

UPDATES FROM BARATZ & ASSOCIATES, P. A. FOR THE HEALTHCARE INDUSTRY

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ASTRAZENECA PAYS \$520 MILLION PLUS 5 YEARS CORPORATE INTEGRITY AGREEMENT. GO BELOW THE SURFACE TO UNDERSTAND.

The Department of Justice (DOJ) announced on April 27, 2010 that AstraZeneca LP (AZ) and AstraZeneca Pharmaceuticals LP will pay \$520 million to resolve allegations that AZ illegally marketed the anti-psychotic drug Seroquel for uses not approved as safe and effective by the Food and Drug Administration (FDA). AZ signed a civil settlement to resolve allegations that, by marketing Seroquel for unapproved uses, AZ caused false claims for payment to be submitted to federal insurance programs including Medicaid, Medicare and TRICARE programs, and to the Department of Veterans Affairs, the Federal Employee Health Benefits Program and the Bureau of Prisons.

In this discussion, we are not going to focus on the main issue of "off-label" use, but instead, discuss the role of Health Care Professionals (HCPs) and Health Care Institutions (HCIs) and the requirements outlined in the 5 year Corporate Integrity Agreement (CIA) that was required as part of the settlement.

The United States contends that AZ promoted the unapproved uses "by improperly and unduly influencing the content of, and speakers, in company-sponsored continuing medical education programs. The Company also engaged doctors to give promotional speaker programs on unapproved uses for Seroquel and to conduct studies on unapproved uses."

The DOJ release stated, "in addition, the company recruited doctors to serve as authors of articles that were ghostwritten by medical literature companies and about studies the doctors in question did not conduct. AZ then used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel" and "that AZ violated the federal Anti-Kickback Statute by offering and paying illegal remuneration to doctors it recruited to serve

as authors of articles written by AZ and its agents". Also, AZ "offered and paid illegal remuneration to doctors to travel to resort locations to "advise" AZ about marketing messages for unapproved uses of Seroquel, and paid doctors to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel" and "that these payments were intended to induce the doctors to prescribe Seroquel for unapproved uses in violation of the federal Anti-Kickback Statute."

If we think through the logic and thought process of the government's contentions, it can be applied to a vast area of the health care industry and not just "off-label" use of pharmaceuticals. The inference is that HCPs and HCIs are in a position to influence the flow of health care dollars and, therefore, are prime targets for vendors, suppliers, manufactures, medical facility providers, etc. to impact on how and where those dollars are spent.

In the CIA that AZ agreed to, there are very specific areas that address the financial relationships and dealings with HCPs and HCIs.

Below we have summarized some relevant areas of the CIA that we think clearly delineates the government's approach to relationships with HCPs or HCIs. These compliance polices required, clearly outline the government's position that duties and responsibilities be clearly defined, be appropriate and in compliance with applicable federal health care program and FDA requirements, and that fair market value rates be determined and preset. In addition, an ongoing review of the arrangements should be performed to insure that the actual work is performed appropriately.

The CIA states that the policies and procedures of AZ must address the following areas as it relates to HCPs and HCIs:

- 1) Consultant or other fee for service arrangements entered into with Health Care Professionals (HCP) or Health Care Institutions (HCI) (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities and any other financial engagement or arrangement with an HCP or HCI and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events.
- 2) Programs to educate sales representatives, including but not limited to presentations by HCP's at sales meetings, preceptorships, tutorials and experience based learning activities.
- 3) Compensation (including through salaries, bonuses and contests) for Relevant Covered Persons who are sales representatives shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales and marketing of AZ government reimbursed products.
- 4) Consultant Arrangement Activities

To the extent that AZ engages U.S. based HCP's or HCI's for services other than for speaker programs, tutorials, preceptorships, or research related functions that relate to Promotional Functions or to Product Related Functions (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as consultants. AZ shall require all consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the consultants. Consultants shall be paid according to a centrally managed, preset rate structure that is determined based on a fair market value analysis conducted by AZ.

Other Considerations

- 1) Quarterly consultant budget
- 2) Needs assessment to justify use of consultant.
- 3) Insure work performed and work product generated.
- 4) Audit program to review and monitor consultant arrangements.
- 5) Same as above for research related activities and publication activities.
- 6) Required public reporting of payments to U.S. based Physicians and related entities.

The above information gives valuable insight as to what the government believes companies should be doing while conducting business. To ignore this insight is at your own peril. At the end of the day you must be able to appropriately answer the following:

- 1) Why did you enter into the arrangement?
- 2) Did you document clearly your plan and intentions?
- 3) Did you prepare an agreement that outlines the requirements of the arrangement, including the purpose, needed expertise, payment structure, deliverables and compliance review?
- 4) Was fair market value established objectively in advance and reviewed at the appropriate levels?
- 5) Has the compliance officer signed off?

If you do the above, it will go a long way to ease your regulatory concerns.

Ending note: The whistleblower in the qui tam lawsuit will receive more than \$45 million from the federal share of the civil recovery.

Reference:

www.justice.gov/opa/pr/2010/April/10-civ-487.html

CIA between DHHS-OIG and AstraZeneca Pharmaceuticals LP and AstraZeneca LP

NOTE: FOR ADDITIONAL INFORMATION AND RESOURCES MAKE SURE YOU CHECK OUT OUR WEBSITE: <http://www.baratzcpa.com>

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