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SUMMARY OF RELEVANT LAWS, REGULATIONS, AND GUIDELINES

Careful consideration must always be given to whether providing a product, service, or grant to a customer could be construed as an attempt to influence those in a position to generate business for Wyeth or could be deemed to be a discount or a reduction in the price being paid for Wyeth products. Giving an additional discount on Wyeth products may trigger the application of a number of federal laws and regulations and industry guidelines, potentially resulting in legal liability and financial losses. This exhibit summarizes some of the pertinent laws, regulations, and guidelines.

A. The Federal Anti-Kickback Statute

The Federal Health Care Program Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. §1320a-7b, imposes criminal penalties on individuals and entities that knowingly and willfully solicit or receive remuneration "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service" or "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under" a Federal Health Care Program. The Anti-Kickback Statute also prohibits a person from knowingly and willfully offering or paying remuneration to any person to induce that person to refer or purchase, lease, order or arrange for or recommend the purchasing, leasing or ordering of items or services for which payment may be made by a Federal Health Care Program.

The types of remuneration prohibited by the Anti-Kickback Statute include, but are not limited to, kickbacks, bribes, and rebates. The Anti-Kickback Statute prohibits both "direct" and "indirect" remuneration. Any person convicted of knowingly and willfully violating the Anti-Kickback Statute shall be found guilty of a felony, and fined not more than $25,000 or imprisoned for not more than five years, or both, for each violation. In addition to these criminal penalties, civil exclusion from the Federal Health Care Programs is possible.

Violators of the Anti-Kickback Statute who bill Medicare or other federal and state health care programs, including Medicaid, also can be subject to exclusion from these programs, regardless of whether a criminal conviction has been obtained. Although Wyeth is a manufacturer and, as such, may not be excluded from the Medicaid program, any person or entity receiving remuneration from a manufacturer will be excluded if the recipient bills government health programs.

Wyeth Pharmaceuticals

EXHIBIT N Committee on Commerce/Labor
Date: 4/2/03 Page 1 of 5

SUMMARY OF RELEVANT LAWS, REGULATIONS, AND GUIDELINES

B. Medicaid Drug Rebate Law

The Medicaid Drug Rebate Law requires that Wyeth give state Medicaid programs the "best price" that it offers to any customer. "Best price" is defined generally as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit entity. Sales to the government also are included in the definition of best price in some instances. Best price also includes free goods that are contingent on any purchase requirement, volume discounts, and rebates. Best price does *not* include prices that are nominal in amount or free goods that are not contingent upon a purchase. Therefore, any benefit that Wyeth gives to a customer that is not nominal in amount or that is tied to or bundled with the purchase of Wyeth's products also must be given to state Medicaid programs. Failure to comply with the Medicaid Drug Rebate Program requirements could result in Wyeth's products being excluded from coverage under the Medicaid program.

C. Veterans Health Care Act of 1992

The Veterans Health Care Act of 1992 ("VHCA") enables certain statutorily defined "covered entities" to purchase outpatient drugs from the manufacturer at a deep discount determined by statute regardless of volume. The VHCA also requires the manufacturer to offer its drugs to the Department of Defense, Veterans Administration, and the Public Health Service at a special discounted price. Failure to comply with the VHCA could result in Wyeth's products being excluded from the Medicaid program.

SUMMARY OF RELEVANT LAWS, REGULATIONS, AND GUIDELINES

D. Industry Guidelines

Since December 1990, the American Medical Association (AMA) has revised its ethical code to incorporate new guidelines on gifts to physicians from the pharmaceutical industry. These guidelines define acceptable and unacceptable offers in some areas. The following are specified as offers that are not appropriate for physicians to accept or pharmaceutical companies to offer:

1. Gifts of cash
2. Gifts that are not related to the physician's work or that do not entail benefits to the patient
3. The cost of travel, lodging, and other personal expenses of physicians attending meetings
4. Subsidies to compensate for the physician's time attending a meeting
5. Token consulting arrangements
6. Gifts with strings attached.

The PhRMA Code on Interactions with Healthcare Professionals has been incorporated into the Policy on Sales and Marketing Practices, Policy 511. The PhRMA Code is available on the PhRMA website at http://www.phrma.org/.

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SPECIAL FRAUD ALERT

OFFICE OF INSPECTOR GENERAL

SPECIAL FRAUD ALERT

Prescription Drug Marketing Schemes

August 1994

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections. To help reduce fraud in the Medicare and Medicaid programs, the OIG is actively investigating violations of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. Section 1320a-7b(b).

What is the Medicare and Medicaid Anti-Kickback Law?

Among its provisions, the anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or kind to induce or in return for:

A. referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid programs; or

B. purchasing, leasing or ordering, or arranging for or recommending purchasing, leasing or ordering, any good, facility, service, or item payable under the Medicare or Medicaid programs.

Violators are subject to criminal penalties, or exclusion from participation in the Medicare and Medicaid programs, or both. In 1987, Section 14 of the Medicare and Medicaid Patient and Program Protection Act, P.L. 100-93, directed this Department to promulgate "safe harbor" regulations, in order to provide health care providers a mechanism to assure them that they will not be prosecuted under the anti-kickback statute for engaging in particular practices. The Department published 11 final "safe harbor" regulations on July 29, 1991 (42 C.F.R. § 1001.952, 56 Fed. Reg. 35,952), and two more on November 5, 1992 (42 C.F.R. § 1001.952, 57 Fed. Reg. 52,723). The scope of the anti-kickback statute is not expanded by the "safe harbor" regulations; these regulations gave those in good faith compliance with a "safe harbor" the assurance that they will not be prosecuted under the anti-kickback statute.

(OIG 94-1-01)

How Does the Anti-Kickback Law Relate to Prescription Drug Marketing Schemes?

In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. Prescription drugs supplied under one of these programs are often reimbursed under Medicaid. Among the specific activities, which the OIG has identified, are the following actual cases:

- A "product conversion" program which resulted in 95,000 brand-name conversions. In this scenario, for instance, Drug Company A offered a cash award to pharmacies for each time a drug prescription was changed from Drug Company B's product to Drug Company A's product. The pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription.
- A "frequent flier" campaign in which physicians were given credit toward airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on the drug company's product.
- A "research grant" program in which physicians were given substantial payments for de minimis record-keeping tasks. The physician administered the drug manufacturer's product to the patient and made brief notes, sometimes a single word, about the treatment outcome. Upon completion of a limited number of such "studies," the physician received payment from the manufacturer.

If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or "safe har-

SPECIAL FRAUD ALERT

[illegible] to protect such activities. Thus a [illegible]cian, pharmacy or other practitioner or supplier receiving payment under these activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the federal government's costs of reimbursing suppliers for the products. The OIG is investigating various drug marketing schemes, and enforcing the anti-kickback laws where these practices affect the federal health care programs.

What to Look For:

Generally, a payment or gift may be considered improper under 42 U.S.C. § 1320a-7b(b) if it is:

- Made to a person in a position to generate business for the paying party;
- Related to the volume of business generated; and
- More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

OIG investigation may be warranted where one or more of the following features is present in prescription drug marketing activities:

- Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies, and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.
- Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented "educational" or "counseling" contacts, or physician and/or patient outreach, etc.
- Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.
- Any payment, [illegible]uding cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with a "safe harbor" regulation, 42 C.F.R. § 1001.952, or other federal provision governing the reporting of prescription drug prices.

What To Do If You Have Information About Suspect Prescription Drug Marketing Activities

If you have information about drug companies or other providers engaging in the types of activities described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Regions	States Served	Telephone
Boston	MA, VT, NH, ME RI, CT	617-565-2660
New York	NY, NJ, PR, VI	212-264-1691
Philadelphia	PA, MD, DE, WV VA	215-596-6796
Atlanta	GA, KY, NC, SC FL, TN, AL, MS (No. District)	404-331-2131
Chicago	IL, MN, WI, MI IN, OH, IA, MO	312-353-3746
Dallas	TX, NM, OK, AR LA, MO (So. District)	214-767-8406
Denver	CO, UT, WY, MT, ND, SD, NE, KS	303-844-7621
Los Angeles	AZ, NV (Clark Co.) So.CA	714-836-2372
San Francisco	No. CA, NV, AZ, HI, OR, ID, WA	415-536-8960
Washington, DC	DC and Metropolitan areas of VA & MD	202-619-1900

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5