signed and delivered) by both parties prior to the payment being made; (b) the contract covers the services to be provided by or on behalf of the recipient in exchange for the payment; (c) the amount of the payment is consistent with fair market value for the services provided in the relevant market; (d) the fully-executed contract is maintained by the Nektar Legal Department in its contract files; and (e) all payments made under the contract are recorded by the Nektar Finance Department in Nektar’s financial books and records maintained by Nektar in the ordinary course of Nektar’s business.

5. Never make or authorize any other Nektar employee or any independent third party to make any payment or provide anything of value (such as a gift or gratuity) to or on behalf of any individual or entity in connection with any clinical trial that does not meet the requirements of Section 3 above. This includes any payment, gift or gratuity to be paid to any employees or other representatives of hospitals, medical schools or medical practices, Investigators, Sub-Investigators, clinical trial coordinators, nurses, orderlies, enrollment staff, referring physicians, or clerical support staff. One example of an improper payment: providing a $50.00 gift card to a study coordinator because an enrollment target was achieved early.

6. Meals and other hospitality should be considered improper unless specifically authorized in the Nektar Compliance Manual.

7. In addition to the examples provided in the Module, warning signs that a bribe or other improper payment is being sought in the context of a clinical trial include the following: a Foreign Official (including a governmental employee or employee of an institution (such as a hospital or medical school), or any Investigator, Sub-Investigator, support staff or consultant) (a) seeks a payment or other item of value that is not covered by a written contract between Nektar and the recipient that is in place (i.e., signed and delivered by both parties) prior to the payment being made or other item of value being transferred to the recipient; (b) seeks a payment or other item of value that is above fair market value for the services to be provided in the relevant market; (c) refuses to enter into a written contract.
contract with Nektar covering the payment or other transfer of value; or (d) seeks a payment or other item of value from Nektar that is not to be recorded by the Nektar Finance Department in Nektar’s financial books and records maintained by Nektar in the ordinary course of Nektar’s business.

8. Never agree to pay a bribe or to make any other payment of any kind that is not covered by all of the provisions of Section 3 or Section 4 (as applicable) above, and is sanctioned by the Nektar Compliance Manual.

9. Never agree to make a payment on behalf of a Foreign Official (including a governmental employee or employee of an institution such as a hospital or medical school), or any Investigator, Sub-Investigator, support staff or consultant) unless covered in advance by all of the provisions of Section 3 or Section 4 (as applicable) above and sanctioned by the Nektar Compliance Manual. Examples include purchasing airline tickets, limo rides or hotel accommodations.

10. If you believe a bribe or other improper payment (any payment not in compliance with Section 3 or Section 4 (as applicable), above) has been sought from you or from anyone else working for or on behalf of Nektar (such as a Nektar employee, consultant or vendor), immediately take one of the following actions: (a) contact your supervisor and report the incident; (b) contact any member of the Nektar Legal Department and report the incident; or (c) report the incident via the Nektar Help Line (1-800-481-7045), which report can be made anonymously.

11. If you believe a bribe or other improper payment (any payment not in compliance with Section 3 or Section 4 (as applicable), above) has been made by any individual or entity working for or on behalf of Nektar (such as a Nektar employee, consultant or vendor), immediately take one of the following actions: (a) contact your supervisor and report the incident; (b) contact any member of the Nektar Legal Department and report the incident; or (c) report the incident via the Nektar Help Line (1-800-481-7045), which report can be made anonymously.

If you have any questions about any of the content of this additional training, please contact either your supervisor or a member of the Nektar Legal Department.