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A PATIENT-CENTERED APPROACH TO HEALTH CARE FRAUD RECOVERY

JOAN H. KRAUSE*

This Article begins with a simple premise: Health care fraud hurts patients. From that premise flows a simple corollary: efforts to combat health care fraud should, if possible, remedy this patient harm. Despite its intuitive appeal, this syllogism does not represent current practice. Funds recovered through health care fraud enforcement are distributed to the Medicare Trust Fund, to the federal agencies that investigate and prosecute health care fraud, and to private parties who initiate suits on the government's behalf under the civil False Claims Act¹—but rarely to patients who may have been harmed by the conduct. While focusing enforcement efforts on returning funds to the Federal Treasury clearly helps to assure that the federal health care programs² remain solvent and continue to provide care to beneficiaries in the aggregate, it offers little solace to injured individuals.

This approach stands in marked contrast to efforts to make the United States health care system more “patient-centered.” In 2001, the Institute of Medicine's Committee on Quality of Health Care in America identified “patient-centeredness” as one of the six health care aims for the next century, “focus[ing] on the patient's experience of illness and health care and on the systems that work or fail to work to meet individual patients’

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¹ See 31 U.S.C. §§ 3729-33 (2000).

² As used in the fraud statutes, “Federal health care program” includes “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government” with the exception of the Federal Employees Health Benefit Program, as well as state-funded health care programs. See 42 U.S.C. § 1320a-7b(f)(1) (2000).

needs.”³ While advocates initially focused their efforts on clinical practice—emphasizing respect for patients, the provision of honest and complete information, physical comfort, and emotional support for patients and their families⁴—these concepts have grown to encompass systemic structural concerns as well. A patient-centered approach to access to health care makes “serving the practical health care needs of patients (1) the focal point of the health care system, (2) the paramount responsibility of health professionals, and (3) *the primary role of private and public financing [of] health care.*”⁵ A health care fraud enforcement system that assures large

³ COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 48 (2001); *see also* THROUGH THE PATIENT’S EYES: UNDERSTANDING AND PROMOTING PATIENT-CENTERED CARE 5 (Margaret Gerteis et al. eds., 1993) (focusing “on the patient’s experience of illness and health care and the systems that work, and fail to work, to meet patients’ needs, as they define them”).

⁴ *See* THROUGH THE PATIENT’S EYES: UNDERSTANDING AND PROMOTING PATIENT-CENTERED CARE, *supra* note 3, at 5-11 (defining dimensions of patient-centered care).

⁵ Laura D. Hermer & William J. Winslade, *Access to Health Care in Texas: A Patient-Centered Perspective*, 35 TEX. TECH. L. REV. 33, 34 (2004) (emphasis added). Even Congress has jumped on the patient-centered care bandwagon. *See* Bill Frist, *Speeches: Frist Outlines Plan for “Putting the Patient at the Heart of Health Care,”* July 23, 2005, available at http://frist.senate.gov/index.cfm?FuseAction=Speeches.Detail&Speech_id=254&Month=7&Year=2005 (text of speech by Sen. Bill Frist to Commonwealth Club of California).

Patient-centered care is in many ways the clinical counterpart to therapeutic jurisprudence, “the study of the use of the law to achieve therapeutic objectives.” David B. Wexler, *An Introduction to Therapeutic Jurisprudence*, in THERAPEUTIC JURISPRUDENCE: THE LAW AS THERAPEUTIC AGENT 4 (David B. Wexler ed., 1990). The core insight of therapeutic jurisprudence is that the legal system—both in terms of substantive legal rules and systemic structure—may have effects that are more or less “healing” in nature. *Id.* at 14 (arguing that “the legal system itself . . . should be examined, and perhaps restructured, to maximize its therapeutic aspects and to minimize its anti-therapeutic aspects”). Although its genesis was in the area of mental health law, the theory has been applied to a variety of legal issues including tort suits and appellate advocacy. *See, e.g., id.* at 4 (discussing application of theory to mental health law); Harold S. Kaplan, *Benefiting from the “Gift of Failure”*: *Essentials for an Event Reporting System*, 24 J. LEGAL MED. 29, 42 (2003) (discussing therapeutic failures of malpractice litigation); Daniel W. Shuman, *Making the World a Better Place Through Tort Law?: Through the Therapeutic Looking Glass*, 10 N.Y.L. SCH. J. HUM. RTS. 739 (1993) (discussing application of theory to tort law); Christopher Slobogin, *Therapeutic Jurisprudence: Five Dilemmas to Ponder*, 1 PSYCHOL. PUB. POL’Y & L. 193 (1995) (identifying issues that may arise in applying theory to practice); David B. Wexler, *Introduction: Therapeutic Jurisprudence in the Appellate Arena*, 24 SEATTLE U. L. REV. 217, 217 (2000) (discussing “the use of therapeutic jurisprudence in the appellate courts”). In the health law literature, recent scholarship by academics such as Mark Hall has used therapeutic jurisprudence as the basis for thought-provoking discussions of the role of trust in the health care system. *See generally* M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919 (2002); Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law*, 39 WAKE FOREST L. REV. 395 (2004); Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002). Despite anecdotal

monetary recoveries for the Federal fisc but makes no attempt to compensate injured beneficiaries does not achieve these goals. In short, current health care fraud recoveries are not patient-centered.

The reasons for this failure are complex, and derive both from the factual context in which health care fraud occurs and from the traditional white collar crime enforcement framework. In large part, health care fraud recovery is not patient-centered because patients are not viewed as the victims of the fraud; that distinction instead belongs to the federal government, the ultimate payer under the federal health care programs. Consistent with that view, the federal statutes most commonly invoked in fraud cases channel recoveries to the federal coffers rather than directing compensation to injured individuals. Indeed, to the extent the government's primary interest in prosecuting health care fraud derives from its role as a defrauded payer, rather than as the more general protector of its citizenry, individualized compensation would appear to be unnecessary.⁶ This focus on financial harm to the government is reinforced by situating health care fraud within the context of white collar crime, an area of law that focuses almost exclusively on economic harm.⁷ In short, the recognition that health care fraud harms individual patients in ways that merit compensation—particularly if such harm is non-financial in nature—does not fit into the dominant conceptual model of health care fraud.

Part I of this Article explores the varied ways in which patients are harmed by fraudulent health care activities. Part II analyzes barriers to patient compensation under current law, addressing not only limitations on the disposition of recovered funds but also the conceptual difficulties posed by the white collar crime framework. Part III discusses recent developments at the state and federal levels, and explores compensation mechanisms common in consumer protection cases to determine whether they could be imported into the health care fraud context. The Article concludes that while there may be good reasons not to convert the entire health care fraud enforcement scheme to a patient-centered model, it nevertheless should be possible to reduce existing barriers to compensating patient harm.

evidence, this approach does not appear to have been applied in detail to the topic of health care fraud—perhaps indicating a fruitful area for future study.

⁶ Note, however, that powerful statutes also permit federal prosecution of private health care fraud in the absence of federal harm as long as jurisdictional requirements are met, thus invoking the federal government's more traditional role as protector. See, e.g., 18 U.S.C. § 1341 (2000) (mail fraud); *id.* § 1343 (wire fraud); *id.* § 1347 (health care fraud).

⁷ See, e.g., J. Kelly Strader, *The Judicial Politics Of White Collar Crime*, 50 HASTINGS L.J. 1199, 1204-14 (1999) (discussing definitions of white collar crime).

I. HEALTH CARE FRAUD AND PATIENT HARM

Health care fraud encompasses activities by a wide range of actors. It includes fraud by and upon health care professionals, health care institutions, health insurers and managed care companies, manufacturers of prescription drugs and other health care supplies, and even patients.⁸ When such activities occur in the federal health care programs, such as Medicare and Medicaid, they are subject to a broad array of civil, criminal, and administrative statutes.⁹ Yet, virtually all of these provisions consider the ultimate victim of the fraud to be the federal government, rather than the individual patient. As a result, health care fraud is largely considered a “bloodless” form of wrongdoing, an image reinforced by characterizations of such fraud as a stereotypical white collar crime.¹⁰ White collar crimes are thus the opposite of “street crimes” in which money and property are taken by violence or the threat thereof.¹¹ In health care, these principles evoke images of highly trained physicians and executives misusing their positions and professional skills for personal financial gain, accomplished through deceptive yet nonviolent tactics such as falsifying bills for services.

⁸ See, e.g., Sharon L. Davies & Timothy Stolfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?*, 31 GA. L. REV. 373, 383-84 (1997) (describing potential for fraud in relationships between health care “consumers, purchasers, providers, and intermediaries”); Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL’Y 55, 64-81 (2003) [hereinafter Krause, *A Conceptual Model*] (describing industries affected by recent health care fraud initiatives). In the federal health care programs, the term “provider” technically refers to institutional entities, such as hospitals, home health agencies, and nursing homes. 42 U.S.C. § 1395x(u) (2000) (defining “provider of services”). Because they face similar fraud liability, this Article will use the term “health care provider” to refer more broadly to both individual health care professionals and institutional health care entities. See DEP’T. OF HEALTH & HUMAN SERVS., SPECIAL ADVISORY BULLETIN: PRACTICES OF BUSINESS CONSULTANTS 1 n.1 (2001), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf> (using the term to include “providers, suppliers, and practitioners that provide items or services payable in whole or in part by a Federal health care program”).

⁹ See, e.g., 42 U.S.C. § 1320a-7 (2000) (exclusion from federal health care programs); *id.* § 1320a-7a (civil monetary penalties applicable to federal health care programs); *id.* § 1320a-7b(b) (Medicare & Medicaid Anti-Kickback Statute); *id.* § 1395nn (limitations on self-referrals).

¹⁰ See Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 857, 870-71 (1989) [hereinafter Bucy, *Fraud by Fright*] (noting that health care fraud shares essential features of white collar crime).

¹¹ See, e.g., Darryl K. Brown, *Cost-Benefit Analysis in Criminal Law*, 92 CAL. L. REV. 325, 342 (2004) (“In criminal law, street crime (theft and violent crime) is especially vivid and frightful for most people. In contrast, white collar crimes, such as financial frauds in which many victims lose small amounts, seem much less threatening. Compared to corporate crime risks, street crime risks are more vivid.”).

The victim—if the term even applies—is a hapless federal bureaucracy that serves as easy prey for unscrupulous individuals.

Not surprisingly, public statements by prosecutors suggest a zero-tolerance approach to those who take advantage of the federal health care programs. In commenting on a recent pharmaceutical settlement, for example, the United States Attorney for the Eastern District of Pennsylvania stated,

This wasn't a mistake. It was a marketing strategy. The result was that programs created to provide healthcare to the poorest among us were actually paying more for drugs than those who have private health insurance. There is a point at which pursuit of market share crosses the line that separates competition and illegal conduct. This case serves as an example that the consequences of stepping over that line can be costly.¹²

Where the federal health care programs are viewed as suffering the greatest losses, it is logical to concentrate enforcement efforts on reimbursing those programs.

But the federal government is not the only victim of fraudulent activities. Health care fraud also causes significant harm to *patients*—harm that may be financial, physical, or less tangible in nature. Although initially slow to recognize these effects, prosecutors and policymakers have now embraced the goal of “patient protection” as a key justification for fraud enforcement. Yet despite this rhetoric, the financial model of health care fraud recovery has not changed accordingly. And while returning funds to the federal Treasury helps to assure that the federal health care programs remain able to provide care to beneficiaries in the aggregate, this approach fails to remedy harm to individual patients.

A. HARM TO THE FEDERAL GOVERNMENT

Health care fraud became a key priority for federal law enforcement officials in the 1990's.¹³ The motivation for these efforts is clear: As the authors of one treatise note, health care fraud is “where the money is.”¹⁴ For a sense of just how much money is at stake, note that the first

¹² Press Release, U.S. Attorney's Office, Schering-Plough to Pay \$345 Million to Resolve Criminal & Civil Cases: Schering to Admit Paying Kickback in Exchange For Preferred Treatment – Will Also Settle False Claims Liability (July 30, 2004), available at http://www.usdoj.gov/opa/pr/2004/July/04_civ_523.htm.

¹³ In fact, former Attorney General Janet Reno identified health care fraud as her “number two priority,” second only to violent crime. ANNUAL REPORT OF THE ATTORNEY GENERAL OF THE UNITED STATES (1994), available at <http://www.usdoj.gov/ag/annualreports/ar94/finalag.txt>.

¹⁴ ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE 1-3 (2004) (paraphrasing statements made by infamous bank robber Willie Sutton).

comprehensive audit of Medicare fee-for-service payments found that more than \$23 billion had been paid out improperly in fiscal year 1996 alone.¹⁵ Although the numbers have improved each year, auditors estimate that the Medicare program still paid \$12.1 billion in improper claims in fiscal year 2005, an error rate of 5.2 percent.¹⁶ Given ongoing concerns over the solvency of the Medicare program, particularly once the so-called “Baby Boomers” become eligible, policymakers may view health care fraud recoveries as a means to offset escalating program costs without raising taxes, reducing the scope of benefits, or otherwise incurring the wrath of the powerful aging lobby.¹⁷

Health care fraud is actionable under a wide range of federal criminal, civil, and administrative statutes. Some of these laws, such as the Medicare and Medicaid Anti-Kickback Statute, the “Stark Law” prohibition on physician self-referral, and the provisions governing exclusion from the federal health care programs, specifically target improper health care activities.¹⁸ Others, such as the civil and criminal false claims prohibitions,¹⁹ apply more broadly to all entities that transact business with

¹⁵ See DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF THE INSPECTOR GEN., IMPROPER FISCAL YEAR 2001 MEDICARE FEE-FOR-SERVICE PAYMENTS, NO. A-17-01-02002, at 1 (2002), available at <http://oig.hhs.gov/oas/reports/cms/a0102002.pdf> (acknowledging that 2002 error rate represented a significant reduction from the \$23.2 billion in improper payments identified in 1996, the first year such audits were conducted).

¹⁶ Centers for Medicare & Medicaid Services, Improper Medicare FFS Payment Short Report (Web Version) for November 2005, https://www.cms.hhs.gov/apps/er_report/preview_er_report.asp?from=public&which=short&reportID=3&tab=2 (last visited Dec. 12, 2005). Of course, it is not clear that all such payments constitute fraud rather than errors or good faith disagreements. See David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 151, 162 (2002) (arguing that these audits are not designed to measure fraud).

¹⁷ See, e.g., OFFICE OF MANAGEMENT AND BUDGET, MID-SESSION REVIEW: MEDICARE TRUST FUNDS (2003), available at <http://www.whitehouse.gov/omb/budget/fy2002/msr03.html> (projecting Medicare shortfalls through 2011); Jonathan W. Emord, *Murder by Medicare: The Demise of Solo and Small Group Medical Practices*, 21-3 REGULATION 31, 32-33 (1998) (arguing that the “Medicare enforcement scheme . . . seeks to expand definitions of improper billing, fraud, and abuse as a means to help Medicare recoup funds from physicians,” with the result that “Congress has been able to take credit for a broad array of seemingly ever-expanding federally funded benefits and for holding down costs, while not being held politically accountable for the program’s adverse effects on medical practices and health care markets”).

¹⁸ See 42 U.S.C. § 1320a-7 (2000) (exclusion from federal health care programs); *id.* § 1320a-7a (civil monetary penalties applicable to federal health care programs); *id.* § 1320a-7b(b) (Medicare & Medicaid Anti-Kickback Statute); *id.* § 1395nn (limitations on self-referrals). For a detailed discussion of these statutes, see Krause, *A Conceptual Model*, *supra* note 8, at 64-81.

¹⁹ See 18 U.S.C. §§ 286-87 (2000) (criminal false claims provisions); 31 U.S.C. §§ 3729-33 (2000) (Civil False Claims Act).

the federal government. Health care fraud also may be prosecuted under broad federal criminal statutes, such as mail and wire fraud, conspiracy, and the Racketeer Influenced and Corrupt Organizations Act (“RICO”),²⁰ which prohibit improper conduct regardless of the industry in which it occurs.

The current centerpiece of the government’s anti-fraud efforts is the Civil False Claims Act (“FCA”), a Civil War-era statute that prohibits the knowing submission of false or fraudulent claims to the federal government.²¹ Because violators are subject to a civil penalty of \$5,500 to \$11,000 per claim, plus three times the amount of damages sustained by the government,²² repeated submission of bills containing small increments of fraud quickly leads to astronomical aggregate liability.²³ Moreover, the FCA’s unique *qui tam* provisions permit private whistleblowers (known as “relators”) who sue on the government’s behalf to retain fifteen to thirty percent of the proceeds of the suit—creating a powerful incentive for private parties to police their neighbors in the health care market.²⁴ The number of health care FCA suits has grown exponentially since amendments in 1986 made it more lucrative to pursue *qui tam* actions, and health care *qui tam* suits now eclipse those in other areas of government contracting.²⁵

²⁰ See 18 U.S.C. § 371 (conspiracy); *id.* §§ 1341, 1343, 1346 (mail and wire fraud); *id.* §§ 1961–62 (RICO). RICO provides for both criminal and civil causes of action. See *id.* § 1964 (setting forth civil remedies).

²¹ 31 U.S.C. §§ 3729–33 (2000). The law was enacted in 1863 in response to reports of “rampant fraud” perpetrated on the United States military during the Civil War. See S. REP. NO. 99-345, at 8 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5273 (noting history of False Claims Act). The most commonly invoked FCA cause of action applies where: (1) a defendant presents (or causes to be presented) a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the defendant’s acts are undertaken “knowingly.” 31 U.S.C. § 3729(a)(1). “Knowingly” includes not only actual knowledge, but also deliberate ignorance and reckless disregard of truth or falsity. See *id.* § 3729(b). An actionable “claim” includes “any request or demand . . . for money or property” if any portion thereof comes from the federal government. *Id.* § 3729(c).

²² See 31 U.S.C. § 3729(a)(7) (listing statutory penalties and treble damages); 28 C.F.R. § 85.3(a)(9) (2005) (increasing statutory penalties by 10% for inflation).

²³ In *United States v. Krizek*, for example, a psychiatrist was alleged to have submitted 8002 false claims, each inflated by approximately \$30; assessing penalties of \$10,000 per claim, the government sued for \$81 million dollars. 111 F.3d 934 (D.C. Cir. 1997); see also Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 260 (1999) (noting that “[e]ven if individually quite small, astronomical sums are quickly reached”).

²⁴ See, e.g., 31 U.S.C. §§ 3730(b), (d) (noting that a private person who brings a civil action may potentially receive fifteen to thirty percent of the proceeds of the suit).

²⁵ By 1998, 61% of the filed *qui tam* cases involved the federal health care programs, compared to only twelve percent in 1987. See FRIED, FRANK, HARRIS, SHRIVER & JACOBSEN

In response to growing concerns about the magnitude of health care fraud, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)²⁶ made significant changes to federal law enforcement authority. In addition to creating new criminal causes of action,²⁷ HIPAA required that more funds be appropriated to the federal agencies with jurisdiction over health care fraud, particularly the Department of Justice (“DOJ”) and the Department of Health and Human Services (“HHS”) Office of the Inspector General (“OIG”). A key aspect of this effort was the creation of a “Fraud and Abuse Control Program,” designed to coordinate federal, state, and local health care fraud enforcement efforts.²⁸ The centerpiece of the Program is the “Fraud and Abuse Control Account,” which funds health care fraud inspections, investigations, and prosecutions undertaken by the DOJ and OIG.²⁹ HIPAA set fiscal year 1997 Control Account appropriations at \$104 million, with an increase of up to 15 percent per year through fiscal year 2003.³⁰

To a certain extent, these investments have paid off. The DOJ recovered more than \$1.4 billion in civil fraud suits in fiscal year 2005, with \$1.1 billion of that amount attributed to health care fraud cases.³¹ While this certainly counts as progress, it represents merely the proverbial drop in the bucket in the face of almost \$20 billion in improper payments each year. Viewed as a return on investment, however, the picture is decidedly more cheerful: Taxpayers Against Fraud, a nonprofit organization that promotes the use of the FCA to combat fraud, has estimated that “for every dollar spent to investigate and prosecute health care fraud in civil cases, the federal government receives nearly thirteen dollars back in return.”³² With

LLP, *QUI TAM* FCA Statistics, available at <http://www.ffhsj.com/quitam/fcastats.htm> (last visited Feb. 23, 2006).

²⁶ Pub. L. No. 104-191, 110 Stat. 1937 (1996).

²⁷ *Id.* at 241-49 (revising criminal law provisions relating to health care fraud) (codified as amended in scattered sections of 18 U.S.C., including, e.g., 18 U.S.C. § 247 (2000) (injunctive relief relating to health care offenses), *id.* § 669 (theft or embezzlement in connection with health care), *id.* § 1035 (false statements relating to health care matters), *id.* § 1347 (health care fraud), *id.* § 1518 (obstruction of criminal investigations of health care offenses)).

²⁸ See 42 U.S.C. § 1320a-7c (2000) (establishing program).

²⁹ *Id.* § 1395i(k)(3) (describing appropriations to the account).

³⁰ *Id.* § 1395i(k)(3)(A)-(B) (setting out the maximum amounts available for appropriation).

³¹ Press Release, U.S. Dep’t of Justice, Justice Department Recoveries total \$1.4 Billion in Fraud & False Claims in Fiscal Year 2005; more than \$15 Billion since 1986 (Nov. 7, 2005), available at http://www.usdoj.gov/opa/pr/2005/November/05_civ_595.html.

³² JACK A. MEYER, FIGHTING MEDICARE FRAUD: MORE BANG FOR THE FEDERAL BUCK 2 (2004), available at www.taf.org/meyerreport.htm.

a positive return on investment, and billions of dollars in improper payments yet to be recouped, federal interest in health care fraud is unlikely to wane any time soon.

B. HARM TO PATIENTS

Given the magnitude of the problem, it is logical that recovery efforts have focused on the government's role as a defrauded payer. While health care fraud clearly causes significant financial harm to the federal Treasury, however, the federal government is not the only—or in some cases even the primary—victim. Health care fraud also causes significant harm to *patients*, be it financial, physical, or less tangible in nature.

1. *Financial Injury*

Financial injury to patients is perhaps the easiest type of harm to recognize, in part because it mirrors the government's own economic injury. Due to the cost-sharing structure of the health care reimbursement system, fraud often has financial repercussions for patients. Under Medicare Part B, for example, beneficiaries are responsible for paying 20% of the Medicare approved charge for covered outpatient services, which include physician services and drugs administered in a physician's office.³³ Under such a cost-sharing mechanism, a fraudulently inflated charge will result in additional expense to both insurer and patient³⁴—expense that may have disproportionately detrimental effects on patients who subsist on limited incomes, such as many federal program beneficiaries.³⁵

These concepts are illustrated by the ongoing controversy over the prices charged by prescription drug manufacturers. The issue received widespread public attention in October 2001, when TAP Pharmaceutical Products agreed to pay \$875 million dollars to settle a variety of civil and criminal fraud allegations stemming from the sale of its cancer drug,

³³ See 42 U.S.C. § 1395i(a) (setting forth 80/20 split for Medicare Part B). This structure also is common in private insurance. See, e.g., ANNE M. STOLINE & JONATHAN P. WEINER, *THE NEW MEDICAL MARKETPLACE: A PHYSICIAN'S GUIDE TO THE HEALTH CARE SYSTEM IN THE 1990s*, at 62-63 (rev. ed. 1993) (describing co-insurance as a cost-sharing mechanism).

³⁴ Although the pricing mechanisms may be slightly different, similar fraud also occurs in private insurance. See, e.g., *Smith v. United Healthcare Servs., Inc.*, No. CIV 00-1163 ADM/AJB, 2002 WL 192565 (D. Minn. Feb. 5, 2002) (certifying class in ERISA suit alleging that insurer overcharged beneficiaries for prescription drug copayments).

³⁵ As Congress recognized while debating the 2003 Medicare reform legislation, "low-income beneficiaries must often make unacceptable choices between life-saving medicines and other essentials." H.R. REP. NO. 108-391, at 427 (2003) (Conf. Rep.), as reprinted in 2003 U.S.C.C.A.N. 1808, 1810.

Lupron.³⁶ TAP was alleged to have inflated the prices it reported to the publications on which Medicare contractors based their “average wholesale price” (“AWP”) calculations for reimbursement purposes, thus assuring that Medicare payment for Lupron would remain artificially high. By actively marketing this “spread” between the discounted price paid by physician customers and the artificially high rate at which Medicare reimbursed the product, TAP was accused of offering its customers a financial inducement to prescribe Lupron in violation of the Medicare & Medicaid Anti-Kickback Statute (and thereby causing customers to submit false claims under the FCA).³⁷ The allegations involved a substantial amount of money: A subsequent private suit against the company alleged that while the actual cost of the drug *dropped* from \$340 to \$207 over several years, the published AWP in fact *increased* from \$418.75 to \$623.79.³⁸

Due to the 20% copayment structure, the Medicare beneficiaries who took Lupron—patients suffering from cancer, no less—were the direct victims of this alleged fraud scheme.³⁹ Because of the widespread use of AWP as a reimbursement benchmark, the scheme was equally applicable to patients who purchased the drug through many private insurers. Following settlement of the federal fraud allegations, a consortium of patients, health plans, and state attorneys general filed a series of civil actions against the company for injunctive relief and damages.⁴⁰ Subsequent investigations have made clear that the problem is not limited to one pharmaceutical company, and virtually all of the major drug manufacturers have been sued for similar activities.⁴¹ At this point, the effect on patients appears incontestable: The Centers for Medicare & Medicaid Services (“CMS”),

³⁶ See Press Release, U.S. Dep’t of Justice, TAP Pharmaceutical Products, Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), available at <http://www.usdoj.gov/opa/pr/2001/October/513civ.htm>.

³⁷ See *id.*

³⁸ See *In re Lupron(R) Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148 (D. Mass. 2003). As the court noted, “[d]efendants repeatedly assert that . . . AWP was a ‘sticker price’ and never intended to reflect the drug’s true average wholesale price. . . . *There is a difference between a sticker price and a sucker price.*” *Id.* at 168 n.19 (emphasis added).

³⁹ As Congress has noted, “[i]n addition to the financial toll on the U.S. Treasury, these large spreads also affect Medicare beneficiaries, who are often required to pay dramatically inflated co-payments for the drugs they receive.” H.R. REP. NO. 108-391, at 583.

⁴⁰ See *In re Lupron(R) Mktg. & Sales Practices Litig.*, 228 F.R.D. 75 (D. Mass. 2005) (certifying class and approving final settlement).

⁴¹ See, e.g., *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005) (resolving class certification issues in suit brought by consumers and third-party payers against pharmaceutical companies); *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196 (D. Mass. 2004) (addressing RICO, antitrust, and consumer protection allegations brought by employee health plans against pharmaceutical companies).

which administers the Medicare and Medicaid programs, reported that the spread for some drugs was so large that the patient's 20% Medicare copayment was greater than the *total* price paid by the physician.⁴² In the aggregate, OIG has estimated "that if Medicare had paid reimbursements equal to widely available wholesale prices, beneficiaries would have paid \$175 million less in coinsurance" annually.⁴³ When the effect on privately insured patients is taken into account, it is clear that the scheme's overall financial impact on patients was substantial.

2. *Physical Injury*

Although financial harm may be the easiest form of injury to recognize, fraudulent activities may also cause physical harm to patients. As one commentator has noted:

Health care fraud is unique among white collar crimes in its ability to cause physical harm. This is true for several reasons: (1) often the fraudulent provider is also an incompetent provider; (2) some types of fraud are also malpractice, such as performing unnecessary medical procedures to increase billing; and (3) some types of fraud lead legitimate providers to render poor health care.⁴⁴

Unlike financial harm, which in fact is the *goal* of the scheme, physical injuries tend to be mere byproducts of the fraud. Rather than being motivated by any malice toward patients, such injury results from the medical activities (or lack thereof) through which the fraudulent scheme was carried out.

One way patients may suffer physical injury is when unnecessary medical procedures are performed solely for the purpose of obtaining payment from the federal health care programs. A substantial medical literature has documented the health effects of overtreatment. Even if not physically harmful in itself, for example, unnecessary diagnostic testing may lead to "a false positive result [that] may trigger a cascade of progressively more invasive and expensive tests," with adverse physical and psychological consequences.⁴⁵ Similarly, the growing literature on

⁴² See Medicare Program; Payment Reform for Part B Drugs, 68 Fed. Reg. 50428, 50430 (Aug. 20, 2003) (proposing to revise Medicare drug reimbursement methodology).

⁴³ *Id.* (emphasis added).

⁴⁴ Pamela H. Bucy, *Crimes By Health Care Providers*, 1996 U. ILL. L. REV. 589, 660-61 [hereinafter Bucy, *Crimes By Health Care Providers*].

⁴⁵ Peter Franks et al., *Gatekeeping Revisited—Protecting Patients from Overtreatment*, 327 NEW ENG. J. MED. 424-25 (1992); see also Elliott S. Fisher & H. Gilbert Welch, *Avoiding the Unintended Consequences of Growth in Medical Care: How Might More Be Worse?*, 281 J. AM. MED. ASS'N 446, 449-50 (1999) (noting that harms caused by over-diagnosis include "labeling" someone who feels well as sick and identification of

iatrogenic complications in hospital settings—adverse events caused in some way by the medical intervention itself, including what have come to be known as “medical errors”—makes clear that such overtreatment is not a benign phenomenon.⁴⁶ As one researcher has noted, “More is not better, and it often is very, very much worse.”⁴⁷

If health care is reimbursed on a fee-for-service basis, in which separate payment is made for each item or service billed, there is a strong incentive to order unnecessary care.⁴⁸ These incentives most clearly exist with regard to minimally invasive tests and other procedures where overuse is difficult to detect. In one such case, a laboratory provider drew blood for unnecessary tests despite being aware that the procedures “would provide no medical or economic benefit (other than to the Lab’s bottom line) and would subject sick patients to needless and intrusive withdrawal of additional blood, with the attendant (albeit incremental) medical risks.”⁴⁹

Yet there also are documented instances of providers performing extremely invasive (and far more lucrative) surgeries on patients who did not need them. Federal prosecutors recently settled allegations that cardiac surgeons at Redding Medical Center performed unnecessary heart surgeries on as many as 700 patients. This included unnecessary open heart and coronary bypass surgeries, often performed on patients who had already undergone procedures such as cardiac catheterization or heart valve replacement.⁵⁰ Similarly, in what is “believed to be the first major scam in

“pseudodisease,” i.e., “disease that would never become apparent to patients during their lifetime without the diagnostic test”).

⁴⁶ See, e.g., COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Krohn et al. eds., 2000) (analyzing magnitude and causes of medical errors); Franks et al., *supra* note 45, at 425 (noting studies of hospital-based complications); Chunliu Zhan & Marlene R. Miller, *Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization*, 290 J. AM. MED. ASS’N 1868, 1873 (2003) (concluding that “medical injuries in hospitals pose a significant threat to patients and incur substantial costs to society”).

⁴⁷ Gina Kolata, *More May Not Mean Better in Health Care, Studies Find*, N.Y. TIMES, July 21, 2002, § 1, at 1 (quoting Dr. Donald M. Berwick, President of the Institute for Healthcare Development).

⁴⁸ See Davies & Jost, *supra* note 8, at 384 (describing incentives for fraud in fee-for-service systems).

⁴⁹ United States *ex rel.* Kneepkins v. Gambro Healthcare Inc., 115 F. Supp. 2d 35, 42 (D. Mass. 2000).

⁵⁰ See Press Release, U.S. Attorney, E. Dist. of Cal., *Doctors Accused of Performing Unnecessary Heart Surgeries at Redding Medical Center Agree to Pay Millions to Settle Fraud Allegations and Accept Restrictions on Their Medical Practice* (Nov. 15, 2005), available at www.usdoj.gov/usao/cae/PRESS/pdf_2005/11-15-05RMC.pdf; *Prosecutors Reach Overall Settlement of Allegations of Unneeded Cardiac Surgery*, 14 HEALTH L. RPTR. (BNA) 1487 (2005).

which clinics and surgeons allegedly paid healthy patients to actually undergo invasive and risky procedures,” several Blue Cross and Blue Shield plans filed suit in March 2005 against a number of Southern California outpatient surgery clinics, alleging a massive “Rent-a-Patient” scheme in which healthy individuals were recruited to travel to the surgery centers for procedures such as colonoscopies and endoscopies.⁵¹

Harm may also occur when medically necessary care is performed in an improper manner in order to maximize reimbursement. In *United States v. Laughlin*, for example, an obstetrician-gynecologist was convicted of multiple counts of Medicaid fraud and mail fraud.⁵² In one case the physician performed a tubal ligation four weeks after delivering a patient’s baby by caesarian—a tactic that permitted him to bill for two surgeries rather than one, which would have been the case had he performed the tubal ligation at the same time as the original procedure.⁵³ Unfortunately, undergoing a second surgery in the same anatomical area so soon after the first also posed a risk of serious harm to the patient.⁵⁴

Even if the unnecessary or ill-timed services do not in themselves pose any risk to patients, courts have recognized that harm may occur if patients rely on these useless treatments to delay seeking legitimate care. In *United States v. Vivit*, a physician was convicted of mail fraud based on the provision of unnecessary services, including physical therapy ultrasound and electrical muscle stimulation performed by unlicensed office personnel.⁵⁵ Acknowledging that patients had relied on the physician to treat their medical conditions, the court noted, “[b]y failing to examine such patients properly, Vivit created a risk that, had these patients suffered serious injuries, their injuries would remain untreated.”⁵⁶ In some cases, the false reliance also endangers third parties. A scheme involving the sale of fraudulent HIV kits, for example, was found to “pose[] a substantial threat to public health because [the defendant] purported to provide reliable HIV

⁵¹ *Blue Cross and Blue Shield Plans File \$30 Million Lawsuit Alleging Rent-A-Patient Fraud in Southern California*, BCBSHEALTHISSUES.COM, Mar. 11, 2004, <http://bcbshealthissues.com/proactive/newsroom/release.vtml?id=152284>; Jonathan D. Glater, *In a Surgery Capital, a Swirl of Fraud Charges*, N.Y. TIMES, July 10, 2005, § 3, at 1 (describing the allegations and some of the “patients”).

⁵² 26 F.3d 1523 (10th Cir. 1994).

⁵³ *Id.* at 1530.

⁵⁴ *Id.* at 1530-31.

⁵⁵ 214 F.3d 908 (7th Cir. 2000). The case also involved more straightforward allegations of billing fraud, including bills submitted for ultrasound therapy a year before the equipment was delivered to the physician’s office. *Id.* at 912.

⁵⁶ *Id.* at 922; see also *United States v. Bachynsky*, 949 F.2d 722, 735 (5th Cir. 1991) (“[W]hile relying on Dr. Bachynsky’s ineffective course of treatment, his patients may have been foregoing more effective, safer, and legitimate treatments elsewhere.”).

screening when in fact there was no scientific basis for the test ‘results’ he sent to customers,” leading to at least one customer “who unwittingly put a new partner at risk.”⁵⁷

Moreover, while overtreatment is the hallmark of fraud in a fee-for-service reimbursement system, the incentives are quite different when payment is made on a lump-sum basis—as under the Medicare inpatient prospective payment system, or in capitated forms of managed care. Where reimbursement is limited to a predetermined amount, the temptation may be to “inappropriately deny necessary care or provide substandard care, thus defrauding and abusing consumers, purchasers, and intermediaries.”⁵⁸ One area of particular interest has been the quality of care provided to beneficiaries in health care institutions, such as nursing homes and hospitals. Since the mid-1990’s, the federal government has investigated allegations that understaffed nursing facilities pose serious threats to patient health, thus resulting in fraudulent bills for care.⁵⁹ Although the nursing facilities have not admitted any liability in these proceedings, common elements of the settlements include the payment of civil penalties, the development of specific training and oversight procedures for problem areas, quality monitoring by outside entities, and the adoption of a corporate compliance program.⁶⁰ More recently, the *Washington Post* ran a series of stories on continuing quality problems in Medicare hospitals, profiling not only Redding Medical Center but also Palm Beach Gardens Medical Center, whose heart surgery unit was long-perceived as “a breeding ground for germs.”⁶¹ In other cases, the fraud scheme results in a combination of

⁵⁷ *United States v. Greene*, 17 F. App’x 722, 724 (9th Cir. 2001).

⁵⁸ *Davies & Jost*, *supra* note 8, at 385-86 (describing potential fraud in managed care).

⁵⁹ *See, e.g., United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051, 1056 (W.D. Mo. 2001) (“At some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient’s quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.”); David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 *ANNALS HEALTH L.* 147 (1997) (describing patient injuries that gave rise to nursing home settlement).

⁶⁰ *See Hoffman*, *supra* note 59, at 154-55 (explaining terms of settlement); Consent Order and Judgment, *United States v. Chester Care Ctr.*, No. 98-CV-139 (E.D. Pa. Jan. 1998), available at <http://www.usdoj.gov/usao/pae/nursing/chester3.pdf> (describing terms of settlement).

⁶¹ Gilbert M. Gaul, *Inefficient Spending Plagues Medicare: Quality Often Loses Out as 40-Year-Old Program Struggles to Monitor Hospitals, Oversee Patients*, *WASH. POST*, July 24, 2005, at A1 (“[Long-standing problems at Palm Beach Gardens included:] Dust and dirt covered some surgical equipment. Trash cans and soiled linens were stored in hallways. IV pumps were spattered with dried blood. One patient’s wife said she saw a medical assistant tear surgical tape with his teeth.”); Gilbert M. Gaul, *At California Hospital, Red Flags and*

over-, under-, and improper treatment. *United States v. Talbott*, for example, involved allegations “that root canal procedures were performed on teeth that should have been extracted as well as on healthy teeth; that some procedures billed as root canals were at best pulpotomies, and that in certain instances teeth were filled for no apparent reason while obvious cavities went undetected.”⁶² From these examples, it is clear that fraudulent activities may cause physical injuries to patients in a variety of ways.

3. *Intangible Harm*

In addition to financial and physical harm, patients can be injured by health care fraud in less tangible ways. One of the key commodities of the health care system is information, specifically *patient information*. At core, information constitutes the sum total of the record of our individual health histories—information that will be used not only as the basis for future treatment decisions, but also for purposes as varied as insurance underwriting and job applications. Professor Peter Jacobson explains: “Health care is a flashpoint for the debate over privacy because of the inherent sensitivity of our medical records. Used properly, medical records can be disclosed for life-saving purposes. Used improperly, the results can be very damaging to one’s reputation or ability to seek employment.”⁶³ From the perspective of those tempted to commit health care fraud, however, information performs a more crass function: it is also the basis on which health care is *reimbursed*. In short, bills are paid only if they list specific services performed for identifiable patients. This creates incentives for the fraudulent use of health care information, and explains why Congress considered the protection of such information to be a federal priority.⁶⁴

Intangible harm may arise when a health care provider misuses patient information to obtain reimbursement for services that were not performed—a traditional form of health care false claim.⁶⁵ In *United States v. Sidhu*, for example, a physician billed the federal health care programs for

an FBI Raid: State Regulators Cited Concerns But Say They Couldn’t Force Change, WASH. POST, July 25, 2005, at A9 (describing problems at Redding Medical Center).

⁶² 590 F.2d 192, 194 (6th Cir. 1978) (affirming convictions of dentists).

⁶³ Peter D. Jacobson, *Medical Records and HIPAA: Is It Too Late To Protect Privacy?*, 86 MINN. L. REV. 1497, 1497 (2002).

⁶⁴ See HIPAA, Pub. L. No. 104-191, 110 Stat. 1935, 2021-34 (1996) (enacting privacy and security protections); 45 C.F.R. §§ 160.101-164.534 (2005) (setting forth privacy regulations).

⁶⁵ See, e.g., *Peterson v. Weinberger*, 508 F.2d 45, 47-48 (5th Cir. 1975) (imposing liability on a physician who submitted bills to Medicare for physical therapy services that were not performed).

biofeedback services, despite the fact that patients “never saw [the] biofeedback machine, and [the provider] generally just talked to the patient, performing more of a counseling role.”⁶⁶ In some cases the provider renders legitimate services to the patient, but also submits bills for additional services the patient did not receive. That was the case in *Del Mazo v. Sanchez*, where a physician who treated a mother also billed Medicaid for the treatment of her five children, whom he had never seen.⁶⁷ In other cases, the goal of the scheme is to permit the provider to generate bills without any patient interaction at all—such as where patient information is stolen or where bills are generated in the names of deceased patients.⁶⁸

When Medicare is billed for services allegedly rendered to nonexistent or deceased patients, the primary harm is to the federal Treasury. Where fraudulent bills are generated in the name of a *living* patient, on the other hand, they may interfere with the patient’s ability to obtain medical services in the future. As Professor Pamela Bucy notes, part of that concern is clinical: “If a fraudulent provider falsifies a patient’s diagnosis or misrepresents medical services that were provided so as to increase billings, the patient’s file may contain false information. Subsequent providers relying on such information may unknowingly render inadequate or inappropriate medical care.”⁶⁹ And even where fraudulent bills do not affect future treatment, they may implicate future *coverage*. Because most insurance benefits have annual or lifetime limits, the submission of fraudulent bills in a patient’s name may mean that little or no coverage will be available when the patient legitimately requires care.⁷⁰ In one reported

⁶⁶ 130 F.3d 644, 648 (5th Cir. 1997).

⁶⁷ 366 S.E.2d 333, 335 (Ga. Ct. App. 1988).

⁶⁸ See U.S. GEN. ACCOUNTING OFFICE, HEALTH CARE FRAUD: SCHEMES COMMITTED BY CAREER CRIMINALS AND ORGANIZED CRIMINAL GROUPS AND IMPACT ON CONSUMERS AND LEGITIMATE HEALTH CARE PROVIDERS 8-9 (1999) [hereinafter GAO, HEALTH CARE FRAUD] (noting fraudulent use of beneficiary information that was stolen, illegally purchased, or otherwise obtained); see also *Sidhu*, 130 F.3d at 647 (accusing physician of billing for psychotherapy on dates when he was out of town and, in one case, for “a patient who was no longer living”). Note that an enterprising criminal could also obtain payment by fraudulently submitting bills in the name of a *provider*. See, e.g., Oregon Medical Association, *Medicare Fraud Alert*, OMA ONLINE, Jan. 7, 2005 (on file with author) (warning physicians of individuals who are obtaining provider information by misrepresenting themselves as Medicare employees).

⁶⁹ Bucy, *Crimes By Health Care Providers*, *supra* note 44, at 661; see also GAO, HEALTH CARE FRAUD, *supra* note 68, at 4 (noting that “false medical histories for some beneficiaries could affect the care prescribed, as the care could be based on false data”).

⁷⁰ See, e.g., 42 U.S.C. § 1395d(a) (2000) (limiting Medicare Part A coverage of inpatient hospital services is limited to 90 days per spell of illness plus 60 lifetime reserve days, and skilled nursing care to 100 days per spell of illness).

case, a psychiatrist was accused of submitting false bills for daily therapy for hospitalized patients.⁷¹ The court noted:

[Patients] were often admitted to the hospital needlessly or their stays in the hospital were extended beyond what was necessary and their insurance companies were billed for treatment not given. Further, the patients' treatment benefits were often exhausted by the time of their discharge. In some cases, patient benefits were exhausted for a life-time; therefore, any future treatment needs would not be covered under their current policy.⁷²

Thus, even if it has no immediate physical or financial effect, the use of fraudulent information has the potential to cause significant harm to patients in the future.

In addition, some fraudulent schemes interfere with patient autonomy by coercing patients into making certain care choices. In one particularly egregious Anti-Kickback case, the head of a chemical dependency program for pregnant women paid illegal remuneration to obtain referrals of patients from a federally-funded drug abuse treatment research program.⁷³ More disturbing than the obvious payment for referrals was the fact that the illegal arrangement directly interfered with the counseling the women received: at trial, several women testified that they had been threatened with the loss of their children if they did not opt to receive treatment from this specific chemical dependency program.⁷⁴ Although such "dignitary" affronts to autonomy are notoriously difficult to compensate under the tort system, they nonetheless constitute a relevant form of harm for the purposes of this inquiry.⁷⁵

II. BARRIERS TO RECOGNITION OF PATIENT HARM IN FRAUD RECOVERY

Despite evidence that health care fraud harms patients, patient compensation has not been a priority of enforcement efforts to date. There are many reasons for this oversight. The failure to make patient compensation an integral component of fraud recovery is due, in large part, to limitations on the uses that can be made of recovered funds under current

⁷¹ United States v. Burgos, 137 F.3d 841 (5th Cir. 1998).

⁷² *Id.* at 844; see also GAO, HEALTH CARE FRAUD, *supra* note 68, at 4 (concluding that beneficiaries "unknowingly risk exhaustion of their insurance benefits, due to false information included in the claims that use their names").

⁷³ United States v. Starks, 157 F.3d 833 (11th Cir. 1998).

⁷⁴ *Id.* at 837.

⁷⁵ See, e.g., Alan Meisel, A "Dignitary" Tort as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent, 16 J.L. MED. & HEALTHCARE 210 (1988) (discussing how dignitary injuries have not adequately been addressed by informed consent law); Richard S. Saver, *Medical Research and Intangible Harm*, 74 CINN. L. REV. (forthcoming 2006) (discussing intangible harm in medical research context).

federal law. Other reasons are more practical in nature: the emphasis on governmental recovery is consonant with the government's goals in pursuing fraud cases, and such recoveries do in fact benefit the patient population (albeit indirectly). Finally, the assumptions underlying the white collar crime framework may well be a contributing factor.

A. WHERE DO HEALTH CARE FRAUD RECOVERIES GO?

Despite the influx of dollars from successful fraud enforcement, current law provides few avenues for these funds to be allocated directly to injured beneficiaries. The disposition of federal health care fraud recoveries is governed by HIPAA.⁷⁶ In a civil false claims case, for example, a portion of the proceeds (usually 15-30%) will be awarded to any *qui tam* relator(s) who initiated the suit.⁷⁷ Most of the remaining funds—as well as those recovered from civil monetary penalties, other civil assessments, and criminal fines and forfeitures⁷⁸—are deposited into the perennially near-insolvent Medicare Part A Trust Fund.⁷⁹ Under the HIPAA Fraud and Abuse Control Program provisions, however, this money is available for appropriation back to the Health Care Fraud and Abuse Control Account, a special expenditure account created to fund DOJ and OIG health care anti-fraud efforts.⁸⁰ Appropriations are controlled by the Secretary of HHS and the Attorney General, who jointly certify the amounts necessary to fund anti-fraud programs each year within broad ranges established by Congress.⁸¹ In loose terms, a portion of the money recovered through federal fraud prosecutions and settlements is available—at the discretion of the agencies themselves—for appropriation *back* to DOJ and HHS.

⁷⁶ Pub. L. No. 104-191, 110 Stat. 1936 (1996).

⁷⁷ See 31 U.S.C. § 3730(d) (2000) (discussing the range of awards for *qui tam* plaintiffs); 42 U.S.C. § 1395i(k)(2)(C)(iv) (2000) (exempting funds awarded to relator from amounts allocated to Trust Fund under HIPAA).

⁷⁸ See 42 U.S.C. § 1395i(k)(2)(C) (setting forth rules for deposits).

⁷⁹ See *id.* § 1395i(k)(2)(C)(iv) (authorizing the transfer of penalties and damages obtained in health care FCA cases to the Trust Fund, with the exception of funds awarded to a relator, funds designated for restitution, or as otherwise authorized by law).

⁸⁰ See *id.* § 1395i(k)(3) (describing appropriations to the Health Care Fraud and Abuse Control Account).

⁸¹ See *id.* § 1395i(k)(3)(A)(i) (setting out the maximum amounts available to HHS and DOJ). In FY 2004, the Secretary and the Attorney General certified \$240 million as necessary for health care anti-fraud efforts; HHS received approximately \$191 million, and DOJ received approximately \$49 million. *Id.*; see DEP'T OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2004, at 4 (2005), available at <http://www.oig.hhs.gov/publications/docs/hcfac/hcfacreport2004.htm>.

This funding structure suggests that HIPAA may have created a “bounty system,” albeit an attenuated one.⁸² To be sure, the very nature of law enforcement provides incentives for prosecutors to be successful, just as an annual appropriations process puts a premium on agencies demonstrating that Congress gets what it pays for. Indeed, DOJ has long had a “3% fund,” under which money from civil recoveries is deposited in a special fund that supports other civil enforcement actions.⁸³ Nonetheless, there is a fear that HIPAA may have tied future funding too closely to past success. Just as critics have warned that the FCA *qui tam* provisions create incentives for relators to file meritless suits in the hopes of reaping financial windfalls,⁸⁴ critics fear that the motivations of OIG and DOJ personnel will be tainted by a structure that permits them to receive a financial boost with each successful prosecution.⁸⁵ In light of long-standing concerns about overzealous health care fraud enforcement, these new developments are decidedly unwelcome.⁸⁶ Nor are these concerns simply academic. Within the health care provider community, the Control Account mechanism is derided as

a self-perpetuating enforcement scheme. . . . Rewarding those who enforce Medicare fraud and abuse regulations with more program funds creates strong institutional incentives for those enforcers to pursue as many investigations and fraud and abuse

⁸² See, e.g., Roger Feldman, *An Economic Explanation for Fraud and Abuse in Public Medical Care Programs*, 30 J. LEG. STUD. 569, 574 (2001) (“Although this is not a pure bounty system, it is much closer than had previously been the case.”). The effect is further attenuated by the fact that appropriations are capped. See 42 U.S.C. § 1395i(k)(3)(A)(i)(III) (capping appropriations at FY 2003 levels).

⁸³ See, e.g., Civil Division, <http://www.usdoj.gov/usao/okn/civil.html> (last visited Mar. 7, 2006) (describing the Affirmative Civil Enforcement (“ACE”) program in the U.S. Attorneys Office for the Northern District of Oklahoma).

⁸⁴ As the Supreme Court cynically has concluded, “*qui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good.” *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 948 (1997).

⁸⁵ Professor Dayna Matthew argues that while “[p]ublic prosecutors do not have a direct personal interest in funds deposited into the Control Account from their prosecutorial efforts . . . they do have an interest in the size of the Control Account as a measure of their professional success and as a source of financing for future professional endeavors.” 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, 580 n.319 (2001); see also *id.* at 580 (noting that “[i]ronically, these financial incentives arguably pose the same threat to prosecutorial discretion, as prosecutors claim self-referral fees pose to providers’ medical judgment”).

⁸⁶ See, e.g., Joan H. Krause, “*Promises to Keep*”: *Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1412-13 (2002) [hereinafter Krause, “*Promises to Keep*”] (discussing complaints of prosecutorial overreaching in health care fraud cases).

prosecutions as possible,⁸⁷ thus increasing the risk that the innocent as well as the guilty will suffer punishment.

The criticism has been vocal enough to put the government on the defensive: vehemently denying the existence of a bounty system, Medicare publications tout the fact that “[a]ll recovered monies are returned to the Medicare Trust Funds” and seek to assure the public that HIPAA-mandated enforcement activities have “a stable source of funding under” the law.⁸⁸

The Control Account is by no means the first productivity-based funding structure that has been alleged to taint the discretion of prosecutors and law enforcement personnel. Virtually identical allegations have been levied against the forfeiture provisions that, since the 1970’s, have supported the nation’s so-called “War on Drugs.”⁸⁹ Similar to the Control Account, federal law has permitted forfeited assets to be placed into a special DOJ Assets Forfeiture Fund, rather than deposited into the general federal Treasury.⁹⁰ This money, in turn, is available to the Attorney General to fund a variety of law enforcement activities, including reimbursement of forfeiture-related expenses by federal, state, and local agencies.⁹¹ According to Professors Eric Blumenson and Eva Nilsen, who have made a detailed study of expenditures and enforcement priorities under this program, these provisions “have not simply enhanced the ability of law enforcement to do its job, but rather have changed the nature of the job itself.”⁹² Blumenson and Nilsen describe two primary objections to the self-funding nature of the law: (1) the conflict of interest between “legitimate law enforcement goals” and initiatives that “maximize funding

⁸⁷ Emord, *supra* note 17, at 32; *see also* Hyman, *supra* note 16, at 158 (“To be sure, CMS does not get to ‘eat what it kills.’ . . . Although this structure prevents the government’s fraud control system from operating on a pure bounty system, there is still considerable suspicion in the provider community on this point.”).

⁸⁸ HEALTH CARE FIN. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., THE MEDICARE INTEGRITY PROGRAM: PAY IT RIGHT! 1, 11 (2001); *see also* Hyman, *supra* note 16, at 158 (noting that CMS publications “go out of their way to label [the bounty allegation] a ‘common misperception’”).

⁸⁹ *See* Eric Blumenson & Eva Nilsen, *Policing for Profit: The Drug War’s Hidden Economic Agenda*, 65 U. CHI. L. REV. 35 (1998).

⁹⁰ 28 U.S.C. § 524(c)(1) (2000); Blumenson & Nilsen, *supra* note 89, at 50-51 (describing funding mechanism).

⁹¹ 28 U.S.C. § 524(c)(1)(A) (describing allowable use of funds). Even if the case is a federal one, state and local law enforcement agencies are permitted to receive funding “that bears a reasonable relationship to the degree of direct participation . . . and will serve to encourage further cooperation between” the agencies. 21 U.S.C. § 881(e)(3)(A)-(B) (2000); *see also* Blumenson & Nilsen, *supra* note 89, at 50-51 (describing effect of the “equitable sharing program,” which directs a significant portion of seized assets to state and local law enforcement).

⁹² Blumenson & Nilsen, *supra* note 89, at 56.

for their operations,”⁹³ and (2) the loss of accountability that occurs when agencies are able to self-fund rather than going through the normal legislative appropriations process.⁹⁴ The result, in their view, is a Drug War that has become self-perpetuating not so much due to the political urgency of its objective, but rather because of the hidden bureaucratic financial incentives.⁹⁵

While there is little empirical research on the topic, the first of these concerns—that the promise of self-funding can skew law enforcement priorities—is a distinct possibility in the health care fraud context. As the Author has argued elsewhere, the vague contours of the fraud laws leave prosecutors with enormous discretion over which activities to target.⁹⁶ The process is complicated by the specter of enormous FCA penalties and the threat of exclusion from federal health care programs, which give health care providers strong incentives to settle fraud allegations rather than pursuing the litigation through trial.⁹⁷ In fact, the potential for skewing priorities may be greater in health care fraud cases than in the drug context, where the prohibitions appear relatively clear (albeit draconian). Because of significant ambiguity in the regulations governing participation in the federal health care programs, however—what Professor James Blumstein has described as regulatory “gray area[s]” rather than “raw fraud”⁹⁸—prosecutors have a great deal of discretion over whether to pursue questionable activities as fraud or to permit them to be resolved through HHS administrative channels. This discretion, in turn, raises the possibility that prosecutors may use the litigation process as a means to resolve such regulatory ambiguities.⁹⁹ Indeed, to the extent federal prosecutors benefit financially from fraud settlements involving gray areas, but do not similarly benefit if HHS personnel address the same behavior by clarifying federal health care program rules, the Control Account mechanism provides yet

⁹³ *Id.*

⁹⁴ *Id.* at 84-100 (noting both separation of powers and policy objections).

⁹⁵ *Id.* at 39-40. Blumenson and Nilsen note that the self-perpetuating nature of these law enforcement activities is particularly ironic in light of the failure to achieve any meaningful improvement in drug usage. *Id.* at 37-39.

⁹⁶ For a discussion of prosecutorial discretion in the context of health care fraud, see Krause, “Promises to Keep,” *supra* note 86, at 1410-15.

⁹⁷ *Id.*

⁹⁸ James F. Blumstein, *What Precisely is “Fraud” in the Health Care Industry?*, WALL ST. J., Dec. 8, 1997, at A25.

⁹⁹ See Krause, *A Conceptual Model*, *supra* note 8, at 110-32 (describing examples of the use of litigation to fill regulatory gaps, and the problems inherent in such an approach).

another motive for pursuing much maligned forms of “regulation by litigation.”¹⁰⁰

In the health care fraud context, Blumenson and Nilsen’s non-accountability concerns may be mitigated by the fact that Congress established upper limits on the amount that may be appropriated to the Control Account, and required the Attorney General and Secretary of HHS to submit a joint annual report accounting for their expenditures.¹⁰¹ While subject to some degree of oversight, however, the Control Account mechanism still permits HHS and DOJ to favor fraud enforcement over other health care funding needs. Because the funds certified for inclusion in the Control Account are transferred from the Medicare Part A Trust Fund, they are not available to be spent on patient care or other efficiency-enhancing administrative program activities.¹⁰² This is analogous to problems noted by Blumenson and Nilsen, who note that forfeited assets that are siphoned off for law enforcement purposes are no longer available for public funding of proactive drug treatment and education programs.¹⁰³ Yet this logic is also somewhat circular: without the Control Account mechanism, Congress would be required to fund all fraud enforcement activities directly in addition to funding the Medicare program, all from the same finite pool of resources.¹⁰⁴ Moreover, such criticism is belied by the

¹⁰⁰ See Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 272-74 (2004) [hereinafter Krause, *Regulating, Guiding, and Enforcing*] (describing dangers of “regulation by litigation” in the health care fraud context). Whether these incentives rise to the level of illegality is unclear. In 1980, the Supreme Court held that a provision of the Fair Labor Standards Act that returned civil penalties from child labor violations to the Department of Labor, rather than the federal Treasury, did not violate the Due Process Clause because the possibility of prosecutorial bias was remote. *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980). In particular, the Court noted that no individual stood to benefit from overzealous collection efforts, the civil penalties accounted for a small percentage of the agency’s budget, and the distribution mechanism functioned in a non-biased way. *Id.* at 250-51. Application of these factors to the Control Account requires an analysis of data that is beyond the scope of this Article. Cf. Blumenson & Nilsen, *supra* note 89, at 62-66 (arguing that an analysis of these factors in the drug forfeiture context suggests the funding scheme is unconstitutional).

¹⁰¹ See 42 U.S.C. § 1395i(k)(3) (2000) (setting caps); *id.* § 1395i(k)(5) (requiring annual report). *But see* 28 U.S.C. § 524(c)(6) (2000) (requiring Attorney General similarly to transmit reports to Congress regarding the Asset Forfeiture Fund).

¹⁰² 42 U.S.C. § 1395i(k) (explaining funding transfer mechanism). As one critic notes, “[b]ecause funds extorted from physicians will not be used to cover Medicare program costs but to extort more funds, Congress will not be able to disguise cost increases in Medicare.” Emord, *supra* note 18, at 32.

¹⁰³ See Blumenson & Nilsen, *supra* note 89, at 82.

¹⁰⁴ As one House Report on the HIPAA legislation noted, “[c]urrently, Medicare’s program integrity functions are subsumed under Medicare’s general administrative budget.” H.R. REP. NO. 104-496 pt. 1, at 79 (1996).

fact that the amount collected in fraud prosecutions—and hence returned to the Trust Fund—far exceeds the amount transferred back to the Control Account.¹⁰⁵ While it is possible to argue that *any* removal of Trust Fund monies is ill-advised, the net effect of this investment strategy appears to be a positive one.

Although the precise nature of prosecutors' stake in health care fraud settlements may not be critical to the debate over patient-centered recovery, it nonetheless raises concerns. For our purposes, what is clear is that the funds recovered from health care fraud enforcement go to the Medicare Trust Fund, to the Control Account, to any relators who initiated the litigation, and to the federal agencies that investigate and prosecute health care fraud—but not directly to remedy the harm suffered by the patients in whose names these investigations are mounted. Combined with the practical considerations underlying the government's approach to these cases and the traditional posture of white collar crime enforcement, these funding rules help to explain why patient compensation has been disfavored, or at the very least overlooked.

B. RECOGNITION OF PATIENT HARM UNDER CURRENT LAW

The laws governing health care fraud and abuse recognize the potential for patient harm as relevant both to the imposition and to the amount of sanctions. A prime example is the "health care fraud" crime enacted by HIPAA, which imposes progressively longer terms of imprisonment on those who defraud a health care benefit program depending on the level of physical harm caused—ranging from a base term of no more than 10 years in prison, to no more than twenty years if the activity "results in serious bodily injury," to "any term of years or for life" if death results.¹⁰⁶ Similarly, in determining the length of a provider's mandatory exclusion from federal health care programs, the fact that the prohibited acts "had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals" is an aggravating factor weighing in favor of more lengthy exclusion.¹⁰⁷ When calculating the amount of civil monetary penalties to be imposed, the fact that "false or

¹⁰⁵ See MEYER, *supra* note 32, at 5 (noting that an estimated \$1.4 billion was returned to the Trust Fund in FY 2002, while only \$209 million was transferred to the Control Account).

¹⁰⁶ 18 U.S.C. § 1347 (2000).

¹⁰⁷ 42 C.F.R. § 1001.102(b)(3) (2005); see also *id.* § 1001.801(c)(2)(iii) (noting that where managed care organization fails to furnish medically necessary items and services, fact that such denial "had or could have had a serious adverse effect" is relevant to length of exclusion). Similarly, in determining the appropriate length of permissive exclusions, aggravating factors include the fact that the actions "had a significant financial impact on program beneficiaries or other individuals." *Id.* § 1001.201(b)(2)(i).

misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission” similarly is an aggravating circumstance warranting higher penalties.¹⁰⁸ In addition, physicians who knowingly and willfully bill Medicare patients for excessive charges are subject to civil monetary penalties,¹⁰⁹ as are managed care organizations that impose excessive premiums on their enrollees.¹¹⁰ It is clear, then, that the federal laws and regulations governing health care fraud acknowledge physical and financial harm to patients as factors relevant to both the necessity and severity of sanctions. The fact that such harm is relevant, however, does not mean that it will be remedied separate from the government’s own injury.

As a practical matter, part of the reason patient compensation is not a more significant aspect of health care fraud recovery is that the government’s motivations for pursuing fraud enforcement are dual in nature and dependent on the factual context in which the fraud occurs. In schemes involving the misappropriation of patient information for the purposes of generating false bills, for example, the harm to the patient is largely incidental to the fraud on the government payer: the fraud occurs when the bill is submitted, regardless of whether the patient has suffered any injury. Other schemes, however, operate in the reverse: the fraud can only occur *after* the patient is harmed. If a nursing home mistreats a resident, for example, the harm to that patient is complete; in contrast, fraud will not occur until the institution submits a bill for the services (and only then, most likely, if the allegations are extensive and systemic).¹¹¹

In essence, then, the federal government’s interest in the former category of cases emanates from its role as a defrauded *payer*, and in the latter category from its authority to *protect* vulnerable individuals.¹¹² Demanding that the federal government be more creative in disbursing the

¹⁰⁸ *Id.* § 1003.106(b)(1)(iv).

¹⁰⁹ *See* 42 U.S.C. § 1395u(j)(1)(A) (2000) (stating prohibition); *id.* § 1395u(j)(2) (setting forth exclusion and CMP authorities).

¹¹⁰ *See id.* § 1395mm(i)(6) (stating prohibition and listing penalties).

¹¹¹ *See, e.g.,* *United States v. NHC Healthcare Corp.*, 163 F. Supp. 2d 1051, 1055 (W.D. Mo. 2001) (noting that “Defendants are not being sued simply for violating the standard of care . . . [r]ather, Defendants are being sued because they allegedly failed to provide the services that they billed for”); *id.* at 1055 n.3 (distinguishing malpractice from FCA liability).

¹¹² Unlike the states, the federal government does not have an explicit “police power” to protect the health of citizens; instead, the federal government’s authority to regulate public health is derived from specific powers enumerated in the Constitution, such as the powers to tax, spend, and regulate interstate commerce. *See* LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 34-55 (2000) (analyzing state and federal public health authorities).

money recovered from health care fraud investigations may conflate these roles. As Professor William Sage has noted, “[a] central, unresolved question is whether the principal purpose of fraud and abuse law is to protect financial integrity or patient welfare.”¹¹³ In both situations, the tendency to overlook patient compensation is based on a concern for diverting recovered funds from their respective primary purposes. Where the federal health care programs are defrauded, the primary goal is to remedy the government’s own harm. Recovered funds are directed to the Medicare Trust Fund because it is the Trust Fund that improperly *paid* for these services; sharing the recovery with individual patients, while a laudable goal, would have the effect of siphoning scarce program resources away from the program.¹¹⁴ Thus, the focus on health care fraud in these cases is largely one of program integrity and solvency, rather than an attempt to invoke a general police power to assure the quality of the country’s medical care. By contrast, where the government is primarily acting in its role as protector, its goals are more in line with the traditional deterrent purposes of criminal law: “to prevent harm to society . . . accomplishe[d] by punishing those who have done harm and by threatening with punishment those who would do harm, to others.”¹¹⁵ But channeling recovered money to patients, at least in significant amounts, would drain the resources needed to fund such public welfare enforcement and might be perceived as weakening the deterrent force of the law.¹¹⁶

¹¹³ William M. Sage, *Fraud and Abuse Law*, 282 J. AM. MED. ASS’N 1179, 1180 (1999).

¹¹⁴ See *supra* Part II.A (describing disposition of federal health care fraud recoveries).

¹¹⁵ WAYNE R. LAFAVE, CRIMINAL LAW § 1.2(e) (4th ed. 2003).

¹¹⁶ One could argue, by analogy, to the analysis done in cases in which a portion of the recovery is diverted to a *qui tam* relator or private attorney general. See, e.g., John C. Coffee, Jr., *Rescuing the Private Attorney General: Why the Model of the Lawyer as Bounty Hunter is Not Working*, 42 MD. L. REV. 215, 246 (1983) (arguing that nonpecuniary settlements, which have become common in such cases, threaten deterrence more than victim compensation); Marsha J. Ferziger & Daniel G. Currell, *Snitching for Dollars: The Economics and Public Policy of Federal Civil Bounty Programs*, 1999 U. ILL. L. REV. 1141, 1152 (noting that “higher bounties would decrease revenues in each individual case because of the higher bounty cost”); Jill E. Fisch, *Class Action Reform, Qui Tam, and the Role of the Plaintiff*, 60 LAW & CONTEMP. PROBS. 167, 201 (1997) (arguing in favor of a hybrid *qui tam*/class action remedy in which “the government would sacrifice its current monetary recovery in enforcement actions in favor of compensation for injured victims”); cf. Geoffrey P. Miller & Lori S. Singer, *Nonpecuniary Class Action Settlements*, 60 LAW & CONTEMP. PROBS. 97, 113 (1997) (arguing that non-monetary class action settlements serve the goal of deterrence to the extent they force “the defendant [to] internalize the costs of harm”); David Rosenberg, *Decoupling Deterrence and Compensation Functions in Mass Tort Class Actions for Future Loss*, 88 VA. L. REV. 1871, 1892 (2002) (noting that “[h]ow damages are distributed among plaintiffs . . . is generally . . . irrelevant to achieving deterrence”).

Lest this Article overstate the case, however, it is important to note that patients *do*, in fact, benefit from general fraud recoveries—both in terms of the quality and the security of their health care benefits.¹¹⁷ When nursing homes or hospitals settle quality-related fraud allegations, for example, the settlement agreement is likely to include provisions directly related to improving the quality of the care rendered—such as specialized training, monitoring and quality assessment, and mandated reporting to the U.S. Attorney’s Office.¹¹⁸ While such provisions may not compensate patients who have suffered harm in the past, they should improve the quality of care provided to facility residents in the future. Moreover, health care fraud recoveries play a role in extending the solvency of the Medicare Trust Fund, which in turn permits the program to provide services to present and future beneficiaries.¹¹⁹ By reclaiming diverted program funds, health care fraud enforcement increases the likelihood that the Medicare program will be able to provide care for the ever-growing beneficiary population (a benefit as well to the future generations of taxpayers who may be called upon to shoulder an increasing portion of the program’s finances). Once again, however, the protection of beneficiary entitlement in the aggregate is not the same thing as compensating individuals who personally have been harmed by fraudulent activities.

A few anti-fraud provisions do provide for a return of money directly to injured patients. For example, under current law physicians who do not participate in the Medicare program cannot charge Medicare patients more than 115% of the Medicare-approved charge.¹²⁰ A physician who violates this provision is subject to exclusion and/or civil monetary penalties, and

¹¹⁷ Nor are patients without options if the federal government declines to engage in more creative efforts to disburse fraud recoveries; a variety of mechanisms exist at the state level to redress direct patient harm, most notably the tort system. *See, e.g.*, W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 1, at 5-6 (5th ed. 1984) (describing tort law as “a body of law which is directed toward the compensation of individuals, rather than the public, for losses which they have suffered within the scope of their legally recognized interests”).

¹¹⁸ *See Hoffman, supra* note 60, at 154-55 (describing settlement in *United States v. GMS Management-Tucker, Inc.*, No. 96-1271 (E.D. Pa. Feb. 21, 1996)); Press Release, U.S. Attorney’s Office, U.S. Attorney’s Office Reaches Agreement with Hospital to Resolve Failure of Care Allegations Stemming From Improper Use of Patient Restraints (July 25, 2005) *available at* www.usdoj.gov/usa/pae/News/Pr/2005/jul/CMMC.html (describing hospital’s agreement to hire a consultant to review the facility’s use of restraints).

¹¹⁹ *See* MEDICARE PAYMENT ADVISORY COMM’N, A DATA BOOK: HEALTHCARE SPENDING AND THE MEDICARE PROGRAM 59 (2003), *available at* http://www.medpac.gov/publications/congressional_reports/Jun03DataBook_Entire_report_links.pdf (projecting that Part A Trust Fund will become insolvent in 2026, and costs may exceed tax revenues as soon as 2013).

¹²⁰ 42 U.S.C. § 1395w-4(g)(2)(C) (2000) (defining the “limiting charge”).

the Secretary of HHS is authorized to use a portion of the funds collected in the proceeding to “make a payment to a beneficiary . . . in the nature of restitution for amounts paid by such beneficiary” that were found to be excessive.¹²¹

In criminal prosecutions under the health care fraud, mail fraud, and wire fraud statutes, even broader authority supports compensation.¹²² Under Title 18 of the United States Code, restitution is a mandatory component of sentencing for “offense against property” and in cases “in which an identifiable victim or victims has suffered a physical injury or pecuniary loss.”¹²³ In prosecutions under the Anti-Kickback Statute¹²⁴ and other health care fraud offenses found in Title 42 of the United States Code, restitution may be ordered as a part of a plea bargain or as a condition of probation or supervised release.¹²⁵ The expenses subject to restitution are defined broadly to include not only financial losses but also the costs of necessary medical care, including psychiatric, psychological, and certain “nonmedical care and treatment.”¹²⁶ To the extent they remain applicable, the federal Sentencing Guidelines also permit an increase in offense level (and hence a more severe sentence) if the crime involves a vulnerable victim, the abuse of a position of trust, or the use of a special skill, as well as upward departures in sentences for crimes resulting in death, physical

¹²¹ *Id.* § 1395u(j)(4). The portion of FCA recoveries awarded for restitution is exempt from allocation to the Trust Fund, thus preventing a direct conflict between the needs of victims and the financial goals of federal prosecutors. *See id.* § 1395i(k)(2)(C)(iv) (exempting restitution amounts from transfer to the Control Account).

¹²² *See* 18 U.S.C. §§ 1341, 1343, 1346-47 (2000) (defining mail, wire, and health care fraud).

¹²³ *Id.* § 3663A(c)(1)(A)(ii), (B) (listing crimes for which restitution must be ordered); U.S.S.G. § 5E1.1 (2005) (providing for restitution under the federal Sentencing Guidelines); *see also id.* § 8B1.1 (restitution for corporate defendants). Mandatory restitution does not apply to offenses against property, however, if

the number of victims is so large as to make restitution impracticable; or determining complex issues of fact related to the cause or amount of the victim’s losses would complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

18 U.S.C. § 3663A(c)(3); *see also* U.S.S.G. § 5E1.1(B)(2).

¹²⁴ 42 U.S.C. § 1320a-7b(b).

¹²⁵ *See* 18 U.S.C. § 3556 (order of restitution); *id.* § 3563 (conditions of probation); *id.* § 3583 (conditions of supervised release after imprisonment); *id.* § 3663 (discretionary restitution authority).

¹²⁶ *Id.* § 3663(b)(2)(A). For certain drug offenses in which there is no identifiable victim, restitution “based on the amount of public harm caused by the offense” is paid to the state agencies that administer crime victim assistance and federal substance abuse block grants. *Id.* § 3663(c); U.S.S.G. § 5E1.1(d).

injury, or extreme psychological injury.¹²⁷ Thus, in criminal health care fraud cases, restitution likely will be an available remedy. Unfortunately, many health care fraud cases involve civil and administrative causes of action that do not independently provide for restitution. As a result, most health care fraud recoveries are destined for the Trust Fund and Control Account, rather than for the individual patient victims.

C. WHITE COLLAR CRIME AND RECOGNITION OF PATIENT HARM

The lack of emphasis on patient harm, especially non-financial harm, is also related to the white collar crime context in which health care fraud is prosecuted. The DOJ has defined white collar crime as

[n]onviolent crime for financial gain committed by means of deception by persons whose occupational status is entrepreneurial, professional or semi-professional and utilizing their special occupational skills and opportunities; also, nonviolent crime for financial gain utilizing deception and committed by anyone having special technical and professional knowledge of business and government, irrespective of the person's occupation.¹²⁸

This definition limits both the universe of individuals who will be subject to prosecution and the actionable forms of harm. Health care fraud fits this definition because the goal of the fraud is to obtain unlawful financial gain by means of deception, and because such fraud is accomplished by persons who utilize their specialized status, training, and knowledge of health care and the relevant reimbursement rules.¹²⁹ The fit is an imperfect one, however, as the definition does not encompass the full range of consequences from fraudulent activities, particularly to patients. The emphasis on the financial goals of the scheme, in particular, suggests not only that other forms of injury (physical and intangible) are irrelevant¹³⁰ but also that the focus is on the primary victim—in this case the federal health care programs. Under such a calculus, there is little incentive to

¹²⁷ See U.S.S.G. §§ 3A1.1, 3B1.3, 5K2.1-2.3; *United States v. Booker*, 543 U.S. 220 (2005) (overturning mandatory nature of Federal Sentencing Guidelines).

¹²⁸ Strader, *supra* note 7, at 1207-08 (quoting U.S. DEP'T OF JUSTICE, BUREAU OF JUSTICE STATISTICS: DICTIONARY OF CRIMINAL JUSTICE DATA TERMINOLOGY 215 (2d ed. 1981)).

¹²⁹ See also Bucy, *Fraud by Fright*, *supra* note 10, at 870-71 (noting, "Fraud by health care providers shares three essential features of all white collar offenses: first, it has a hybrid criminal/civil nature; second, it is difficult to investigate and prove; and third, successful prosecution necessitates a careful development of a theory of the case that accomplishes certain goals").

¹³⁰ See Jennifer S. Recine, Note, *Examination of the White Collar Crime Penalty Enhancements in the Sarbanes-Oxley Act*, 39 AM. CRIM. L. REV. 1535, 1559-60 (2002) (noting that "optimal penalty theorists," such as Richard Posner, suggest that "white-collar criminals do not pose a threat of physical harm to the public") (citing Richard A. Posner, *Optimal Sentences for White-Collar Criminals*, 17 AM. CRIM. L. REV. 409, 409-10 (1980)).

characterize cases in a patient-focused way, and little urgency to seek compensation for individual patients with small-dollar (let alone intangible) injuries. In the words of one former prosecutor, “[b]ecause the legal theories historically used to prosecute health care providers have failed to identify the patients as fraud victims, the powerful evidence that a provider delivered poor medical care has seldom been used to its maximum advantage.”¹³¹

Despite the emphasis on financial gain, it has been recognized “that white-collar crimes, particularly corporate crime, may have violent consequences.”¹³² This is perhaps acknowledged most clearly for environmental crimes, which have the potential to cause harm to large numbers of people.¹³³ While recognition that financially motivated crimes may have physical consequences is a welcome step, it still does not capture the essence of the problem in the health care context. Due to the underlying medical nature of the activities, the potential for physical harm is in many ways a defining characteristic of health care fraud.¹³⁴ The fact that the misuse of individual patient information is not merely a foreseeable consequence of the scheme but is in many ways a *precondition* to its success makes health care fraud very different from other crimes in which unknown individuals may, at some future point, suffer harm from causes such as environmental toxins, workplace hazards, or substandard products. Where the success of the fraud is linked so closely to the perpetrator’s ability to affect an individual patient’s medical care, or at the very least to utilize individual patient information, it is troubling that this harm remains

¹³¹ Bucy, *Fraud by Fright*, *supra* note 10, at 928. As a practical matter, however, a patient-centered focus might offer distinct prosecutorial advantages. *See id.* (noting that “[a] prosecutor able to identify a patient as a victim of the fraud will present a more complete picture of the scope of the provider’s fraud and thus will have a stronger case”).

¹³² Elizabeth Szockyj, *Imprisoning White-Collar Criminals?*, 23 S. ILL. U. L.J. 485, 487 (1999) (noting that physical costs of white collar crimes include “[p]ersonal injuries, diseases, and death due to occupational workplace hazards, environmental pollution, and the marketing of dangerous products”). Some theorists clarify that white collar crime is crime committed by non-violent *means*, although it may have violent *effects*. *See, e.g.*, Gilbert Geis, *White-Collar Crime – What Is It?*, in *WHITE-COLLAR CRIME RECONSIDERED* 31, 39 (Kip Schlegel & David Weisburd eds., 1992) (describing American Bar Association definition of “economic” crime).

¹³³ *See, e.g.*, 42 U.S.C. § 6928(e) (2000) (specifying penalties for persons who knowingly endanger others by their handling of hazardous waste); Neal Shover & Aaron S. Routhe, *Environmental Crime*, 32 CRIME & JUST. 321, 322, 329-30 (2005) (noting “the financial and human costs of environmental crime,” as well as the difficulty of ascertaining a dollar value for harm to non-human victims); Szockyi, *supra* note 132, at 487 (providing examples of environmental harms).

¹³⁴ *See* Bucy, *Crimes by Health Care Providers*, *supra* note 44, at 660 (“Health care fraud is unique among white collar crimes in its ability to cause physical harm.”).

undervalued. For that reason, alternate recovery mechanisms may need to be drawn from sources outside the white collar crime enforcement framework.

III. DEVELOPING A PATIENT-CENTERED APPROACH TO FRAUD RECOVERY

The fact that compensation of patient injuries has not been a key component of fraud recoveries to date does not mean that such an approach is infeasible. Even within the limits imposed by HIPAA, alternative settlements may be possible. When these tactics are combined with approaches taken in other contexts, such as consumer class actions—particularly given the flexibility traditionally accorded to state governments in crafting compensation for injured individuals—there appears to be ample leeway to structure settlements that more directly benefit patients without significantly reducing the federal share of recovery.

A. RECENT FEDERAL SETTLEMENTS

On occasion, federal prosecutors have undertaken direct efforts to return money to individual victims of health care fraud. Among the most prominent examples was the “72-Hour Window Project,” a national investigation of hospitals that submitted separate Medicare bills for outpatient services (usually laboratory tests) provided within 72 hours of a related inpatient admission—services that, by law, are included in the lump-sum hospital inpatient payment.¹³⁵ As a result, patients were charged copayments for the additional outpatient services, rather than only their share of the inpatient costs. The settlements required the hospitals to reimburse patients for the improperly collected amounts.¹³⁶ Restitution appears to have been feasible due to the limited universe of claims for which each hospital was audited, making it possible to identify both the patient victims and the amounts by which they were overcharged.

Even where the victim population is significantly larger, federal prosecutors may have some ability to craft patient-centered settlements. For example, the Civil Injunction Statute, which permits the Attorney General to commence a civil action to enjoin a defendant from committing

¹³⁵ See 42 C.F.R. § 412.2(c)(5) (2005) (defining certain preadmission services as included in inpatient prospective payment); U.S. GEN. ACCOUNTING OFFICE, *MEDICARE: APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES* 3 (1998) [hereinafter *GAO, MEDICARE*] (describing project).

¹³⁶ See, e.g., *GAO, MEDICARE, supra* note 135, at 9 (describing settlements); Settlement Agreement ¶ 10, *United States v. Miss. Baptist Med. Ctr.* (Oct. 10, 1999), cited in *COMPLIANCE REP. (CCH)* ¶ 130,318 (requiring hospital to refund copayments and deductibles to patients).

a health care offense, authorizes the court to “take such . . . action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought.”¹³⁷ Federal prosecutors have suggested that this statute provides the basis for broad remedies in health care fraud cases, which could include some form of restitution.¹³⁸ Perhaps the most prominent public use of this tactic to date has been in *United States v. Merck-Medco Managed Care*, in which the government sought an injunction against fraudulent activities by a mail order pharmacy company that included “shorting” prescriptions by delivering too few pills and “switching” patients to alternate drugs for which the company received financial benefits (including alternate drugs manufactured by its parent company, Merck).¹³⁹ As part of the federal Consent Order, Medco was required to reimburse patients for all out-of-pocket costs for health care services incurred in connection with the unauthorized switches.¹⁴⁰

Similar flexibility may be afforded by 18 U.S.C. § 3573, which permits the government to petition for a remission of a criminal fine under certain circumstances.¹⁴¹ In October 2003, for example, United Memorial Healthcare Association (“UMH”) pleaded guilty to one count of mail fraud in connection with an investigation of a physician who was convicted of performing medically unnecessary procedures at a UMH pain clinic.¹⁴² In an interesting procedural turn, the plea was deferred by the presiding judge, which enabled the government to petition for remission of the fine. Using the flexibility afforded by the remissions statute, the U.S. Attorney’s Office agreed to match up to \$500,000 of the criminal fine, with the money designated for a specific patient-directed purpose: funding a program sponsored by UMH’s new owner to provide health care and health education services to disadvantaged individuals in the hospital’s service

¹³⁷ 18 U.S.C. § 1345 (2000).

¹³⁸ Conversation with James G. Sheehan, Associate U.S. Attorney, E. Dist. of Pa., in Wilmington, Del. (June 6, 2003); see, e.g., Entry of Consent Decree at *1, *United States v. Corson*, No. 93-CV-3637, 1993 WL 332268 (E.D. Pa. July 12, 1993) (requiring physician, under 18 U.S.C. § 1345, to reimburse Medicare beneficiaries who were overcharged for his services).

¹³⁹ See Amended Complaint, *United States v. Merck-Medco Managed Care*, No. 00-737 (E.D. Pa. Dec. 9, 2003); Consent Order for Permanent Injunction, *United States v. Merck-Medco Managed Care*, No. 00-737, 2004 WL 977210 (E.D. Pa. 2004).

¹⁴⁰ Consent Order, *Merck-Medco Managed Care*, 2004 WL 977210, at *7.

¹⁴¹ 18 U.S.C. § 3573 (permitting judge to modify or remit an unpaid fine or assessment); Telephone Interview with Glenn Martin, Assistant U.S. Attorney, Western District of Michigan (Nov. 6, 2003).

¹⁴² Press Release, W. Dist. of Mich. Dep’t of Justice, Matching Fund Program to Provide Indigent Medical Care (Oct. 6, 2003) (attaching Matching Fund Agreement).

area.¹⁴³ The agreement essentially allowed UMH to pay only half the fine, but directed those funds (plus an equal amount of government funds) specifically to improve the health of indigent people in the population. While this strategy did not attempt to compensate any of the individual patients who were harmed by the unnecessary procedures, it did accomplish an important health-related goal by extending health care services to a disadvantaged local community. However, it is clear that devising such an alternative path for the funds required extreme procedural steps, as well as the cooperation of both prosecutors and the presiding judge. While intriguing, these examples may not provide an adequate model for large-scale alternative settlements.

B. LESSONS FROM CONSUMER PROTECTION

The limited options available to federal prosecutors stand in stark contrast to the broad consumer protection remedies available to state attorneys general, who have been able to craft innovative health care fraud settlements that target—at times with near poetic elegance—the disadvantaged patient populations. For example, in settlements with drug and medical device manufacturers accused of illegally excluding Medicare and Medicaid patients from their marketing promotions (usually in an attempt to avoid liability under the Anti-Kickback Statute), the Massachusetts Attorney General has required the defendant companies to donate free products to indigent patients in the state.¹⁴⁴ In Utah, a pediatrician accused of charging private insurers for vaccines that were supposed to have been given away to indigent children paid \$64,000 to settle the claims, with the money earmarked for a vaccination program

¹⁴³ *Id.* (citing the Matching Fund Agreement ¶ 6).

¹⁴⁴ *See, e.g.*, Press Release, Commonwealth of Mass. Office of the Attorney Gen., N.J. Pharmaceutical Corporation Settles with Attorney General: 21,000 Nitroglycerin Patches to be Distributed Free to Public (May 21, 1995) (on file with author) (describing settlement with Schering Corporation, which agreed to distribute free Nitro-Dur patches to state public hospitals); Press Release, Novo Nordisk, Novo Nordisk and Massachusetts Extend NovoPen 1.5 Delivery System Promotion to Medicaid Patients (Mar. 19, 1997) (on file with author) (announcing company's agreement to provide hundreds of free insulin delivery systems to indigent and Medicaid patients at certain hospitals in the state); *see also* Press Release, Attorney Gen. Bob Butterworth, Humana Medical Plan to Refund \$800,000 to Settle Allegations (Feb. 16, 2000) (requiring Medicare HMO to refund money to beneficiaries who were overcharged for hearing aids), available at <http://myfloridalegal.com/newsrel.nsf/newsreleases/AAECA64080033E5085256887004AC291?OpenDocument> (last visited Apr. 3, 2006).

administered by the state.¹⁴⁵ In Connecticut, drug manufacturer Dey Inc. settled pricing fraud allegations, in part, by donating \$800,000 of its respiratory drugs to community health centers and other free clinics in the state.¹⁴⁶ Such settlements clearly confer a financial benefit on the state and local governments, which otherwise would be required to purchase similar items for publicly funded hospitals and health care programs. But more importantly, these settlements impose sanctions that are tailored to the underlying harm, making the previously denied products available to a disadvantaged population within the state. This more holistic approach to remedying the effects of fraud confers an advantage on those who were disadvantaged—if not the exact victims, then at least patients who are similarly situated.

While some of these settlements may hinge on specific state anti-fraud laws, conceptually they are drawn from a rich history of consumer protection lawsuits, especially class actions. Indeed, many of the factors that have driven the development of these doctrines pose equally vexing problems in health care fraud cases. In the antitrust and consumer protection arenas, for example, it has been possible to devise workable remedies in cases involving large numbers of potential victims, even where it is difficult to identify all injuries and where individual recoveries are likely to be small.¹⁴⁷ In such cases, commentators have argued in favor of more “fluid” forms of recovery that can meet the twin goals of benefiting injured consumers and forcing the wrongdoer to disgorge its ill-gotten gains¹⁴⁸—goals that resonate with equal urgency in the health care fraud context.

¹⁴⁵ Press Release, Utah Attorney Gen. Mark Shurtleff, Doctor Pays Up for Selling Free Vaccine (Oct. 21, 2005), available at <http://attorneygeneral.utah.gov/PrRel/proctoer212005.htm>.

¹⁴⁶ *Dey Inc. Settles Overcharge Case Filed by Connecticut AG, Will Pay \$1.7M*, 9 HEALTH CARE FRAUD REP. (BNA) 614 (2005).

¹⁴⁷ See Gail Hillebrand & Daniel Torrence, *Claims Procedures in Large Consumer Class Actions and Equitable Distribution of Benefits*, 28 SANTA CLARA L. REV. 747, 750 (1988) (noting that “[a] hallmark of the consumer class action is large class size and relatively small damages per class member”). Note that the feasibility of such actions in the future will be affected by the Class Action Fairness Act of 2005, which addresses not only the jurisdictions in which such suits may be brought but also the structure of non-monetary remedies, particularly coupons. Pub. L. No. 109-2, 119 Stat. 4 (2005).

¹⁴⁸ See, e.g., Hillebrand & Torrence, *supra* note 147, at 762-63 (noting that fluid recovery assures the disgorgement of illegal profits and “ensure[s] that the class will in fact receive benefits, whether direct or indirect, of some minimum amount”); Michael Malina, *Fluid Class Recovery as a Consumer Remedy in Antitrust Cases*, 47 N.Y.U. L. REV. 477 (1972) (describing fluid distribution of remainder after compensation of direct claims of harm in antitrust suit); James R. McCall et al., *Greater Representation for California Consumers—Fluid Recovery, Consumer Trust Funds, and Representative Actions*, 46

Although fluid recovery may include mechanisms such as coupons, price rollbacks, or medical monitoring, the more relevant approaches for our purposes require deposit of all or part of the recovered money into a designated fund—accomplished, for example, by escheat to a general or specific state account, or by the establishment of a new consumer fund.¹⁴⁹ This is most often accomplished through application of the equitable doctrine of *cy pres*, in which settlement funds that cannot be delivered directly to injured individuals are instead used for their “next best use” by distributing them more generally, as through a consumer trust fund, to subsidize related consumer protection efforts.¹⁵⁰ Such funds “can be structured to serve the purposes of the underlying litigation The benefit takes the form of increased services to, or protection of rights of the entire class, which is preferable to limiting benefits only to those who successfully complete a claim.”¹⁵¹ The doctrine is most attractive in cases where:

- (1) the class of consumers represented is large and practically unidentifiable; (2) the individual damage suffered by each consumer is relatively small; (3) there are no creative alternatives to provide value directly to consumers; and (4) the recipients who will most likely benefit, albeit indirectly, are the consumers in whose name the original action is brought.¹⁵²

HASTINGS L.J. 797, 807-12 (1995) (describing fluid forms of recovery in consumer class actions); Miller & Singer, *supra* note 116, at 102-07 (dividing “nonpecuniary settlements” into coupon settlements, monitoring settlements, securities settlements, reverter fund settlements that return excess funds to the defendant, and fluid recovery settlements); Anna A. Durand, Note, *An Economic Analysis of Fluid Class Recovery Mechanisms*, 34 STAN. L. REV. 173 (1982) (arguing in favor of nonprice fluid recovery mechanisms). One impediment to the application of these principles in the health care fraud context may be the necessity that each class member suffer similar harm. See Malina, *supra*, at 488 (requiring that damage be “identical, if not in dollar amount, then in common percentage or like measure”).

¹⁴⁹ See, e.g., McCall et al., *supra* note 148, at 808-10 (describing fluid recovery mechanisms of price rollback, general escheat, earmarked escheat, and the establishment of a trust fund). Under this framework, note that the current HIPAA Control Account mechanism resembles a federal form of earmarked escheat.

¹⁵⁰ Historically, the doctrine of *cy pres* permitted a court to avoid invalidation of a charitable trust when the testator’s conditions could not be satisfied. As the California Supreme Court explained, “[w]here compliance with the literal terms of a charitable trust became impossible, the funds would be put to ‘the next best use,’ in accord with the dominant charitable purposes of the donor.” *California v. Levi Strauss & Co.*, 715 P.2d 564, 570 (Cal. 1986). For a discussion of the *cy pres* doctrine in the antitrust and consumer protection contexts, see, for example, Susan Beth Farmer, *More Lessons from the Laboratories: Cy Pres Distributions in Parens Patriae Antitrust Actions Brought By State Attorneys General*, 68 FORD. L. REV. 361 (1999).

¹⁵¹ Hillebrand & Torrence, *supra* note 147, at 766.

¹⁵² Farmer, *supra* note 150, at 365 (setting forth factors relevant to *cy pres* remedies in *parens patriae* antitrust actions).

While the *cy pres* approach initially contemplated disbursement for a purpose closely related to the origin of the funds, courts have recognized that the modern doctrine “permit[s] use of funds for other public interest purposes by educational, charitable, and other public service organizations” more tangentially related to the original harm.¹⁵³

One of the key questions is whether this mechanism can be used to distribute an entire award, or whether it is limited to disposing of the remainder once the claims of identified class members have been satisfied. The latter use appears to be more common, as it prevents the non-compensatory (and potentially anti-deterrent) effects of returning the remaining funds to the defendant or having them escheat to a general state fund.¹⁵⁴ In a class action suit against Toshiba for the sale of allegedly defective computers, for example, the court ordered that funds remaining after all individual claims were exhausted be distributed to a charity, which in turn would use the funds to purchase computers for distribution to “schools, churches, non-profit organizations, libraries, hospitals, and the poor.”¹⁵⁵ Thus, even if full compensation is not available, *cy pres* makes it

¹⁵³ *Superior Beverage Co. Inc. v. Owens-Illinois, Inc.*, 827 F. Supp. 477, 479 (N.D. Ill. 1993).

¹⁵⁴ See Hillebrand & Torrence, *supra* note 147, at 762 (noting that “[f]luid recovery is generally used to distribute the residue of a fund created by settlement or judgment when the claims rate is less than 100%”); McCall et al., *supra* note 148, at 850-51 (calling on plaintiffs’ counsel to recommend fluid recovery for the undistributed portion of an award to “ensure that the funds will be used either to promote the purposes of the statutory prohibitions to be enforced or to protect the interests of the persons injured by the illegal conduct”).

¹⁵⁵ *Shaw v. Toshiba Amer. Info. Sys., Inc.*, 91 F. Supp. 2d 942, 981 (E.D. Tex. 2000); see also Patricia Studevant, *Using the Cy Pres Doctrine to Fund Consumer Advocacy*, TRIAL, Nov. 1997, at 80 (advocating use of *cy pres* distribution to fund advocacy efforts). A similar approach may be used for punitive damages in states with split-recovery statutes directing a portion of such damages to victim compensation funds. See *DeMendoza v. Huffman*, 51 P.3d 1232 (Or. 2002) (upholding Oregon Revised Statute § 18.540, which allocates 60% of punitive damage awards to the Criminal Injuries Compensation Account). The success of these statutes has spurred proposals for broader use of the mechanism for “a societal compensation goal: the redress of harm caused by defendants who injure persons beyond the individual plaintiffs in a particular case.” Catherine M. Sharkey, *Punitive Damages as Societal Damages*, 113 YALE L.J. 347, 351-52 (2003) (suggesting that the Supreme Court’s recent decision overturning a massive punitive damages award in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), may have unwittingly authorized this alternative). Such goals would be achieved, for example, by the statutory allocation of a portion of the punitive damage award to state funds created to address the type of harm caused by the defendant’s activities, or to nonprofit organizations pursuing similar goals. *Id.* at 420-21; Dede W. Welles, *Charitable Punishment: A Proposal to Award Punitive Damages to Nonprofit Organizations*, 9 STAN. L. & POL’Y REV. 203, 205, 210 (1998) (arguing in favor of funding targeted activities that are likely to benefit victims, rather than society more generally).

possible to achieve some measure of rough justice. Disbursing an entire settlement via a *cy pres* mechanism, however, has proven to be more controversial. As one commentator notes, “unless the costs of distribution are overly burdensome, it is preferable to distribute settlement funds directly to consumers rather than to put the entire fund to a related use that will only indirectly benefit those who were injured by the violation alleged.”¹⁵⁶ As such, this option has been reserved for cases in which the compensation of individual class members appears to be unrealistic due to the size of the class and the small amount of each award.¹⁵⁷

Despite these uncertainties, it is intriguing to consider whether this approach might be applied to health care fraud recoveries. The mechanism would appear particularly well-suited to situations in which the harm suffered by patients is diffuse and intangible, rather than discrete and of a serious nature. Of course, there are significant differences between consumer protection and antitrust suits and health care fraud enforcement actions (not the least of which is the lack of an enabling statute permitting the use of such remedies).¹⁵⁸ Nonetheless, to the extent these disbursement options represent the “next best use” of settlement funds by advancing both consumer protection and deterrence goals, they address many of the same issues seen in health care fraud cases and might provide a fruitful avenue for future patient compensation efforts.

C. PATIENT-CENTERED STRATEGIES FOR HEALTH CARE FRAUD RECOVERY

The state and federal governments already have begun to work together to apply these strategies in health care fraud cases. In the Merck-Medco litigation described above, for example, Medco negotiated a separate consent order with the Attorneys General of twenty states pursuant

¹⁵⁶ Farmer, *supra* note 150, at 394.

¹⁵⁷ See, e.g., *New York v. Reebok Int'l Ltd.*, 96 F.3d 44, 49 (2d Cir. 1996) (approving broader distribution “[b]ecause of the unlikelihood of there being any significant ‘net monetary relief’ for individual claimants if an attempt were made to distribute the settlement proceeds among them,” due to the large number of claimants and the minimal injury suffered per shoe purchase).

¹⁵⁸ Another key difference is the government’s role. In consumer protection or *parens patriae* antitrust actions, for example, the states sue on behalf of their injured citizens. See 15 U.S.C. § 15c (2000) (permitting *parens patriae* suits under the federal antitrust statutes); Richard P. Ieyoub & Theodore Eisenberg, *State Attorney General Actions, The Tobacco Litigation, and the Doctrine of Parens Patriae*, 74 TUL. L. REV. 1859, 1863 (2000) (noting that in “*parens patriae* actions . . . a state may recover costs or damages incurred because of behavior that threatens the health, safety, and welfare of the state’s citizenry”). In contrast, many health care fraud cases are brought on the government’s own behalf as a defrauded payer. See *supra* notes 112-16 and accompanying text.

to which the company additionally agreed to pay: (1) \$6.6 million, to be used for “attorney’s fees and investigative costs, consumer education, litigation, public protection purposes or local consumer aid funds;”¹⁵⁹ (2) \$2.5 million, to reimburse consumers up to \$25 each for expenses incurred in connection with a particular cholesterol drug switch scheme;¹⁶⁰ and (3) \$20 million, for the affected states to distribute via a *cy pres* mechanism to state agencies or programs, nonprofit corporations, or charitable organizations “to benefit low income, disabled, or elderly consumers of prescription medications, to promote lower drug costs for residents of that State, to educate consumers concerning the cost differences among medications, or to fund other programs reasonably targeted to benefit a substantial number of persons affected by the” conduct at issue.¹⁶¹

A similar approach was taken against pharmaceutical manufacturer Warner-Lambert, which was accused of extensive civil and criminal conduct in connection with the marketing of its drug Neurontin.¹⁶² The company pled guilty to two counts of violating the federal Food, Drug & Cosmetic Act by “misbranding” the drug and agreed to a \$240 million criminal fine, as well as a civil FCA fine of \$83.6 million for the federal portion of relevant Medicaid losses.¹⁶³ In a separate settlement with the states, the company also agreed to pay \$68.4 million plus interest for losses caused to the state Medicaid programs, as well as \$38 million to fund a consumer protection program to remedy the harm caused by the improper marketing efforts.¹⁶⁴ Under the terms of the state settlement, \$6 million of the consumer fund was earmarked for the development of a National Advertising Program to provide information to prescribers regarding the appropriate use of Neurontin and similar drugs, and \$21 million was designated for grants to “national programs, regional programs, or programs in individual states or in a group of states, relating to prescriber and

¹⁵⁹ Consent Order at 24, *State v. Medco Health Solutions, Inc.*, No. CV-04 (Me. Super. Ct. Apr. 26, 2004) (on file with author).

¹⁶⁰ *Id.* at 18-19.

¹⁶¹ *Id.* at 21. As an alternative to a monetary payment, states were permitted to receive pharmaceuticals (of equivalent value plus 25%) from Medco in bulk and/or via the provision of prepaid generic drug cards. *Id.* at 22-23.

¹⁶² 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/usao/ma/presspage/May2004/Warner-Lambert-globalsettlemnt.htm.

¹⁶³ *Id.* (noting that the violation was a felony due to the company’s prior, unrelated FDCA convictions); Food, Drug & Cosmetic Act, 21 U.S.C. § 301 (2000).

¹⁶⁴ *In re Warner-Lambert Company LLC, Assurance of Voluntary Compliance*, available at http://209.190.248.167/upload/1084551748_Assurance_of_Voluntary_Compliance.pdf (last visited Dec. 23, 2005).

consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed.”¹⁶⁵ The government’s sentencing memorandum noted the unique nature of this remedy, stating “the proposed resolution does include a significant state consumer protection component, which has not routinely been part of prior health care fraud settlements arising out of federal Department of Justice investigations.”¹⁶⁶

Several things are notable about these recent efforts. First, the fact that they arose in the pharmaceutical context was not a coincidence. Not only is the pharmaceutical industry under intense scrutiny regarding drug pricing and promotional activities,¹⁶⁷ but the fraud alleged in these cases contributed to the types of patient harm most easily addressed via a *cy pres* mechanism: widespread, often intangible harm to a diffuse population of patients whose care may have been affected (coupled, in the Merck-Medco litigation, with discrete financial harm to a large but identifiable subpopulation). Given the huge nationwide market for prescription drugs, the direct financial impact of pricing fraud on patients, and the potential for significant consumer confusion from improper marketing campaigns, this is a particularly attractive context in which to test a *cy pres* remedy. Second, it is notable that neither the federal nor state governments were able to achieve these settlements alone; only by banding together were prosecutors able to combine the flexibility of state consumer protection efforts with the threat of severe federal sanctions for fraud. In accordance with HIPAA, no portion of the *federal* recovery was diverted to compensate patients—Medco agreed to an injunction against the disputed conduct, and Warner-Lambert paid a hefty fine in direct settlement of the federal civil and criminal fraud allegations. Without the participation of the states, therefore, significantly less money would have been directed toward patients. While the results were extremely favorable for consumers, they appear to be feasible only in fraud investigations that similarly merit extensive joint enforcement efforts.

¹⁶⁵ *Id.*

¹⁶⁶ Sentencing Memorandum of the United States at 43 n.10, *United States v. Warner-Lambert Company LLC*, No. 04-10150 RGS (D. Mass. May 13, 2004) (on file with author).

¹⁶⁷ *See, e.g., In re Pharma. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005) (resolving class certification issues in suit brought by consumers and third-party payers against pharmaceutical companies). Moreover, with the advent of the new Medicare Prescription Drug Benefit in January 2006, the federal government has an even stronger interest in prescription drug fraud. *See* 42 U.S.C. § 1395w-101 (2000 & Supp. 2005); *Enforcement Officials Detail New Weapons, Concerns Posed by New Medicare Rx Benefit*, 14 HEALTH L. RPTR. (BNA) 947 (2005) (describing heightened opportunities for fraud in new program, as well as new enforcement plans).

Whether these strategies can be applied more broadly remains to be seen. Current class action and consumer protection mechanisms may well be sufficient for situations in which discrete harm is suffered by an identifiable population of patients, such as harm arising from prescription drug price manipulation.¹⁶⁸ In such cases it may well be more efficient to leave the existing procedures in place, rather than create an additional level of federal bureaucracy. In other situations, however, the harm to patients may be so diffuse or intangible that broader fluid recovery will be superior to traditional class action mechanisms. For example, one of the allegations in the Warner-Lambert litigation was that the company marketed Neurontin “off-label,” for conditions for which the drug had not been approved by the Food and Drug Administration (and, in fact, for one condition for which approval explicitly had been denied).¹⁶⁹ Because the off-label restrictions limit only the manufacturer’s *promotion* of the drug, rather than a physician’s *use* of the drug, physicians generally may prescribe an approved drug for any condition, even an unapproved one.¹⁷⁰ Compared to pricing fraud, where it safely can be assumed that any consumer who paid above a certain price for the drug was harmed, identifying the victims of an off-label promotional scheme is much more difficult. In the Warner-Lambert case, this would not simply have required the identification of all patients who received Neurontin, but rather the identification of those patients who were prescribed the drug for an off-label purpose (which likely would require review of individual medical records)—as well as consideration of the perhaps unanswerable question of whether the prescribing physician was influenced by Warner-Lambert’s marketing efforts or would have prescribed the drug off-label anyway in his/her independent medical judgment. Given this daunting prospect, it is no wonder that a broader consumer fund approach was considered to be appropriate.

Moreover, it is possible that federal health care program beneficiaries are harmed in unique ways by health care fraud. Because many beneficiaries live on fixed incomes, fraud schemes that overcharge for health care items and services may have particularly detrimental effects.¹⁷¹

¹⁶⁸ See, e.g., *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 516 (E.D. Mich. 2003) (describing plan for compensating consumers who overpaid for a drug due to illegal anti-competitive agreements by manufacturers to keep cheaper generic versions of the drug off the market).

¹⁶⁹ See Sentencing Memorandum, *supra* note 166, at 10, 13-26 (documenting centralized decisions to engage in off-label marketing, as well as failed attempt to gain approval for the use of Neurontin as solo therapy for epilepsy).

¹⁷⁰ *Id.* at 10.

¹⁷¹ Anecdotes abound about the difficulties of paying for medical care in addition to other necessities. See, e.g., Roger Alford, *More Seniors Jailed for Prescription Drug Sales*,

Similarly, medically frail beneficiaries may be at greater risk of harm from fraudulent schemes with physical effects, such as those involving unnecessary diagnostic tests.¹⁷² Indeed, there may even be a unique, intangible injury that arises from being targeted solely due to one's status as a federal health care program beneficiary. While a discussion of these subjects is beyond the scope of this Article, it is worth noting that beneficiaries may not fully be compensated even by traditional consumer remedies.

How might beneficiary harm be addressed? At a minimum, direct compensation should be available for patients who have suffered identifiable harm. While Congress would need to enact a federal mechanism for this purpose, a similar result may be achieved currently through global resolutions that incorporate state-based consumer compensation mechanisms, as in the Merck-Medco case. But what of less tangible, or at least less demonstrable, forms of harm? Certainly, devoting money to the education of vulnerable beneficiaries is a good investment, but it may not be enough. An alternative might be to create a modified form of consumer fund tailored to the unique types of injuries experienced by federal health care program beneficiaries. Although beneficiaries who suffer physical harm due to fraud schemes are fortunate in that they have access to health care through the relevant federal health care programs, they are likely to face new financial burdens in the form of additional copayments and deductibles—not to mention the possibility of exceeding their coverage limits, either due to actual medical needs or as an effect of the fraudulent bills submitted in their names.¹⁷³ A Beneficiary Copayment Fund, for example, might be set aside for the payment of such expenses for patients who can meet defined eligibility criteria.¹⁷⁴ Because it would be

HOUSTON CHRON., Dec. 12, 1995, at A39 (describing increases in arrests of Appalachian senior citizens for selling their prescription drugs). As one law enforcement official noted, "When a person is on Social Security, drawing \$500 a month, and they can sell their pain pills for \$10 apiece, they'll take half of them for themselves and sell the other half to pay their electric bills or buy groceries." *Id.* (quoting Floyd County jailer Roger Webb).

¹⁷² See, e.g., *United States ex rel. Kneepkins v. Gambro Healthcare Inc.*, 115 F. Supp. 2d 35, 42 (D. Mass. 2000) (alleging performance of unnecessary blood tests).

¹⁷³ See *supra* notes 69-72 and accompanying text.

¹⁷⁴ Although beyond the scope of this Article, such a process could be modeled on that used to disburse awards in mass products liability claims involving bankrupt corporations. See, e.g., SETTLEMENT FACILITY AND FUND DISTRIBUTION AGREEMENT BETWEEN DOW CORNING CORPORATION AND THE CLAIMANTS' ADVISORY COMMITTEE 1 (2004), available at http://www.tortcomm.org/downloads/SETTLEMENT_FACILITY_AGMT.pdf (last visited Feb. 26, 2006) (setting forth breast implant claims settlement criteria and procedures). In the health care fraud context, the criteria could be tailored so as to restrict the universe of

unclear initially how many beneficiaries would incur such future liability, this mechanism would perhaps most closely resemble the use of medical monitoring funds in mass tort actions in which exposure to a toxic substance may have increased the risk of future harm to an identifiable population.¹⁷⁵ Although the details of such a “fraud monitoring” fund are beyond the scope of this Article, the mechanisms likely would be drawn from an amalgam of existing consumer protection and mass tort litigation strategies.

Clearly, congressional action would be necessary if the money for such a fund came from the federal government’s share of fraud recovery, since the disposition of that money is tightly controlled by HIPAA. If federal prosecutors were so inclined, however, they might be able to test this strategy in individual cases through some of the mechanisms identified above, such as the § 1345 civil injunction statute or the § 3573 remissions provisions. In the alternative, creation of such a fund might be demanded—or at least strongly encouraged—as an additional state or private mechanism outside the official federal settlement process. However accomplished, the use of a Beneficiary Copayment Fund mechanism on an experimental basis is an option that should be considered.

IV. CONCLUSION

How can we make health care fraud recovery more patient-centered? Amendments to current federal law, to permit either direct compensation of injured patients or a broader co-payment fund, would most efficiently achieve this goal. In the absence of such legislative changes, expanded use of global federal-state negotiations, in which consumer protection remedies are incorporated into the state settlements, remains the best option. To the extent federal health care fraud cases provide an opportunity for creative use of existing law to craft patient-centered remedies, as in the Medco suit, such creativity should be encouraged—within DOJ and HHS, by Congress, and in public debate. Without a congressional mandate to incorporate patient-centered values into health care fraud settlements, however, the success of such efforts will turn on prosecutorial priorities: on whether prosecutors truly believe that “the bigger issues are what is happening to the patients.”¹⁷⁶

claimants to deserving beneficiaries, but far less onerous than those required to prove causation in a tort suit, for example.

¹⁷⁵ See Miller & Singer, *supra* note 116, at 103-04 (describing monitoring settlements as a category of nonpecuniary fluid recovery).

¹⁷⁶ James Sheehan, *Biotech Fraud: Reality or Fantasy?*, 2 HOUS. J. HEALTH L. & POL’Y 11, 26 (2002).

