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Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation- Through-Litigation

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ABSTRACT: Fraudulent or abusive sales and marketing practices by pharmaceutical companies can result in costly overutilization of products that are increasingly paid for by government health-care programs and may result in adverse health and safety consequences to the patient-beneficiaries of those programs. Federal enforcement efforts in this area are largely modeled on those used to combat white-collar crime, with cases taking years to reach conclusion. This approach overlooks the impact on patients who receive unnecessary care or are denied access to appropriate care during the course of the investigation. Many states are beginning to regulate certain pharmaceutical sales and marketing practices, but state-by-state regulation ignores the importance of a uniform federal regulatory and enforcement approach in an area already occupied by federal law. This Article explores current federal and state efforts to limit overutilization, fraud, and abuse in the sale and marketing of prescription drugs, and illustrates the merits of an expanded role for the U.S. Food and Drug Administration (FDA) to regulate pharmaceutical sales and marketing practices. This approach borrows lessons learned from the FDA's efficient and

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effective regulatory and enforcement methods and maintains a careful balance between the interests of patient-beneficiaries, the government and industry.

Federal and state governments are increasingly called upon to cover the cost of prescription drug products as part of Medicare, Medicaid, and other federal and state healthcare programs.¹ Fraudulent or abusive marketing practices by pharmaceutical companies can result in over-utilization of prescription drugs reimbursed by the government, which may result in adverse consequences affecting the health and safety of the patient-beneficiaries of these programs.² Current government enforcement efforts often take years to conclude and do not account for the consequences to patients who receive unnecessary care or are denied access to appropriate care while the gears of the criminal and civil enforcement processes grind forward.³

¹ See Dana Milbank & Claudia Deane, *Expansion of Medicare Becomes Law*, WASH. POST, Dec. 14, 2003, at A03. The Centers for Medicare and Medicaid Services (CMS) administers Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP) and other government healthcare programs. U.S. DEP'T OF HEALTH & HUMAN SERV. (HHS), CMS FINANCIAL REPORT, FISCAL YEAR 2005 at 1 (2005) [hereinafter CMS FINANCIAL REPORT], available at www.cms.hhs.gov/CFOReport/Downloads/2005_CMS_Financial_Report.pdf (last visited Mar. 28, 2006). In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (known as Medicare Part D), the largest expansion in a federal entitlement program since the inception of the program some forty years ago. See Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 42 U.S.C. § 1395w); Milbank & Deane, *supra*. Not coincidentally, government enforcement officials have been raising concern about the likelihood of fraud in the new benefit program, pointing out that at a cost of some \$720 billion over the next ten years, "[t]his is the largest new social benefit program in the history of the country There are vulnerabilities, and there is going to be fraud" Nathan Vardi, *Rx For Fraud*, FORBES MAG., June 20, 2005, at 124 (quoting remarks of James Sheehan, Associate U.S. Attorney, Eastern District of Pennsylvania).

² See David A. Kessler, *Addressing the Problem of Misleading Advertising*, 116 ANNALS INTERNAL MED. 950, 950 (1992).

Misleading advertisements can result in significant adverse consequences [N]eedless injury or even death may occur because physicians have been persuaded to prescribe products for uses for which they have not been adequately tested or to substitute therapies that may be less safe or less effective than the alternatives.

Id.

³ See, e.g., *United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003). The case was brought in 1996 but was not settled until 2004—eight years later—by Parke-Davis' successor Pfizer, Inc. See Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm (last visited Mar. 30, 2006) [hereinafter Press Release, Warner-Lambert].

This Article discusses the current government enforcement approaches and reviews two of the leading cases that illustrate the government's approach.

Some marketing practices, such as providing meals, gifts, and free product samples to physicians, may raise concern about industry influence over physician prescribing.⁴ Other activities, such as industry support for continuing medical education (CME), are likely to be of benefit to the patient-beneficiaries of federal healthcare programs and are intended to advance the practice of medicine.⁵ Many of these practices are the subject of government guidance developed for the pharmaceutical industry and are the subject of regulatory or statutory "safe harbors" or "Advisory Opinions."⁶ These practices are also governed by voluntary industry or professional standards that are sometimes incorporated by reference into government guidance.⁷

⁴ See Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000) (describing a positive association between physician prescribing practices and gifts, meals, consulting fees, and the like provided by pharmaceutical companies in the course of promoting their products).

⁵ See Am. Med. Ass'n, Op. E-8.061 (1992), available at www.ama-assn.org/ama/pub/category/8484.html (last visited Mar. 30, 2006) (discussing gifts given to physicians by the pharmaceutical and medical product industry).

⁶ See Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,734–39 (May 5, 2003) (notice indicating that business courtesies and other gratuities given by pharmaceutical companies to physicians could violate the Anti-kickback Statute); see also Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001) (final rule promulgating the first ten safe harbors to the Anti-kickback Statute). The ten original safe harbors covered: investment interests; space rental; equipment rental; personal services and management contracts; sale of practice; referral services; warranties; discounts; employees; and group purchasing organizations. *Id.* at 35,953, 35,984–87. These practices, if undertaken in compliance with the specified terms of the safe harbor, will not be deemed a violation of the Anti-kickback Statute and may in fact reduce costs to the government and to program beneficiaries. *Id.* at 35,954. The initial safe harbors have been supplemented from time to time with additional regulatory safe harbors. 42 C.F.R. § 1001.952 (2006) (further defining safe harbors). See generally OIG, HHS, Safe Harbor Regulations and Preambles, at www.oig.hhs.gov/fraud/safeharborregulations.html (last visited Mar. 30, 2006) (providing a history of the safe harbor regulations). The OIG Advisory Opinion process enables individuals and entities to seek advice from OIG on the application of the Anti-kickback Statute based on presentation of specific facts and scenarios. See 42 C.F.R. pt. 1008 (2006).

⁷ For example, the Office of the Inspector General has stated that compliance with the guidance established by the Pharmaceutical Researchers of America, while not necessarily protecting a manufacturer from liability, will demonstrate a good faith effort to comply with the Anti-kickback Statute. Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23,737. See PHARM. RESEARCHERS OF AM. (PHRMA),

Nevertheless, the government remains concerned that these activities raise an enormous potential for abuse.⁸

The government's general concerns regarding fraudulent or abusive sales and marketing practices for prescription drugs are articulated in its statement of interest filed in the case of *United States ex rel. Franklin v. Parke-Davis*.⁹ The government claimed that Parke-Davis "engaged in a scheme to defraud federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals—judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor."¹⁰ More broadly, the government's interest relates to the extent that pharmaceutical marketing practices impact: "(1) [the] [i]ntegrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples."¹¹ Given that federal spending on Medicare, Medicaid, and other federal health programs alone accounted for approximately \$521.7 billion in 2005, covering some eighty-seven million people, the government's interest in minimizing fraud, waste, and abuse in federal healthcare programs is understandable.¹²

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The Health Care Fraud and Abuse Control Program provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate that the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) share responsibility for combating healthcare fraud and abuse.¹³

CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 2002 [hereinafter PhRMA CODE], available at www.phrma.org/files/PhRMA%20Code.pdf (last visited Mar. 30, 2006); ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., STANDARDS FOR COMMERCIAL SUPPORT 2004, available at www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (last visited May 20, 2006).

⁸ See Judith A. Thorn & Kendra D. Casey Plank, *Final Voluntary Compliance Guidance For Drug Manufacturers Issued by HHS IG*, 7 *Healthcare Fraud Rep.*, (BNA), 325 (Apr. 30, 2003).

⁹ Statement of Interest In Opposition to Defendant's Motion for Summary Judgment at 2, *United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 WL 22331142 (D. Mass. May 23, 2003).

¹⁰ *Id.*

¹¹ See Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23,732.

¹² See CMS FINANCIAL REPORT, *supra* note 1, at 2. The Medicare and Medicaid programs have 42 million and 44.7 million beneficiaries, respectively. *Id.* at inside front cover.

¹³ See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, 1992-2003 (codified as amended in scattered sections of 42 U.S.C.); see also HHS & U.S. DEP'T OF JUSTICE (DOJ), HEALTH CARE FRAUD AND

This technically complex and dense area of law, focused on the regulation of private conduct, resembles the sort of *malum prohibitum* context well suited to the work of administrative agencies such as the Occupational Health and Safety Administration or the FDA.¹⁴ These agencies oversee a regulatory infrastructure established for the protection of the public where companies that are subject to regulation have “the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce.”¹⁵ Thus, the regulations place the burden of these protections on companies, “rather than to throw the hazard on the innocent public who are wholly helpless.”¹⁶ Industries so regulated often have “a positive duty to seek out and remedy violations when they occur . . . and . . . a duty to implement measures that will insure that violations will not occur.”¹⁷

Unlike the laws that govern the work of administrative agencies and the private activities they regulate, the federal health-care fraud and abuse statutes are broad and general. There are relatively few regulations and little definitive government guidance.¹⁸ In the area of pharmaceutical healthcare fraud and

ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2003 (2004) [hereinafter FRAUD AND ABUSE ANNUAL REPORT], at www.usdoj.gov/dag/pubdoc/hcfacreport2003.htm (last visited May 20, 2006). The joint HHS/DOJ report states:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program), under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS), acting through the Department’s Inspector General (HHS/OIG), designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. In its seventh year of operation, the Program’s continued success again confirmed the soundness of a collaborative approach to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud or abuse, and to protect program beneficiaries.

Id.

¹⁴ See WILLIAM F. FUNK ET AL., ADMINISTRATIVE PROCEDURE AND PRACTICE 13 (1997). A *malum prohibitum* act is “an act which is not inherently immoral, but becomes so because its commission is expressly forbidden by positive law.” BLACK’S LAW DICTIONARY 960 (6th ed. 1990).

¹⁵ United States v. Dotterweich, 320 U.S. 277, 285 (1943).

¹⁶ *Id.*

¹⁷ United States v. Park, 421 U.S. 658, 672 (1975).

¹⁸ See generally LINDA A. BAUMANN, HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES 9 (2002) (summarizing federal healthcare fraud and abuse laws). For example, in the preamble to the final rule publishing the initial safe harbor regulations for the Anti-kickback Statute, OIG observed that the Anti-kickback Statute “is extremely broad[, so much so that] . . . concern has arisen among a number of

abuse, there are only sporadic (though sometimes spectacular) enforcement actions that may provide some guidance for industry compliance activities.¹⁹

Given the complexities of the activities concerned and the lack of definitive and specific guidance, even federal prosecutors admit that it is “sometimes . . . hard to tell when a marketing method ‘crosses the line.’”²⁰ Judges complain that “any solid grasp of . . . [federal healthcare program] matters . . . [is] merely a passing phase.”²¹

Calling to mind the adage “when all you have is a hammer, everything looks like a nail,” the DOJ groups enforcement of pharmaceutical marketing fraud and abuse with the department’s other efforts to combat high profile criminal activity, including organized crime, child pornography, and other intrinsically immoral *mala in se* crimes.²² In short, the DOJ

health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.” Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001). OIG makes clear that while transactions involving small (*de minimis*) payments may be unlikely to impact the integrity of federal healthcare programs, it is unwilling to “blur these lines” by carving out exceptions for *de minimis* amounts. *Id.* at 35,954.

¹⁹ See, e.g., Press Release, DOJ, TAP Pharm. Products Inc. & Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), available at www.usdoj.gov/opa/pr/2001/October/513civ.htm (last visited May 20, 2006). The settlement agreement between the government and Bayer Pharmaceuticals in September 2000 was the first in a series of pharmaceutical industry-government settlements. Each year since 2000, the government has announced settlement of less than a handful of cases. See *Bayer Drug Prices To Be Monitored By HHS Under Medicaid Fraud Settlement*, THE PINK SHEET, Sept. 25, 2000, at 23. All the settlements have required corporate integrity agreements and have imposed fines ranging from a few million dollars to nearly one billion dollars. E.g., Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Services and Pfizer Inc., May 11, 2004 [hereinafter Corporate Integrity Agreement], available at http://oig.hhs.gov/fraud/cia/agreements/pfizer_5_11_2004.pdf (last visited May 20, 2006); see generally OIG, HHS, Corporate Integrity Agreements (CIAs) and Settlement Agreements with Integrity Provisions, available at www.oig.hhs.gov/fraud/cia/index.html (last visited May 20, 2006).

²⁰ See Peyton M. Sturges, *Medicare Prescription Benefit Program Poses Opportunities for Fraud*, *Sheehan Says*, 7 *Healthcare Fraud Rep.*, (BNA) 524 (July 9, 2003) (citing remarks of James Sheehan, Associate US Attorney, Eastern District of Pennsylvania).

²¹ *Rehab. Ass’n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).

²² See generally DOJ, FY 2004 PERFORMANCE AND ACCOUNTABILITY REPORT at II-4 (2004) [hereinafter DOJ REPORT], available at www.usdoj.gov/ag/annualreports/pr2004/P2/p04-13.pdf (last visited May 20, 2006). A *malum in se* act is one that “is inherently and essentially evil . . . without any regard to the fact of its being

approaches alleged pharmaceutical marketing fraud and abuse not as an administrative agency responsible for regulating private conduct, but as a law-enforcement agency targeting high profile criminal activity.

For its part, the responsibilities of HHS under the HIPAA Healthcare Fraud and Abuse Control Program fall largely to the HHS Office of the Inspector General (HHS OIG).²³ HHS OIG is focused on assuring the integrity and efficient operation of HHS programs.²⁴ Its work is comprised of audits and inspections, and it periodically issues new or updated safe harbor regulations and prepares advisory opinions in response to specific queries.

The combined effort of the HHS and DOJ have focused on alleged illegal acts such as outright kickbacks to physicians, sale of prescription drug samples, and schemes by drug companies to disguise promotion of unapproved use of their products as independent educational activities.²⁵ Applying the machinery of the criminal justice system requires multi-year investigations that have yielded settlements imposing strict corporate integrity agreements and fines in the hundreds of millions of dollars.²⁶ Given that one possible penalty under the fraud and abuse statutes is exclusion from participation in federal healthcare programs, effectively a “corporate death sentence,” few cases proceed to a contested trial.²⁷

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It is difficult to judge the actual impact of these federal efforts on the government’s goal of reducing waste, fraud, and abuse. It is clear, however, that these efforts have not been sufficiently

noticed or punished by the law of the state.” BLACK’S LAW DICTIONARY, *supra* note 14, at 959.

²³ See *supra* note 13.

²⁴ See OIG, HHS, OIG Mission [hereinafter OIG Mission], at www.oig.hhs.gov/organization/OIGmission.html (last visited May 20, 2006).

²⁵ See *supra* note 19.

²⁶ See *supra* note 19.

²⁷ Ronald H. Clark et al., *HHS Expanded Use of Fraud Law’s “Corporate Death Sentence” Is Legally Suspect*, LEGAL BACKGROUNDER, June 6, 2003, at 1, 1–2, available at www.wlf.org/upload/060603LBCClark.pdf (last visited May 20, 2006). The authors offer the following reasoning as to why so few cases brought under the False Claims Act proceed to court:

For those not privy to the inner-workings of DOJ or the HHS Office of Inspector General (“OIG”), or who have not participated in settlement negotiations, it may be a mystery as to why large publicly-traded companies settle highly suspect allegations for hundreds of millions of dollars without ever forcing the government to prove its case. The answer is simple: the government asserts that it will exclude these companies

successful so as to deter the advance of state legislation aimed at controlling marketing practices that states regard as contributing to the high cost of drugs.²⁸ Instead of approaching pharmaceutical fraud and abuse as primarily a law enforcement matter, many states have promulgated laws and regulations aimed at governing certain pharmaceutical marketing practices.

Fraudulent or abusive marketing practices can cause patients to be exposed to the risks associated with unnecessary treatments or to be denied access to appropriate care.²⁹ Neither the federal nor the state efforts, however, focus attention on the need to protect the health and safety of patient-beneficiaries by assuring speedy and efficient resolution of alleged fraudulent or abusive marketing practices. The profusion of state-by-state efforts overlooks the importance of a uniform federal approach—in a

from participation in Medicare and Medicaid, and other government insurance programs, if they are unwilling to pay an exorbitant amount of money. Exclusion for many healthcare providers would be catastrophic since Medicare and Medicaid are frequently a primary source of revenue. As a result, even those FCA defendants possessing substantial litigation resources, or who are confident that they have not violated the Act, face terrible consequences in the event that—for whatever reason—they should lose at trial. Settlement becomes not only an attractive alternative, but for most FCA defendants it is the *only* alternative they dare pursue.

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Id.; see *TAP Execs Acquitted Of Conspiracy Charges Related To Marketing Practices*, THE PINK SHEET, July 19, 2004, at 14. The outcome of the case where the company pled guilty, among other things, for acts involving its employees who were themselves acquitted raises interesting questions regarding possible differences between corporate liability and liability of company employees. The judge instructed the jury in the employee trial that

It's not the purpose or within the scope of the anti-kickback statute to prohibit transactions that reflect the mere hope or expectation or belief the (sic) that drug purchases might ultimately ensue from the business relationship A person does not violate the anti-kickback statute by providing things of value solely as part of a routine cultivation of a business relationship

Jury Instructions at 54-55, *US v. Alan Mackenzie, et al.*, CR-01-10350-DPW (D. Mass. July 14, 2004). Note that, while the company settled its case with the government, eight individual employees who were named in the case challenged the government's claim and were acquitted.

²⁸ See NAT'L CONF. OF STATE LEGIS., 2006 PRESCRIPTION DRUG STATE LEGISLATION [hereinafter 2006 PRESCRIPTION DRUG LEGISLATION], at www.ncsl.org/programs/health/drugbill06.htm (last visited Mar. 31, 2006); See NAT'L CONF. OF STATE LEGIS., 2005 PRESCRIPTION DRUG STATE LEGISLATION, at www.ncsl.org/programs/health/drugdisc05.htm (last visited May 20, 2006).

²⁹ See *supra* note 2.

field already occupied by federal law—to minimizing pharmaceutical healthcare fraud and abuse.

It seems clear that there is a need for government to balance its law enforcement priorities with the public health impact that can result from protracted, multiyear, civil and criminal enforcement efforts. The current approach amounts to “regulation through litigation” and is ill-suited to serving the needs of patient-beneficiaries of government healthcare programs, the government itself, and the pharmaceutical industry.³⁰ Regulation through litigation may be better than no regulation at all,³¹ but it is clearly neither the best nor the only choice available with regard to regulation of pharmaceutical marketing practices. In accomplishing the needed changes, it is instructive to look at the comparatively efficient and effective administrative regulatory scheme employed by the FDA to regulate pharmaceutical advertising and promotion practices.

A major premise of this Article is that patient-beneficiaries of government healthcare programs, the government itself, and the pharmaceutical industry would be well served to examine some of the lessons learned from the FDA’s role as “The Nation’s Premier Consumer Protection And Health Agency.”³² The FDA accomplishes its role within the mandate that requires it to balance its responsibility to protect the public health with other regulatory and law enforcement duties.³³ The Article ends with a proposal for reform, illustrating how the FDA could play a larger role in the creation of a uniform federal approach to the regulation and enforcement of pharmaceutical marketing practices.

I. Background

A. Brief Overview of the Fraud and Abuse Laws

A thorough discussion of the legal basis for the government’s prosecution of alleged pharmaceutical healthcare fraud is beyond the scope of this Article. A brief summary of the two

³⁰ See Robert B. Reich, *Regulation is Out, Litigation is In*, USA TODAY, Feb. 11, 1999, at 15A.

³¹ *Id.*

³² See U.S. FOOD & DRUG ADMIN. (FDA), *FDA: The Nation’s Premier Consumer Protection and Health Agency* (2002) [hereinafter *FDA Premier Agency*], at www.fda.gov/oc/opacom/brochure/fdahealthbro.html (last visited May 20, 2006).

³³ See FDA, *FDA’s Mission Statement* [hereinafter *FDA Mission*], at www.fda.gov/opacom/morechoices/mission.html (last visited May 20, 2006).

laws upon which many healthcare fraud enforcement efforts are based—the Medicare and Medicaid Anti-kickback Statute³⁴ (AKS) and the Civil False Claims Act³⁵—will illustrate the government’s current approach to pharmaceutical healthcare fraud prosecution.

1. Anti-kickback Statute

The AKS is extraordinarily broad and makes illegal the offer or payment of anything of any value to any person if any one purpose is to influence the sale, purchase, or utilization of goods or services paid for by the federal healthcare system.³⁶ Because the statute is so broad, Congress has empowered the HHS OIG to establish “safe harbors” for such activities as discounts, payments to *bona fide* employees of healthcare providers, and a number of other activities that, when undertaken in compliance with the specified terms of the safe harbor, are not deemed a violation of the AKS.³⁷

In an effort to clarify the distinction between permitted and prohibited remuneration under the AKS, the HHS OIG has published industry guidance laying out factors that manufacturers should consider when evaluating whether any particular item or service provided to customers may run afoul of the AKS. These factors are:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?

³⁴ 42 U.S.C. § 1320a-7b (2006).

³⁵ 31 U.S.C. §§ 3729–3733 (2006).

³⁶ 42 U.S.C. § 1320a-7b(b)(1)–(2) (2006).

³⁷ See *supra* notes 6, 18.

- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?³⁸

2. False Claims Act

The Civil False Claims Act makes it illegal to submit or “cause” the submission of a false or fraudulent claim to the government for payment.³⁹ This Civil War era statute has enjoyed wide use in part because of its *qui tam*, or whistle-blower, provisions that allow private parties to bring claims on behalf of the government.⁴⁰ Successful whistle-blowers can receive between fifteen and thirty percent of the monetary settlement recovered by the government.⁴¹ The False Claims Act has been expanded by creative theories whereby otherwise truthful and accurate claims can be “tainted” by other illegal acts, such as the payment of prohibited remuneration under the AKS and thus be deemed “fraudulent.”⁴² While pharmaceutical companies do not typically submit claims for payment to government healthcare programs, at least one case has held that a viable cause of action exists under the False Claims Act where illegal conduct such as payment of prohibited kickbacks or illegal promotion of uses of a product not approved by the FDA (off-label uses) can “cause” the submission of a false claim by healthcare providers.⁴³

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³⁸ Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,734 (May 5, 2003).

³⁹ 31 U.S.C. § 3729(a)(1) (2006).

⁴⁰ *Id.* § 3730(b); BAUMANN, *supra* note 18, at 21–22; see TAP to Audit Marketing Documents Related to Top Lupron, Prevacid Buyers, THE PINK SHEET, Oct. 8, 2001, at 3. The article discusses the \$77.9 million fee that a former company employee-turned-whistle-blower received as a share of the government’s overall settlement of a case against TAP Pharmaceuticals.

⁴¹ 31 U.S.C. § 3730(d)(1)–(2).

⁴² Lisa Michelle Phelps, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1004–05 (1998); Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 527 (2001).

⁴³ *United States ex rel. Franklin v. Parke-Davis*, No. 96–11651–PBS, 2003 U.S. Dist. LEXIS 15754, at *15, *20 (D. Mass. Aug. 22, 2003) The *Parke-Davis* case survived the defendant’s motion for summary judgment. The court held, in part, that while Parke-Davis did not submit claims directly to the government for payment, illegal conduct by Parke-Davis, if proved, could “cause” healthcare providers to submit false or fraudulent claims.

⁴⁴ See FRAUD AND ABUSE ANNUAL REPORT, *supra* note 13.

B. Government Players

The principal government entities involved in pursuing pharmaceutical marketing fraud and abuse enforcement are the HHS OIG and the DOJ.⁴⁴ The HHS OIG and DOJ in turn work with CMS and the FDA within their respective areas of responsibility. Neither CMS nor the FDA, however, has so far played a lead role in healthcare fraud enforcement efforts. A growing number of states also have enacted, or are considering enactment of, various laws governing the marketing and advertising of prescription drugs with the aim of controlling increasing expenses for prescription drugs.⁴⁵

Importantly, among these five entities, only the FDA has resources dedicated to both regulation of industry practices and enforcing the law; and, it is the only agency among the four whose mission and history is expressly centered on protection of the public health.⁴⁶

1. Department of Health and Human Services' Office of the Inspector General

The HHS and DOJ are jointly responsible for the federal government's Fraud and Abuse Control Program as authorized under HIPAA.⁴⁷ The HHS OIG has been charged with the majority of the healthcare fraud and abuse prevention efforts for the department. The mission of HHS OIG is to "protect the integrity of . . . [HHS] programs, as well as the health and welfare of the beneficiaries of those programs."⁴⁸ The OIG exercises its responsibilities through audits, investigations, and other efforts aimed at furthering its mission.⁴⁹ During 2005, the OIG's efforts included collaboration with other federal law enforcement agencies, such as the Federal Bureau of Investigation (FBI), to undertake investigations of healthcare fraud in the

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⁴⁵ See *supra* note 28; see also NAT'L CONF. OF STATE LEGIS, MARKETING AND DIRECT-TO-CONSUMER ADVERTISING (DTCA) OF PHARMACEUTICALS, at www.ncsl.org/programs/health/rxads.htm (last visited May 20, 2006) (describing the efforts of state lawmakers to lessen the impact of expensive pharmaceutical advertising on state-funded programs).

⁴⁶ See each organization's mission statement: OIG *Mission*, *supra* note 24; DOJ, *Mission Statement* [hereinafter DOJ *Mission*], at www.usdoj.gov/02organizations/index.html (last visited May 20, 2006); CMS, *Overview* [hereinafter CMS *Overview*], at www.cms.hhs.gov/MissionVisionGoals/ (last visited May 30, 2006); FDA *Mission*, *supra* note 33.

⁴⁷ See FRAUD AND ABUSE ANNUAL REPORT, *supra* note 13.

⁴⁸ OIG *Mission*, *supra* note 24.

⁴⁹ *Id.*

pharmaceutical industry.⁵⁰ The OIG also investigated the effectiveness of the FDA's oversight responsibilities in the area of direct-to-consumer advertising and off-label drug promotion.⁵¹ The OIG's work also extends to the provision of guidance to the industry on appropriate compliance activities.⁵² The OIG works with the DOJ to structure and oversee the administration of corporate integrity agreements entered into by companies pursuant to settlement agreements arising from healthcare fraud prosecutions.⁵³

2. Department of Justice

The DOJ and the HHS OIG collaborate to pursue prosecution of healthcare fraud, fulfilling their responsibilities under the HIPAA Fraud and Abuse Control Program (including responsibilities for pharmaceutical marketing fraud and abuse).⁵⁴ Because DOJ is the lead law enforcement agency in the United States, it has many other responsibilities beyond healthcare fraud prosecutions.⁵⁵ Its resources are vast. The DOJ employs approximately 110,000 people and has an annual budget of approximately \$20 billion.⁵⁶ Its key priorities include: preventing terrorism; enforcing federal law; assisting state and local governments to reduce crime and violence; and ensuring the

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⁵⁰ OIG, HHS, FISCAL YEAR 2005 WORK PLAN—CENTERS FOR MEDICARE & MEDICAID SERVICES 44–45 (2005), available at <http://oig.hhs.gov/reading/workplan/2005/2005WPCMS.pdf> (last visited Mar. 31, 2006) (In undertaking these efforts, OIG “aims to stop the inflating of drug prices common in the pharmaceutical industry.”).

⁵¹ OIG, HHS, FISCAL YEAR 2005 WORK PLAN—PUBLIC HEALTH AGENCIES 6 (2005), available at <http://oig.hhs.gov/reading/workplan/2005/2005WPPHAs.pdf> (last visited Mar. 31, 2006).

⁵² See Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (OIG May 5, 2003).

⁵³ See, e.g., Corporate Integrity Agreement, *supra* note 19. The corporate integrity agreement was entered into by Pfizer as a consequence of its decision to settle the United States *ex rel.* Franklin v. Parke-Davis case subsequent to its purchase of Parke-Davis.

⁵⁴ See FRAUD AND ABUSE ANNUAL REPORT, *supra* note 13.

⁵⁵ See DOJ *Mission*, *supra* note 46.

⁵⁶ OFF. OF MGMT. & BUDGET (OMB), THE WHITE HOUSE, BUDGET OF THE UNITED STATES GOVERNMENT FY 2006, DOJ, at www.whitehouse.gov/omb/budget/fy2006/justice.html (last visited Mar. 31, 2006) (stating the DOJ has a \$20.3 billion estimated discretionary budget authority for 2006); OMB, THE WHITE HOUSE, BUDGET OF THE UNITED STATES GOVERNMENT FY 2005, DOJ, at www.whitehouse.gov/omb/budget/fy2005/justice.html (last visited Mar. 31, 2006) (stating the DOJ had 112,557 employees and \$18.7 billion discretionary budget authority in 2005); OMB, THE WHITE HOUSE, BUDGET OF THE UNITED STATES GOVERNMENT FY 2004, DOJ, at www.whitehouse.gov/omb/budget/fy2004/justice.html (last visited Mar. 31, 2006) (stating the DOJ had 105,953 employees in 2004 and spent \$22.2 billion in 2003).

federal justice system is operated efficiently.⁵⁷ Though considerable, its resources are limited; thus, its healthcare fraud prosecution efforts compete directly for the same resources dedicated to the war on terrorism and other important law enforcement priorities.⁵⁸

The DOJ groups its efforts in pharmaceutical healthcare fraud with other high profile criminal enforcement efforts aimed at combating white collar crime committed by individual criminals and “criminal enterprises that seek illicit gains through fraud and guile.”⁵⁹ Indeed, the DOJ approaches pharmaceutical marketing fraud and abuse not as a matter of regulating complex private activities involving commercial, scientific, and medical practices that require a public health focus and a balance between competing interests, but as a high priority criminal activity, largely undistinguished from its other high profile criminal enforcement efforts, such as organized crime, child pornography, drug trafficking, and internet fraud, which it pursues using an arsenal of crime-fighting weapons.⁶⁰

The DOJ devotes considerable resources to combating healthcare fraud. During 2004 and 2005, approximately 800 FBI personnel were assigned specifically to the healthcare fraud area.⁶¹ Further, the offices of many U.S. Attorneys employ staff specifically dedicated to healthcare fraud matters.

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3. CMS

CMS is responsible for administering Medicare, Medicaid, and other federal healthcare programs. It manages an enormous annual budget that comprises 19.6% of the federal government’s spending.⁶² The mission of CMS is to “assure health care security for beneficiaries.”⁶³ CMS aims to accomplish this through

⁵⁷ DOJ, FY2006 BUDGET AND PERFORMANCE SUMMARY 3–4 (2006) [hereinafter DOJ SUMMARY], available at www.usdoj.gov/jmd/2006summary/pdf/BPSCComplete.pdf (last visited May 20, 2006).

⁵⁸ See Kendra D. Casey & Judith A. Thorn, *Medicare Outlook: Pharmaceutical, Quality Issues Top Agenda For Anti-Fraud Activities of Federal Agencies*, 7 Health Care Daily Report (BNA) (Jan. 15, 2002) (stating that although antiterrorism efforts are not likely to divert resource in the immediate future, because healthcare fraud cases take years to develop, there is speculation that as the years go on the government will intervene in fewer cases).

⁵⁹ DOJ REPORT, *supra* note 22, at II-11.

⁶⁰ See generally DOJ REPORT, *supra* note 22.

⁶¹ DOJ SUMMARY, *supra* note 57, at 107.

⁶² HHS, 2005 CMS STATISTICS 3 (2005), available at http://new.cms.hhs.gov/MedicareMedicaidStatSupp/downloads/2005_CMS_Statistics.pdf (last visited May 20, 2006).

⁶³ CMS Overview, *supra* note 46.

its vision as steward of its programs to serve beneficiaries and to “improve quality and efficiency in an evolving health care system.”⁶⁴ The agency’s goals are to:

- Protect and improve beneficiary health and satisfaction.
- Foster appropriate and predictable payments and high quality care.
- Promote understanding of CMS programs among beneficiaries, the health care community, and the public.
- Promote the fiscal integrity of CMS programs and be an accountable steward of public funds.
- Foster excellence in the design and administration of CMS programs.
- Provide leadership in the broader health care marketplace to improve health.⁶⁵

Although its goals include the protection of the health of the beneficiaries of federal health programs, CMS can accomplish that goal only indirectly by controlling access and utilization through its coding, coverage, and payment decisions.⁶⁶ CMS is further distanced from direct control because the great majority of coverage and medical necessity determinations are not made nationally, but locally by regional carriers, intermediaries, and peer review organizations—private entities engaged by CMS to perform these functions.⁶⁷ At the national level, CMS employs a sort of administrative alchemy by which its decisionmaking can seem to be the product of an obscure, amorphous, and often drawn-out collection of internal practices and external influences.⁶⁸ The agency has been the subject of criticism for its lack of openness, accountability, and speed and its widespread use of

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ See 42 U.S.C. §§ 1395(c), (l), (m), (o) (2005). CMS regulation of market access is achieved through its coding, coverage, and payment decisions. Failure to achieve favorable coding, coverage, or payment for a new drug or device means that the product either may be entirely unavailable under Medicare or is underutilized because it may not be reimbursed in a manner that adequately covers the costs associated with the product or is covered or coded in such a manner as to strictly limit the utilization of the technology.

⁶⁷ See Timothy S. Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 82–83 (1999).

⁶⁸ See BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 738 (5th ed. 2001). The authors note that “[u]ltimately, whether any particular service is provided to any particular Medicare beneficiary will depend on the decision of a private [carrier or intermediary] . . . interpreting federal policy as mediated by Medicare regulations, manuals and manual transmittals, regional office instructions . . . rumor, and innuendo.” *Id.*

“subregulatory” means to accomplish its work.⁶⁹ Indeed, there have been occasional suggestions that a large part of the work of CMS should be merged into the FDA, in part because of the FDA’s comparative efficiency and effectiveness at administering regulations that affect patient care or access to care.⁷⁰ All of these factors tend to limit considerably any direct ability of CMS to protect the beneficiaries of its programs from current or near-term public health issues arising from fraudulent or abusive pharmaceutical marketing practices.

4. FDA

In contrast to the DOJ, HHS OIG, and CMS, the FDA’s central mission is to protect the public health.⁷¹ The FDA styles itself as “The Nation’s Premier Consumer Protection And Health Agency.”⁷² Given that the FDA regulates approximately twenty-five percent of all commerce in the United States, and its historical role, dating back to 1906, in building and maintaining public trust in the nation’s supply of food and drugs, this claim has considerable merit.⁷³

Faced with a need to balance government regulatory responsibilities with the public health impact of speedy and efficient regulatory processes, Congress enacted sweeping reforms at the FDA in 1997.⁷⁴ In enacting the Food and Drug Administra-

⁶⁹ See Jost, *supra* note 67, at 88–89.

⁷⁰ E.g., Christopher D. Zalesky, *Considering Changes to CMS’s National Coverage Decision Process: Applying Lessons Learned from FDA as a Regulator of Access to Healthcare Technology*, 57 FOOD & DRUG L.J. 73 (2002) (suggesting the use of a CMS/FDA cooperative process for making national coverage decisions under which CMS would authorize the FDA to perform the majority of the scientific review necessary to make such decisions).

⁷¹ FDA *Mission*, *supra* note 33.

⁷² FDA *Premier Agency*, *supra* note 32.

⁷³ See FDA, *Protecting Consumers, Promoting Public Health*, at www.fda.gov/oc/opa-com/fda101/fda101text.html (last visited May 20, 2006).

⁷⁴ Food and Drug Administration Modernization Act § 101, 21 U.S.C. § 379(g) (1997). It states:

Congress finds that—(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease; (2) the public health will be served by making additional funds [under re-authorization of PDMA] available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; (3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be . . . carried out by the Food and Drug Administration with new commitments to implement more

tion Modernization Act of 1997 (FDAMA), Congress mandated that the FDA balance its responsibility to assure that drugs are safe and effective with the need to speed access to life-saving therapies.⁷⁵ Prior to the enactment of FDAMA, patient advocates, medical specialty societies, and industry clamored for speedier access to new, life-saving drugs.⁷⁶ Recent concerns have arisen that the FDA's responsibility to balance speed and public health protections may be in need of an adjustment.⁷⁷ In any case, this balancing act remains part of the FDA's congressionally mandated mission.⁷⁸ The FDA is further charged with reviewing and approving applications to market new drugs and medical devices, monitoring the safety of those products after they are marketed, and regulating prescription drug and device advertising and promotion, as well as the distribution of prescription drug samples.⁷⁹

The body of law enforced by the FDA may serve as an interesting model for two reasons. First it imposes on a regulated industry "a positive duty to seek out and remedy violations when they occur . . . and . . . a duty to implement measures that will ensure that violations will not occur."⁸⁰ Second, the FDA's approach

ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and (4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications

Id.

⁷⁵ *Id.* § 393(b). In recognition of the need for FDA to balance its historical mission to protect the public health with the need to speed the availability of new medical advances, Congress included a mission statement when enacting FDAMA. FDA's mission is in part to "promote the public health by . . . taking appropriate action . . . in a timely manner . . . [while] . . . ensuring that . . . human . . . drugs are safe and effective." *Id.*

⁷⁶ MICHAEL J. MALINOWSKI ET AL., BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION at 11-31 (1999). Malinowski describes FDAMA arising out of "near unanimous bipartisan support" that was a result of the efforts of a "[c]ollaboration among well-organized consumer advocacy groups, industry, and the Republican majority in Congress" (citing Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J., 651, 651-52 (1996)).

⁷⁷ See, e.g., Judith Graham, *New FDA Chief's Exit Further Clouds Agency*, CHI. TRIB., Sept. 25, 2005, at C20. Graham suggests "Public confidence in the FDA has been deeply shaken over the past year amid a rising tide of questions about the agency's performance in ensuring the safety of drugs such as Vioxx and medical devices such as implantable cardiac defibrillators."

⁷⁸ See FDA Mission, *supra* note 33; 21 U.S.C. § 393(b).

⁷⁹ See FDA, *Laws Enforced by the FDA and Related Statutes*, at www.fda.gov/opacom/laws/default.htm (last visited May 20, 2006).

⁸⁰ JOHN KAPLAN ET AL., CRIMINAL LAW: CASES AND MATERIALS 192 (3d ed. 1996); see *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (The purposes of the Food and Drug Act "touch phases of the lives and health of people which . . . are largely beyond self-protection.").

to enforcement is largely based on voluntary measures embodied in its concept of “prior notice.”⁸¹ The prior notice concept centers on the FDA’s “belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.”⁸² The FDA is under no obligation to provide prior notice before taking legal action; however, the agency often gives such notice through its use of inspectional observations, Warning Letters, and “untitled letters.”⁸³ Use of voluntary measures, backed-up with considerable enforcement powers, permits better use of scarce government resources.

In the area of prescription drug sales and marketing practices, the FDA already plays an important role. Under the U.S. Food, Drug, and Cosmetic Act, the FDA is responsible for the regulation and enforcement of law in the area of labeling, advertising, and promotion of prescription drug products.⁸⁴ This includes regulation of activities such as print ads, broadcast ads, scientific exchange, continuing medical education, even the ubiquitous pens, notepads, and coffee mugs emblazoned with drug names.⁸⁵ The FDA is also responsible for regulating and enforcing the provision of prescription drug samples to physicians, as well as for protection of the nation’s drug supply through safeguarding drug distribution.⁸⁶

⁸¹ See FDA, REGULATORY PROCEDURES MANUAL § 10-1 (2004) [hereinafter FDA MANUAL], available www.fda.gov/ora/compliance_ref/rpm/pdf/ch10.pdf (last visited May 29, 2006).

⁸² *Id.*

⁸³ See *id.* §§ 4.1, 4.2, available at www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf (last visited May 20, 2006).

A *Warning Letter* is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations Warning Letters [are] issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action A Warning Letter is one of the Agency’s principal means of achieving prompt voluntary compliance An *Untitled Letter* is an initial correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter. Untitled Letters are intended to cover those circumstances where the Agency has a need to communicate with regulated industry about violations that do not meet the threshold of regulatory significance as described above.

Id.

⁸⁴ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(n), 352(n) (2006).

⁸⁵ 21 C.F.R. §§ 202.1(l)(1), 202.1(l)(2) (2005).

⁸⁶ See 21 U.S.C. § 331(t).

5. The States

With the aim of controlling the impact of increased spending on prescription drugs, states are taking on a more active and prominent role, fashioning legislative remedies aimed at pharmaceutical marketing practices perceived to be related to cost and utilization increases. For example, the National Conference of State Legislatures reports that all fifty states have legislative efforts underway comprising six hundred separate bills and resolutions aimed at some aspect of prescription drug pricing, access, or marketing. It identifies at least twenty-eight states with legislation at some stage of promulgation.⁸⁷ Some states have already enacted such legislation requiring, for example, mandatory compliance programs, disclosure of gifts and other things of value provided to physicians, disclosure of advertising costs, disclosure of comparative prices, and posting requirements for clinical trials conducted by drug companies.⁸⁸

Of particular interest is California's recently enacted law requiring that pharmaceutical companies implement comprehensive compliance programs that accord with the voluntary OIG Guide

⁸⁷ See 2006 PRESCRIPTION DRUG LEGISLATION, *supra* note 28; see also NAT'L CONFERENCE OF STATE LEGIS., DIRECT TO CONSUMER ADVERTISING OF PHARMACEUTICALS, at www.ncsl.org/programs/health/rxads.htm (last visited May 21, 2006) (listing examples of state bills and laws related to direct to consumer advertising of pharmaceuticals).

⁸⁸ See, e.g., ME. REV. STAT. ANN. tit. 33, § 2698-A (2005) (Maine statute requiring disclosure of marketing costs for prescription drugs sold in the state of Maine); ME. REV. STAT. ANN. tit. 22, § 2700-A (2005) (Maine statute requiring disclosure of pharmaceutical company clinical trial results in accordance with standards established by the state of Maine); MINN. STAT. ANN. § 151.461 (West 2005) (Minnesota laws prohibiting gifts to medical practitioners and requiring reporting to the state of certain payments for consulting and other services from pharmaceutical companies to Minnesota practitioners); VT. STAT. ANN. tit. 33, §§ 2005, 2005a (2005) (Vermont laws requiring disclosure of gifts and other things of value to practitioners in the state of Vermont and requiring disclosure of comparative prices of prescription drugs).

The advocacy group Consumer's Union has also developed model legislation for states contemplating disclosure requirements for pharmaceutical companies about marketing expenditures to physicians. See PHARMACEUTICAL MARKETING DISCLOSURE MODEL BILL §§ 1-3 (Consumer's Union), available at www.consumersunion.org/pdf/market_bill.pdf (last visited May 21, 2006). Consumer's Union contends that marketing practices increase utilization of newer, more expensive drugs and thereby increase costs to patients and state-funded medical benefits. It also contends that gifts to physicians erode the trust between doctors and patients. See Consumer's Union Prescription for Change, *Requiring Drug Companies to Disclose Marketing Expenditures to Physicians*, Jan. 27, 2005, at www.consumersunion.org/campaigns/prescriptionforchange/001813indiv.html (last visited May 21, 2006).

and PhRMA Code.⁸⁹ The law also requires that companies: (1) set annual dollar limits on gifts, incentives, promotional materials, or items and activities provided to medical or healthcare professionals; (2) make a written declaration confirming compliance with the company's compliance program and the California law each year; (3) provide public access to the company's compliance program and declaration by posting both on the company website; and (4) provide a toll-free number where copies of the compliance program and the written declaration of compliance may be obtained.⁹⁰

It remains to be seen what impact, if any, these state laws will have on reducing the cost or decreasing utilization of prescription drugs. Of greater concern is that nearly all of these laws dabble in the dense and technically complex fields already occupied by laws and regulations administered by the FDA or CMS at the federal level. This raises concerns about consistency and federal preemption of state law.⁹¹ For example, Vermont has enacted a statute requiring comparative price disclosures of drugs grouped in the same therapeutic class.⁹² This requirement arguably interferes with the FDA's exclusive jurisdiction to regulate prescription drug labeling and advertising.⁹³ Although it has not yet been challenged, Vermont's price disclosure law appears to create implied product comparisons of precisely the sort prohibited by the FDA's regulations governing prescription drug advertising and promotion.⁹⁴ This technically places companies in a bind between the requirements of Vermont state law and the FDA's federal advertising regulations.

⁸⁹ CAL. HEALTH & SAFETY CODE § 119402 (West 2006). The PhRMA Code on Interactions with Healthcare Professionals is published by the Pharmaceutical Research and Manufacturers Association of America. See PhRMA CODE, *supra* note 7. The PhRMA Code lays out various voluntary standards related to industry-paid gifts, meals, entertainment, travel and the like.

⁹⁰ CAL. HEALTH & SAFETY CODE § 119402 (West 2006).

⁹¹ See *Pac. Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 212-13 (1983).

⁹² VT. STAT. ANN. tit. 33, § 2005a.

⁹³ See *Courts Should Defer to FDA's Drug Ad, Label Decisions, Agency's Top Lawyer Says*, 7 Health Care Daily Rep. (BNA) (Sept. 12, 2002) (Daniel E. Troy, chief counsel of the FDA, states, regarding a California law, that "state law should not second-guess FDA, when FDA has decided the precise claim at issue and where [FDA] has rendered a scientific judgment about what is or is not false or misleading.").

⁹⁴ See 21 C.F.R. § 202.1(e)(6)(ii) (2005) (stating that an advertisement violates § 502(n) if it contains a comparison to another drug suggesting that it is safer or more effective than that drug if such claims have not been proven by substantial evidence).

II. Recent Pharmaceutical Healthcare Fraud Cases

A. TAP Pharmaceutical Products Inc., Astra-Zeneca

The government's case against TAP Pharmaceutical Products Inc. (TAP) was settled in 2001 for \$875 million.⁹⁵ The allegations against TAP revolved around marketing practices for its drug Lupron. The alleged illegal practices included kickbacks in the form of sham educational grants, trips to resorts, and free medical equipment provided to physicians in violation of the AKS.⁹⁶ TAP was also alleged to have violated the Prescription Drug Marketing Act through a scheme of encouraging physicians to submit claims for payment to Medicare for samples of Lupron provided free of charge to physicians.⁹⁷ Additionally, the government claimed violations of the False Claims Act, alleging that TAP's illegal kickbacks and sample scheme "caused" submission of false claims for payment to the government.⁹⁸

Two years following the TAP case, the government and Astra-Zeneca settled a parallel case for \$355 million involving the company's product Zoladex.⁹⁹ AstraZeneca's Zoladex competed head-to-head with TAP's Lupron and the company was accused of using essentially the same kickback and sample scheme employed by TAP.¹⁰⁰ Interestingly, both cases were brought by the same whistle-blower, a sales and marketing executive formerly employed by both companies.¹⁰¹ His combined share from both settlements totaled more than \$125 million under the *qui tam* provisions of the False Claims Act.¹⁰²

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B. United States ex rel. Franklin v. Parke-Davis

As with TAP, pharmaceutical company Parke-Davis was the subject of a "whistle-blower" claim by a former employee.¹⁰³ The employee accused the company of: (1) engaging in an orchestrated plan to illegally promote its product Neurontin for uses not approved by the FDA; (2) providing kickbacks in

⁹⁵ Press Release, DOJ, *supra* note 19.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ See Joshua Partlow & Marc Kaufman, *U.S., Drug Company Settle Scam Charges; AstraZeneca Admits Free-Sample Scheme*, WASH. POST, June 21, 2003, at E01.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ See *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 43 (D. Mass. 2001).

violation of the AKS; and (3) “causing” the submission of false, fraudulent, or otherwise tainted claims submitted to the government for payment in violation of the False Claims Act.¹⁰⁴ The case was settled in May of 2004 by Pfizer, Inc., the successor to Parke-Davis. The settlement required that the company pay a fine of \$430 million, plead guilty to violations of the U.S. Food, Drug, and Cosmetic Act, and enter into a “groundbreaking” five-year corporate integrity agreement with rigorous requirements and limitations applied to the company’s sales and marketing practices.¹⁰⁵

During the course of the case, the government filed a statement of interest that concisely described its general theory of liability in pharmaceutical healthcare fraud prosecutions.¹⁰⁶ The government argued that the “Defendants engaged in a scheme to defraud federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals—judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor.”¹⁰⁷

III. Regulating Prescription Drug Advertising and Promotion—A Model to Build On?

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The FDA currently regulates a range of pharmaceutical marketing practices including advertising and promotion, and the provision of prescription drug samples.¹⁰⁸ During 2003, these promotional activities comprised approximately \$25.3 billion in annual expenditures by pharmaceutical manufacturers, including approximately \$16.4 billion in drug samples and \$8.9 billion spent promoting products in hospitals and doctors offices, and through advertising aimed at healthcare professional consumers.¹⁰⁹

¹⁰⁴ *Id.* at 45–46.

¹⁰⁵ See Press Release, Warner-Lambert, *supra* note 3.

¹⁰⁶ See Statement of Interest in Opposition to Defendant’s Motion for Summary Judgment, *supra* note 9, at *6–14.

¹⁰⁷ *Id.* at *2.

¹⁰⁸ 21 U.S.C. §§ 321(n), 352(n), 331(t) (2006).

¹⁰⁹ See PHRMA, WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINES, 17–18 (June 2005), available at http://members.phrma.org/publications/publications/What_goes_into_the_Cost_of_Prescription_Drugs_2005.pdf (last visited May 21, 2006).

A. FDA's Regulation and Enforcement of Prescription Drug Advertising

The provisions of the Food, Drug, and Cosmetic Act governing prescription drug advertising comprise only a few paragraphs of the law and generally provide that advertising may not be misleading as a consequence of "representations made or suggested by statement, word, design, device, or any combination thereof," or by failure to "reveal facts material in the light of such representations."¹¹⁰ Further elaboration is found in the regulations that govern prescription drug advertising, various FDA guidance documents, and in the FDA enforcement actions communicated publicly via the issuance of various forms of regulatory letters to manufacturers.¹¹¹ Except in "extraordinary circumstances," the FDA is prohibited from requiring pre-approval or pre-clearance of prescription drug advertising, although manufacturers may voluntarily seek FDA review prior to dissemination of promotional materials.¹¹²

B. Organization

In contrast to the hundreds of employees within the DOJ and HHS OIG dedicated to healthcare fraud and abuse under HIPAA, the FDA has only thirty or so full time staff in place to regulate and enforce prescription advertising through the work of its Division of Drug Marketing, Advertising, and Communications (DDMAC).¹¹³ DDMAC is responsible for review, surveillance, enforcement, and research activities associated with prescription drug advertising, including advertisements directed to medical professionals and to consumers (direct

¹¹⁰ 21 U.S.C. § 321(n); *see id.* §§ 331(t), 352(n).

¹¹¹ *See generally* 21 C.F.R. pts. 201–203 (2006). *See also* CTR. FOR DRUG EDUC. & RESEARCH, FDA, *Laws, Regulations, Guidances, and Enforcement Actions*, at www.fda.gov/cder/ddmac/lawsregs.htm (last visited Mar. 31, 2006); CTR. FOR DRUG EVALUATION & RESEARCH, FDA, *Warning Letters and Notice Letters of Violations to Pharmaceutical Companies* [hereinafter FDA, *Warning Letters*], at www.fda.gov/cder/warn/ (last visited May 21, 2006).

¹¹² *See* 21 U.S.C. 352(n).

¹¹³ *See* CTR. FOR DRUG EVALUATION & RESEARCH, FDA, *DDMAC Organization Listing*, at www.fda.gov/cder/ddmac/organization.htm (last visited May 21, 2006). DDMAC has a sister organization within FDA's Center for Biologics Evaluation and Research (CBER) known as the CBER Advertising and Promotional Labeling Branch (APLB). APLB is responsible for analogous functions to DDMAC but for products such as vaccines and blood products regulated by CBER. *See* CTR. FOR BIOLOGICS EVALUATION & RESEARCH, FDA, *Manual of Standard Operating Procedures and Policies*, Aug. 15, 2002 at www.fda.gov/cber/regsopp/80014.htm (last visited Apr. 7, 2006).

to consumer (DTC)).¹¹⁴ These include television and radio DTC ads, DTC print, and electronic or internet-based advertising.¹¹⁵

DDMAC also reviews advertising and promotional efforts aimed at medical professionals, including print and electronic advertising, promotional presentations delivered by physician-consultants to pharmaceutical companies, and the like. DDMAC also publishes guidance for the pharmaceutical industry, such as its guidance document on Industry-Supported Scientific and Educational Activities.¹¹⁶

C. Enforcement of Prescription Drug Advertising Rules

As a general matter, the FDA is empowered to take enforcement action against violative advertising, and its enforcement practices include injunction, seizure, fine, and criminal and civil prosecution.¹¹⁷ The FDA's preferred approach to enforcement, however, including that in the area of prescription drug advertising, is through the use of voluntary means; this concept is known as "prior notice."¹¹⁸ In the context of alleged advertising and promotion violations, prior notice takes the form of regulatory letters, including so-called "untitled letters" and Warning Letters, to companies engaged in practices DDMAC regards as violative of the U.S. Food, Drug, and Cosmetic Act or of the FDA's regulations governing the advertising of prescription drugs.¹¹⁹

Warning and untitled letters can be prompted by routine review of materials that manufacturers are required to submit at the time of first use,¹²⁰ or by FDA surveillance of pharmaceutical company promotional activities at meetings of medical professional societies. Often, however, enforcement action is

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¹¹⁴ See CTR. FOR DRUG EVALUATION & RESEARCH, FDA, *Policy Development and Guidance to Industry* [hereinafter CDER Policy Development], at www.fda.gov/cder/handbook/pol_guid.htm (last visited May 21, 2006)

¹¹⁵ *Id.*

¹¹⁶ See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (U.S. Food and Drug Admin. Dec. 3, 1997) (notice). These regulations describe various factors that weigh into FDA's consideration of the propriety of company support for independent continuing medical education. *Id.* If the factors are met, FDA will likely regard the company's support as non-promotional and thus not subject to its advertising and promotion regulations. *Id.*

¹¹⁷ See 21 U.S.C. §§ 332–337 (2006).

¹¹⁸ See FDA, REGULATORY PROCEDURES MANUAL, *supra* note 81, at § 10-1.

¹¹⁹ See FDA, *Warning Letters*, *supra* note 111.

¹²⁰ See 21 C.F.R. 314.81(b)(3)(i) (2005). Manufacturers are required to submit to the FDA samples of advertising and promotional labeling being used for the first time. *Id.*

prompted by the FDA's consideration of written complaints lodged by a company's competitors (trade complaints).¹²¹

The FDA's Warning and untitled letters typically identify the product or products that are the source of its concern, the advertising or promotional item or activity at issue, and the nature of the FDA's concern, for example that the advertisement is false, misleading, lacks the required balance between safety and efficacy, or states or suggests that the product is safe and effective in a manner more broadly than is supported by its approved labeling.¹²²

The FDA usually directs firms to immediately cease the allegedly violative activity, and, in some cases, may require the company to issue corrective advertising.¹²³ Companies are usually required to respond to the FDA within a few days following receipt of the letter with their proposed corrective actions. Companies may choose to voluntarily comply with the FDA's requests, or they may disagree with some or all of the FDA's allegations and choose to further discuss the matter with the agency. For example, a company may produce evidence supporting its belief that its advertising is properly substantiated or is otherwise in compliance with regulations. Most matters are resolved through discussion with the FDA; however, the agency can proceed with other, more severe enforcement options at its disposal.¹²⁴

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From 1995 to 2004, DDMAC issued a total of 1,359 regulatory letters, peaking in 1997 with 245 letters and reaching a low of thirty-seven letters during 2002.¹²⁵ The FDA reports issuing fifty-six regulatory letters citing drug promotion violations during 2004.¹²⁶

¹²¹ See PIÑA & PINES, A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 248 (1998) ("FDA enforcement actions [for alleged violations of the agency's advertising and promotion rules] are generally premised on its review of materials submitted voluntarily by companies and on its own surveillance of the marketplace. Many actions, however, are also based on "competitor" complaints.").

¹²² See generally FDA, *Warning Letters*, *supra* note 111.

¹²³ See, e.g., Warning Letter from Thomas W. Abrams, Director, FDA Division of Drug Marketing and Communications, to David E.I. Pyott, President and CEO, Allergan, Inc. (Sept. 6, 2005), available at www.fda.gov/cder/warn/2005/Lumigan-wl.pdf (last visited May 21, 2006).

¹²⁴ See 21 U.S.C. §§ 332–337 (2006).

¹²⁵ See CTR. FOR DRUG EVALUATION & RESEARCH, FDA, 2004 REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 45 (2005) [hereinafter FDA REPORT TO THE NATION], available at www.fda.gov/cder/reports/rtn/2004/rtn2004.pdf (last visited May 21, 2006).

¹²⁶ *Id.*

The FDA's approach to regulating prescription drug advertising and promotion is not without its critics. At one end, the FDA finds itself the subject of claims that it is lax and is responsible for perpetuating a "crisis of non-enforcement" or that voluntary industry standards, sometimes incorporated by reference into FDA guidance, are ineffective.¹²⁷ At the other end are criticisms that the agency's enforcement actions are thinly supported, inconsistent, and infringe the commercial free speech protections afforded by the First Amendment.¹²⁸ The FDA's level of enforcement of prescription drug advertising does appear to vary considerably over time, perhaps in response to both external and internal pressures, influences, or agency resources.¹²⁹

The time is ripe to consider some of the points raised by critics and to expand the FDA's role beyond regulation of prescription drug advertising and promotion to a larger role in the regulation of pharmaceutical marketing practices.

IV. Proposal for Reform

Fraudulent or abusive sales and marketing practices by pharmaceutical companies raise real and perceived concerns about

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¹²⁷ See *Drug Advertising Masquerades as Education*, PUBLIC CITIZEN, Feb. 13, 2002, available at www.citizen.org/pressroom/release.cfm?ID=1022 (last visited May 21, 2006). Public Citizen's Health Research Group (HRG) cites an editorial written by Dr. Sidney Wolfe in asserting that "there has been a significant—almost 50 percent—decrease in the number of actions taken by the U.S. Food and Drug Administration (FDA) to enforce prescription drug advertising regulations for doctors and patients alike over the past five years, which has allowed grossly misleading and manipulative information to pass as educational material." *Id.* See also Commentary, Docket No. 02N-0209, PUBLIC CITIZEN, Oct. 28, 2002, available at www.citizen.org/publications/release.cfm?ID=7214#_ftnref2 (last visited May 21, 2006) (stating that patients are injured by the FDA's failure to control the truthfulness of advertising and promotions); *Drug Industry's Voluntary DTC Plan is Placebo; Real Reform Needed to Ensure Accurate, Informative Drug Advertising*, CONSUMER'S UNION, July 21, 2005, available at www.consumersunion.org/pub/campaignprescriptionforchange/002525.html (last visited May 21, 2006) (criticizing PhRMA's GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES (Nov. 2005)).

¹²⁸ See Washington Legal Foundation, *Litigation Projects, Health Care Project*, at www.wlf.org/Litigating/litprojects.asp#3 (last visited May 21, 2006). The WLF asserts that "[i]n its zeal to regulate, FDA occasionally steps over the line by [suppressing] important medical breakthroughs." *Id.* Among other actions, WLF has recently initiated a program known as "FDA/DDMAC Watch." Washington Legal Foundation, FDA/DDMAC Watch, at www.wlf.org/Resources/DDMAC/default.asp (last visited May 21, 2006). The program is aimed at WLF's concerns that the DDMAC "has been using letters to pharmaceutical companies to advance questionable legal theories and request remedial actions [to correct allegedly violative advertising and promotional practices] that the agency could not require under the law." *Id.*

¹²⁹ See FDA REPORT TO THE NATION, *supra* note 125.

cost and patient safety. The current federal approach amounts to regulation through litigation. The approaches employed currently or under consideration by various states run the risk of creating a helter-skelter patchwork of inconsistent and potentially conflicting laws in an area already occupied by federal law. Neither federal nor state approaches are currently accountable to balance fiscal and law enforcement interests against the impact to the public health of either overly aggressive enforcement or of enforcement efforts that take years to reach conclusion. In view of these challenges and limitations, it makes sense to consider consolidating these disparate efforts into a single administrative agency within DHHS, with the power and resources to effectively regulate pharmaceutical sales and marketing practices. Given the FDA's statutory responsibility to balance its regulatory and public health responsibilities and given that it is already responsible for regulating \$25 billion each year in advertising, promotion, and sampling activities, the FDA should be designated as the lead agency responsible for these duties and be supported by an appropriate legal and regulatory foundation, adequate budget, staff, and other resources. Such an approach could have the characteristics discussed below.

A. Single Lead Agency

Pharmaceutical marketing practices should be subject to a single body of regulation administered by the FDA with expanded statutory authority, dedicated staff, and other resources. The FDA would be the lead federal agency and would work closely with HHS OIG and the DOJ to assure a coordinated and consistent federal approach.

B. Regulatory Framework

The FDA would be responsible to promulgate “good pharmaceutical marketing practices” (GPMP) regulations, monitor industry marketing practices, and take the lead in enforcement activities. Such regulations have strong precedent in FDA's Good Manufacturing Practices (GMP) regulations for drugs and medical devices.¹³⁰ The GMPs generally require that companies establish appropriate organizations, adequate trained staff, production and control systems and processes, review and approval mechanisms, corrective action approaches, and appropriate records to document and substantiate compliance with the GMPs.¹³¹ At a high level, the FDA's GMP regulations bear a

¹³⁰ See 21 C.F.R. §§ 211.1–211.208 (2006) (drug Good Manufacturing Practices (GMPs)); *id.* §§ 820.1–820.250 (medical device GMPs)).

¹³¹ *Id.* §§ 211.1–211.208, 820.1–820.250.

remarkable resemblance to the “seven elements [of an] effective compliance program” articulated in the OIG Manufacturer’s Guide.¹³² Those elements include:

Implementing written policies and procedures; Designating a compliance officer and compliance committee; Conducting effective training and education; Developing effective lines of communication; Conducting internal monitoring and auditing; Enforcing standards through well-publicized disciplinary guidelines; and Responding promptly to detected problems and undertaking corrective action.¹³³

C. Industry Obligations

All companies engaged in pharmaceutical marketing, whether they are the manufacturer or license-holder marketing and selling their products directly, or another firm acting in a sales and marketing capacity under agreement with the manufacturer, would be required to: 1) register with the FDA as a pharmaceutical marketer; 2) list the products for which it engages in promotion (product promotion listing); 3) comply with the GPMP regulations; 4) comply with current advertising and promotional regulations under 21 C.F.R. § 202 and labeling regulations under 21 C.F.R. § 201; and 5) comply with the provisions of the Prescription Drug Marketing Act and its implementing regulations under 21 C.F.R. § 203.

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D. Transparency of Interactions with Healthcare Providers

Borrowing from California’s approach, the GPMP regulations should incorporate measures not already included in the OIG Guide, such as the requirement for companies to establish and declare an annual dollar limit for gifts, incentives, or other materials or activities provided to medical or healthcare professionals in connection with promotion of the company’s products. Companies could also voluntarily comply with industry or professional standards such as the PhRMA Code¹³⁴ and the Standards for Commercial Support (of medical education) published by the Accreditation Council for Continuing Medical Education (ACCME).¹³⁵

¹³² See Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (OIG May 5, 2003).

¹³³ *Id.*

¹³⁴ PhRMA Code, *supra* note 7.

¹³⁵ ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC. (ACCME), STANDARDS FOR COMMERCIAL SUPPORT 2004, available at www.accme.org/dir_docs/doc_upload/

E. Agency Oversight

Ongoing oversight by the agency could be accomplished through: 1) field inspections of companies, including periodic inspections, inspections for-cause, and inspections undertaken at the request of the DOJ or OIG;¹³⁶ 2) evaluation of complaints and other information submitted by industry competitors, physicians, patients and consumers, and other third parties; 3) investigations undertaken at the discretion of the agency or of the HHS OIG or of the DOJ pursuant to their responsibilities under HIPAA; 4) self-certification/declaration of company compliance with the good pharmaceutical marketing practices regulations and appropriate voluntary standards; 5) voluntary FDA advisory review of the company's proposed activities or programs submitted by companies to the FDA; and 6) voluntary company self-disclosure.

F. Enforcement

In keeping with current FDA policy, the agency would be authorized to undertake: advisory actions, including the issuance of untitled regulatory letters and Warning Letters; administrative actions, including revocation or suspension of product listings (the product could remain on the market and available to physicians and patients, but the agency would have the authority to order the company to cease some or all promotional activities related to the product until it was satisfied with company efforts to achieve compliance); and judicial actions, including injunctions, inspection warrants, search warrants and prosecutions.¹³⁷

Consistent with current FDA practice, most initial enforcement actions would be advisory in nature, including agency-issued

68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (last visited May 21, 2006). ACCME is the principle private regulatory body in the U.S. that accredits the development, content and delivery of continuing medical education often required for physicians to comply with state licensure requirements. *Id.* ACCME's Standards for Commercial Support (SCS) are aimed at assuring that continuing medical education meets recognized educational needs and is non-promotional. *Id.* The SCS are incorporated by reference in FDA's Policy Development and Guidance to Industry Guidance and the Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

¹³⁶ Under its inspectional authority, FDA would have authority, at reasonable times, to have access to company facilities to verify and copy company records relating to compliance with the GPMP regulations. This would permit FDA to compare the company's compliance records, systems and activities to its current GPMP requirements.

¹³⁷ See FDA MANUAL, *supra* note 81, §§ 10-2 to 10-5.

warning letters and untitled letters. Through this approach, the FDA would continue to employ its doctrine of prior notice when consistent with its responsibilities and depending on the nature of the violation. This approach affords firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of more serious enforcement actions. Further, it offers the potential for improved protections of the health and safety of patient-beneficiaries by assuring speedy and efficient resolution of alleged improprieties.

G. Federal Preemption of State Law

The federal regulatory scheme would expressly preempt state laws and regulations inconsistent with federal law, thus recognizing the importance of a uniform federal regulatory and enforcement approach in an area already occupied by federal law.

V. Conclusion

Federal and state governments are increasingly called upon to cover the cost of prescription drug products as part of government healthcare programs. The current approaches to detecting and preventing pharmaceutical fraud and abuse focus largely on a limited number of high-profile, resource-intensive cases. These efforts compete directly for scarce law enforcement resources with other national law enforcement and security priorities; moreover, the nature of the work is much better suited to that of an administrative agency. The current approach is an inefficient means by which to detect and prevent fraudulent or abusive pharmaceutical marketing practices. It overlooks the need to balance fiscal and law enforcement responsibilities with the impact to public health of either overly-aggressive enforcement, or of enforcement efforts that take years to reach conclusion because they rely on the use of processes designed for civil and criminal law enforcement. It also overlooks the importance of a unified federal approach to regulating an area already occupied by federal legal and regulatory controls. Expanding on the current methods employed by the FDA, in its regulation of prescription drug advertising, and borrowing some new ideas originating from the states, offers a solution that is better for patients, taxpayers, and the industry.