

# A Voluntary Disclosure Program for FDA — The Time Has Come

JOHN R. FLEDER \*

## I. INTRODUCTION

The Food and Drug Administration (FDA) should establish a voluntary disclosure program that would offer incentives to companies and others to voluntarily discover, disclose, and correct violations of the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>1</sup> and other FDA-enforced statutes. To be successful, the program must provide meaningful benefits to persons who otherwise would be liable for civil and criminal sanctions, but who opt to self-report the violation.

## II. ENFORCEMENT TOOLS AVAILABLE TO FDA

FDA's wide ranging statutory authorities enable the federal government to take enforcement actions against persons and products that violate the FDCA. Despite possessing these broad powers, the agency has cloaked its enforcement in a shroud of mystery — persons have to guess whether the agency will recommend an enforcement action. In many situations, they cannot know if the agency will be more or less likely to commence an enforcement action if the person voluntarily discloses a violation. This quandary benefits no one. Many persons undoubtedly decide it is better to take their chances and hope the agency never learns of the violation. In those instances, the agency must employ its enforcement resources to uncover violations by persons who have chosen not to self-report. Violative products may remain in the marketplace simply because the firm that sold the product is afraid to self-report the problem.

On the other hand, firms that want to act in good faith cringe at the thought that they will be unduly targeted by FDA simply because the company self-reports a violation. In fact, some firms that have self-reported have regretted the decision after FDA gave them little or no "credit" for making a voluntary disclosure.

FDA has considerable discretion in deciding whether to initiate or recommend to the Department of Justice (DOJ) the commencement of an enforcement action under the FDCA and other federal statutes.<sup>2</sup> In light of the severe sanctions available, this discretion is a powerful tool in the overall enforcement of the FDCA. There is a wide range of sanctions for violating the FDCA, as will be discussed below.

### A. *Civil Injunction Actions — Section 302 of the FDCA*

The United States can commence a civil action in a federal district court to enjoin a person from violating the FDCA. At times, FDA has used this provision to seek

---

\*Mr. Fleder is a Partner in the law firm of Olsson, Frank & Weeda, P.C., Washington, D.C. Before joining the firm in 1993, Mr. Fleder was the Director of the Department of Justice's Office of Consumer Litigation from 1985 to 1992. Tristan Loanzon and Melissa K. Cantrell assisted in writing this article while employed at Olsson, Frank & Weeda, P.C.

<sup>1</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

<sup>2</sup> See, e.g., 21 U.S.C. § 336 (FDCA § 309) (FDA is not required to recommend criminal, injunctive, or seizure actions, based on "minor violations"); Heckler v. Chaney, 470 U.S. 821, 837 (1985).

ancillary relief from the courts beyond ordering the cessation of the alleged unlawful conduct at issue, such as seeking a recall of products that violate the FDCA.<sup>3</sup> In addition, FDA has employed an injunction statute governing alleged fraud to seek injunctive relief that includes equitable remedies, such as asset freezes.<sup>4</sup>

### B. Criminal Actions — Section 303 of the FDCA

The United States can commence a criminal action in a federal district court to punish a person who has violated the FDCA. FDA can recommend criminal prosecution even when the person to be prosecuted did not intend to violate the FDCA.<sup>5</sup> More serious sanctions are provided for “second offenses,” or when the person commits a violation with the intent to defraud or mislead.<sup>6</sup> Other provisions enforced by FDA also carry criminal sanctions.<sup>7</sup> In addition, federal prosecutors often charge persons who have violated the FDCA with a crime under title 18 of the *United States Code*.

### C. Civil Penalties

FDA asserts that it can assess civil penalties against persons who have violated a number of statutes enforced by FDA including: the National Childhood Vaccine Safety Injury Act of 1986;<sup>8</sup> the Prescription Drug Marketing Act of 1987;<sup>9</sup> the Safe Medical Devices Act of 1990;<sup>10</sup> the Generic Drug Enforcement Act of 1992;<sup>11</sup> the Mammography Quality Standards Act of 1992;<sup>12</sup> and the Food Quality Protection Act of 1996.<sup>13</sup> Additionally, FDA can ask DOJ to commence a civil penalty action in a federal district court against persons who have violated the Radiation Control for Health and Safety Act of 1968.<sup>14</sup>

### D. Civil Seizures — Section 304 of the FDCA

The United States can commence a civil action in a federal district court to con-

<sup>3</sup> See *United States v. Bowen*, 172 F.3d 682 (9th Cir. 1999); *United States v. K-N Enters.*, 461 F. Supp. 988 (N.D. Ill. 1978); *United States v. Universal Mngmt. Servs., Inc.*, 999 F. Supp. 974 (N.D. Ohio 1997), *aff'd*, 172 F.3d (6th Cir. Sept. 13, 1999) (No. 98-3310, U.S. App.) Lexis 21935 .

<sup>4</sup> See 18 U.S.C. § 1345 (1994).

<sup>5</sup> 21 U.S.C. § 333(a)(1) (FDCA § 303(a)(1)); see also *United States v. Park*, 421 U.S. 658, 672-73 (1975).

<sup>6</sup> See 21 U.S.C. § 333(a)(2) (FDCA § 303(a)(2)).

<sup>7</sup> See *id.* § 333(b) (FDCA § 303(b)) (violations of the Prescription Drug Marketing Act); *id.* § 333(e) (prohibited distribution of human growth hormones); 42 U.S.C. § 262(f) (1994) (violating requirements regarding biological products); 18 U.S.C. § 1365 (tampering with consumer products).

<sup>8</sup> Pub. L. No. 99-660, 100 Stat. 3756 (codified as amended 42 U.S.C. §§ 300aa et seq).

<sup>9</sup> Pub. L. No. 100-293, 102 Stat. 95 (codified at 21 U.S.C. §§ 301 note, 331, 333, 353, 353 notes).

<sup>10</sup> Pub. L. No. 101-629, 104 Stat. 4511 (codified at 21 U.S.C. §§ 301 note, 321, 333, 333 note, 351, 353, 360, 360c, 360c note, 360d-360i notes, 360j, 360j note, 360l, 360gg-360hh note, 360ii-360ss, 383, 383 note).

<sup>11</sup> Pub. L. No. 102-282, 106 Stat. 149 (codified at 21 U.S.C. §§ 301 note, 321, 335a-335c, 335 note, 336-37, 355).

<sup>12</sup> Pub. L. No. 102-539, 106 Stat. 3547 (codified at 42 U.S.C. §§ 201 note, 263b, 263b note).

<sup>13</sup> Pub. L. No. 104-170, 110 Stat. 1489 (amending 7 U.S.C. §§ 136 et seq. (1994)).

<sup>14</sup> 21 U.S.C. §§ 360gg-360ss. On May 18, 1999, FDA published a Draft Civil Money Penalty Reduction Policy for Small Entities, 64 Fed. Reg. 26,984 (May 18, 1999). Among the factors that FDA proposes would be relevant to reducing or waiving civil penalties for small entities under some (but not all) of these provisions are “[w]hether the small entity voluntarily reported the violations to FDA promptly after discovering them.” *Id.* at 26,985; see also Food & Drug Admin., Ctr. for Device and Radiological Health, Guidance for FDA Staff: Civil Monetary Penalty Policy 7 (June 8, 1999) (noting FDA will consider whether a person disclosed a violation to FDA “within a reasonably prompt time after becoming aware of the offense — and before and without knowledge of the commencement of a formal investigation of that violation” in determining the amount of penalty).

demn articles that FDA believes violate the FDCA. FDA occasionally combines a civil seizure action with a request for injunctive relief.<sup>15</sup>

### E. Debarment — Section 306 of the FDCA

FDA can “debar” persons from submitting or assisting in the submission of an application for approval of certain drug products. While some debarment actions are mandatory, in other situations (e.g., permissive debarment), FDA has considerable discretion.<sup>16</sup> Among the factors FDA considers in deciding whether to debar a person or terminate a debarment is whether the person has cooperated with government investigations, including the extent of disclosure.<sup>17</sup>

In addition, FDA has used a variety of statutory provisions to require companies to undertake recalls. A voluntary disclosure program could and should impact FDA’s discretion to require a recall where such discretion is consistent with protection of the public health and safety.

## II. THE BENEFITS OF A VOLUNTARY DISCLOSURE PROGRAM

A voluntary disclosure program encourages companies and others to discover, disclose, and correct potential violations of the law. Employed in similar forms, voluntary disclosure programs are utilized by other federal government agencies, including the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS). A voluntary disclosure program is an acknowledgment that an agency’s enforcement resources are limited and that the industries regulated by the agency can and should police themselves. “There is no way for the government to be everywhere to monitor everything,”<sup>18</sup> remarked one Justice Department official in discussing the Environmental Protection Agency’s (EPA’s) voluntary disclosure program.

The concept of voluntary disclosure programs is hardly a novel proposition to FDA. In 1990, the agency proposed a policy on fraud, material false statements, bribery, and illegal gratuities (commonly known as the “Fraud Policy”), designed to prevent applicants from subverting the agency’s review and approval processes for premarket applications. The proposed policy offered no incentives to encourage companies to voluntarily disclose their own wrongdoing. Commentors suggested that FDA consider including in the fraud policy a voluntary disclosure program similar to the Department of Defense’s (DOD’s) program.<sup>19</sup> FDA agreed that the “issue of incentives for voluntary disclosure is important.”<sup>20</sup> FDA, however, decided a voluntary disclosure program would be better addressed not in a fraud policy, but in a “broader context” involving civil and criminal actions for misconduct.<sup>21</sup> Eight years later, FDA has not formulated a voluntary disclosure program.

---

<sup>15</sup> 21 U.S.C. § 332 (FDCA § 302).

<sup>16</sup> *Id.* § 335a(b) (FDCA § 306(b)).

<sup>17</sup> *Id.* §§ 335a(c)(3)(C), 335a(d)(4)(B)(iii) (FDCA §§ 306(c)(3)(C), 306(d)(4)(B)(iii)).

<sup>18</sup> U.S. SENTENCING COMM’N, CORPORATE CRIME IN AMERICA: STRENGTHENING THE “GOOD CITIZEN” CORPORATION, PROCEEDINGS OF THE 2D SYMPOSIUM ON CRIME & PUNISHMENT IN THE U.S. 310 (Sept. 7-8, 1995) [*hereinafter* CORPORATE CRIME]. The Sentencing Commission’s Guidelines for organizations convicted of crimes in federal courts give credit to firms that self-report a violation. U.S. SENTENCING COMM’N, GUIDELINES MANUAL § 8C2.5(g)(i) (Nov. 1998).

<sup>19</sup> 56 Fed. Reg. 46,191 (Sept. 10, 1991).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

A voluntary disclosure program could lead to companies uncovering and reporting to the government violations the government might not have discovered on its own. In fact, voluntary disclosures often have led to the government's collection of money that might not have been recovered otherwise.<sup>22</sup>

By creating an incentive for companies to conduct their own investigations and implement corrective actions, a voluntary disclosure program produces substantial savings to the government in precious investigative, audit, and legal resources. In most voluntary disclosure cases the government avoids the expense of a full-scale investigation and subsequent litigation.<sup>23</sup> By encouraging companies to make voluntary disclosures of their own wrongful conduct, agencies also minimize the risk to the public health and safety stemming from illegal and fraudulent activities. When a business self-reports a violation to an agency, such as FDA, the business can work closely with the agency to remove any potential or actual health threat caused by violative products that already have been placed into commerce.<sup>24</sup>

Many businesses will participate in a voluntary disclosure program only if they know they will receive tangible, meaningful benefits from the self-disclosure. There must be a bona fide decrease in the likelihood of civil and/or criminal prosecution, or other enforcement action by the agency. Alternatively, the agency must mitigate any potential sanction as a result of the voluntary disclosure. Companies must understand that a disclosure could maintain or improve the firm's standing with the regulators and avoid disruption of business brought by a government investigation. Companies that are given incentives to conduct their own investigation for purposes of making a voluntary disclosure present a more favorable perspective of the violation.<sup>25</sup> Of course, such a program will work only if FDA provides concrete evidence that persons who self-report will obtain tangible benefits. If FDA is unwilling to promise such benefits, the program will not be as successful as voluntary disclosure programs of other agencies that provide definitive benefits to firms that self-disclose.

The need for a voluntary disclosure program has been made clear by statutes that recently have received much attention. Some of these statutes can be enforced by FDA through DOJ, while others are enforced by different agencies. The statutes govern conduct of firms operating in the health-care field, including most pharmaceutical and medical device companies.

One statutory provision<sup>26</sup> makes it a crime if someone who has knowledge of events affecting a right to a benefit or payment under a federal health-care program — any plan or program that provides health benefits and is funded directly, in whole or in part, by the U.S. government — conceals or fails to disclose such events, if he intends fraudulently to secure such benefit or payment.<sup>27</sup>

---

<sup>22</sup> See Scott Arnold, *Voluntary Disclosure Program Benefits All Concerned*, LEGAL TIMES, June 17, 1996, at S32.

<sup>23</sup> *Id.*

<sup>24</sup> Many businesses will self-audit if they know that the government will provide incentives for voluntary disclosures. Of those firms responding to a 1995 Price-Waterhouse survey, "more than 40% said that penalty mitigation for self-identified, reported, and corrected violations would encourage the company to conduct more auditing." *Environmental Self-Audits, Subcomm. on Oversight and Investigations of the House Commerce Comm.*, 105th Cong., 2d Sess. (Mar. 17, 1998) (statement of Steven A. Herman, Ass't Admin., EPA) [*hereinafter* HERMAN TESTIMONY].

<sup>25</sup> See OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., ASSESSMENT OF THE HEALTH CARE VOLUNTARY DISCLOSURE PROGRAM: THE OFFICE OF INSPECTOR GENERAL'S PERSPECTIVE 4 (1998) [*hereinafter* OIG REP.].

<sup>26</sup> 42 U.S.C. § 1320a-7b(a)(3).

<sup>27</sup> *Id.* § 1320a-7b(f).

Does this statute require a company involved in health-care programs to “voluntarily” disclose its wrongdoing? Would the statute apply to legal counsel consulted about past abuses by a client? Unfortunately, there are no reported cases under this provision to provide guidance as to its scope. Moreover, federal prosecutors expect to see increasing use of it.<sup>28</sup> FDA can remove some uncertainties this provision has created by setting forth its expectations regarding disclosures by regulated industry and the benefits that will accrue to persons who self-report. A myriad of other federal statutes arguably provide similar disclosure “obligations.”<sup>29</sup> This panoply of federal statutes can only increase the uncertainty of a company’s potential exposure for violations of law applicable to firms operating in the health care field.

### III. VOLUNTARY DISCLOSURE PROGRAMS AT OTHER FEDERAL AGENCIES

Many federal agencies have implemented voluntary disclosure programs. A number of these programs have benefited both the agencies and the persons regulated by those agencies.

#### A. *Antitrust Division of the Department of Justice*

A company that reports illegal activity to the DOJ’s Antitrust Division will be granted leniency if the company satisfies certain conditions that signify, among others, voluntariness and candor. The conditions originally established were: 1) at the time the business came forward to report the illegal activity, the Division had not received information about the illegal activity being reported from any other source; 2) on discovery of the illegal activity, the company took prompt and effective action to terminate its part in the activity; 3) the corporation reported the wrongdoing with candor and completeness, and provided full, continuing, and complete cooperation to the Division throughout the investigation; 4) the confession of wrongdoing was truly a corporate act, as opposed to isolated confessions of individual executives or officials; 5) where possible, the corporation made restitution to injured parties; and 6) the corporation did not coerce another party to participate in the illegal activity and clearly was not the leader in, or originator of, the activity.<sup>30</sup> The benefits to cooperating companies have been called “dramatic” by one top DOJ official.<sup>31</sup> One example given was an “amnesty applicant” that paid no fine while another nonamnesty corporation in a similar situation was forced to pay \$29,000,000.<sup>32</sup>

Because of the program’s success, in August 1993 the Antitrust Division “expanded its Corporate Leniency Policy to increase the opportunities and raise incentives for companies to report criminal activity and cooperate with the Division.”<sup>33</sup> The policy was amended in three significant respects. First, when an investigation was not initiated by the government, the amnesty became automatic.<sup>34</sup> Second, amnesty was created for companies reporting after the investigation had begun.<sup>35</sup> Finally, in cases

<sup>28</sup> 2 Health Care Fraud Rep. (BNA) 167 (Mar. 11, 1998).

<sup>29</sup> 42 U.S.C. §§ 290cc-32(a)(2), 300d-320(a)(2), 408(a)(4), 707(a)(2), 1383a; *see also* 18 U.S.C. §§ 641, 669, 1001, 1035(a)(1) (applying specifically to healthcare benefit programs, including private programs), 2315.

<sup>30</sup> *See* Gary Spratling, Remarks Presented at the Am. Bar Ass’n Antitrust Section 1998 Spring Meeting 11 (Apr. 1, 1998) (transcript available at <[www.usdoj.gov/atr/public/speeches/1626.htm](http://www.usdoj.gov/atr/public/speeches/1626.htm)>).

<sup>31</sup> *Id.* at 4.

<sup>32</sup> *See id.*

<sup>33</sup> *Id.* at 1.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 2.

where the corporation receives amnesty for disclosing wrongdoing, its directors, officers, and employees are eligible for individual amnesty if they decide to “come forward with the corporation and agree to cooperate.”<sup>36</sup>

### B. *Department of Defense*

In 1986, DOD established a voluntary disclosure program concerning government contractors’ fraud. In return for encouraging firms to disclose potential violations and to cooperate in any government audit or investigation, generally the government allows a contractor to conduct its investigation before the government conducts its own investigation.<sup>37</sup> In exchange for voluntarily disclosing a procurement law violation, a contractor can expect the following benefits:

[L]iability, in general, will be less than treble damages, actions on any suspension will be deferred until after the disclosure is investigated, the overall settlement will be coordinated with government agencies, the disruption from adversarial government investigations will be reduced, and the information may be kept confidential to the extent permitted by law and regulation.<sup>38</sup>

### C. *Environmental Protection Agency*

In 1996, the EPA implemented an audit policy that “encourage[d] self-policing by cutting penalties for any violations that are discovered, disclosed, and corrected through voluntary audits or compliance management programs.”<sup>39</sup> In return for cooperation, the EPA generally will not recommend criminal prosecution.<sup>40</sup> Companies that take advantage of the program also receive no or reduced “gravity-based” penalties.<sup>41</sup> The program, however, does not cover repeat violations, violations that result in serious actual harm, and violations that may present an imminent and substantial endangerment to the environment.<sup>42</sup>

One EPA official recently testified about the benefits of the agency’s voluntary disclosure program to its enforcement program.<sup>43</sup> Deputy Administrator Steven A. Herman stated that “more than 247 companies have disclosed violations under the policy at more than 760 facilities.”<sup>44</sup> For example, in one situation involving more than 600 violations of the Clean Water Act at 314 GTE facilities in twenty-one

<sup>36</sup> *Id.* at 3.

<sup>37</sup> See GENERAL ACCOUNTING OFFICE, DEP’T OF DEFENSE PROCUREMENT: USE AND ADMINISTRATION OF DOD’S VOLUNTARY DISCLOSURE PROGRAM 3 (Feb. 6, 1996) (GAO/NSIAD-96-21). The GAO reported that DOD’s recoveries “were overstated because they included \$75 million in premature progress payments and amounts from disclosures made prior to the program.” *Id.* at 1. The report did not conclude that the voluntary disclosure program is not a useful or effective means of identifying or combating fraud. Indeed, the GAO Report noted that the program’s value may extend beyond that which can be measured by available statistics and that corporate compliance through voluntary disclosure can have long-term effects on business honesty and integrity. *Id.*

<sup>38</sup> *Id.* at 4.

<sup>39</sup> ENVIRONMENTAL PROTECTION AGENCY, AUDIT POLICY UPDATE, LETTER FROM THE ASSISTANT ADMINISTRATOR 1 (Jan. 1997); see also Incentives for Self-Policing: Discovery, Disclosure, and Correction and Prevention of Violations, 60 Fed. Reg. 66,706 (Dec. 22, 1995).

<sup>40</sup> 60 Fed. Reg. at 66,711.

<sup>41</sup> A gravity-based penalty is that “portion of a penalty over and above the economic benefit, i.e., the punitive portion of the penalty, rather than that portion representing a defendant’s economic gain from non-compliance.” *Id.*

<sup>42</sup> See *id.* at 66,712.

<sup>43</sup> HERMAN TESTIMONY, *supra* note 24, at 2.

<sup>44</sup> *Id.*

states, the EPA and GTE settled for over \$52,000. The settlement figure represented the amount of money GTE saved during its period of noncompliance. In return for the company's cooperation and prompt correction of the violations, the EPA, pursuant to its audit policy, waived \$2,380,000 in potential penalties. According to the EPA, "the GTE settlement protects communities, firefighters, police, and others in case of a chemical spill or release, lowers the risk that hazardous chemicals will pollute our waterways, and ensures a level economic playing field for complying competitors."<sup>45</sup>

Another EPA voluntary disclosure program, in place between 1991 and 1996, provided incentives to companies to identify toxic chemicals and submit scientific studies conducted on those chemicals. According to Deputy Administrator Herman, the program was "a flexible, common-sense approach,"<sup>46</sup> especially in light of the fact that traditional deterrence tools were ineffective given the size of the industry and the complex set of environmental laws.<sup>47</sup> The EPA viewed the program as an "important success" and has attempted to duplicate it in other areas.<sup>48</sup>

#### D. Department of Health and Human Services

In March 1995, the OIG of DHHS, in cooperation with the Justice Department, established a pilot voluntary disclosure program called "Operation Restore Trust." The OIG acknowledged that "an effective enforcement strategy against healthcare fraud includes voluntary disclosures."<sup>49</sup> The program encouraged healthcare providers to report any possible fraud or abuse in healthcare programs, such as Medicare and Medicaid. In return for their cooperation, providers would "earn considerable credibility in [their] dealing[s] with the agency," and would be allowed to conduct their own investigation prior to an OIG investigation.<sup>50</sup> Thus, the providers had an opportunity to "frame the issue in the most favorable light, present mitigating factors, and contain the scope of disclosure."<sup>51</sup>

This pilot program was limited to five states and only applied to home health agencies, skilled nursing facilities, durable medical equipment suppliers, and hospice providers.<sup>52</sup> There were several criteria for qualification to participate in the program:

- disclosure could be made only on behalf of a corporate entity, not an individual person, officer, or employee;
- the health care provider had to approach the OIG before an investigation had been commenced by a federal or state law enforcement agency; and

---

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Marianne Lavelle, *Incentives to Identify Toxic Chemicals Have Deluged the Agency With Reports*, NAT'L L.J., Feb. 24, 1997, at A1.

<sup>48</sup> *Id.* Two similar programs have been implemented since 1995. One is an amnesty-style program called the Inventory Update Rule Record and Search. In return for disclosing the location of the company's toxic chemicals — as already required by law — the company gets a reduced monetary penalty. *Id.* Another program attempts to increase compliance with the Emergency Planning and Community Right to Know Act by reducing penalties for violators who disclose inventories of harmful toxins. *Id.*

<sup>49</sup> OIG REP., *supra* note 25, at 1.

<sup>50</sup> *Id.* at 3-4.

<sup>51</sup> *Id.* at 4.

<sup>52</sup> This was a joint federal and state project to detect fraud and abuse in the Medicare and Medicaid programs by coordinating the efforts of various federal and state agencies. *Id.* at Appendix, OIG Procedures for Administering the Pilot Disclosure Program 1.

- the provider had to disclose specific information about the nature of the wrongdoing and potential harm to the Medicare and Medicaid programs, as well as the origin of the information, promising to cooperate fully with the government.<sup>53</sup>

Recently, Deborah Heart and the Lung Center of Browns Mills, New Jersey, were among the first Medicare healthcare providers to self-report under this program. They voluntarily disclosed overbilling to Medicare and, as a result of the self-disclosure, the government refrained from seeking treble damages and other penalties.<sup>54</sup>

On October 30, 1998, the OIG issued its "Provider Self-Disclosure Protocol,"<sup>55</sup> based on insights gained from the pilot voluntary disclosure program. Now, the program is open to all health-care providers, whether individuals or entities, even if the disclosing party is under investigation.<sup>56</sup> There are no predisclosure requirements or admission applications.<sup>57</sup> Although there is still no immunity from criminal prosecution or civil action under the False Claims Act,<sup>58</sup> the OIG stated that disclosure could be a mitigating factor in the OIG's recommendation to prosecuting attorneys, could minimize cost and disruption of a full-scale audit, and possibly could lead to a "fair" out of court settlement.<sup>59</sup> The OIG has stated, however, that a self-reporting entity may face exclusion from further participation in the Medicare and Medicaid programs if it submits false information or intentionally omits relevant information.<sup>60</sup> If the confession is made within thirty days of discovery, damages could be limited to double damages as opposed to treble damages.<sup>61</sup>

All disclosures under the Protocol must be accompanied by a report of an internal investigation of the questionable practice and an internal financial assessment of the monetary impact of the disclosed matter.<sup>62</sup> Once the disclosure and accompanying reports have been submitted, the OIG will verify the information.<sup>63</sup> It is important to note that new matters found during the OIG's verification process will be treated as matters outside the Provider Self-Disclosure Protocol.<sup>64</sup> Unfortunately, the OIG refuses to make any commitment as to how a particular disclosure will be resolved or the specific benefit that will inure to the self-disclosing entity. There are obvious risks associated with voluntary disclosure under this program, including:

- no immunity from criminal prosecution or civil liability;
- the government otherwise may not discover the violation;
- the government may find the violation more severe than expected and may take a more aggressive approach than anticipated;
- less than full disclosure based on inadequate and quickly gathered facts may be worse than no disclosure at all;

---

<sup>53</sup> *Operation Restore Trust Voluntary Disclosure Program*, DHHS Press Release, May 3, 1995 (visited June 15, 1999) <[hhs.gov/progorg/oig/other/ortvolun.txt](http://hhs.gov/progorg/oig/other/ortvolun.txt)>.

<sup>54</sup> *IG Brown Announces \$840,000 Settlement With N.J. Hospital*, OIG Press Release, Oct. 21, 1998 (visited June 15, 1999) <[dhhs.gov/progorg/oig/modcomp/settlement.pdf](http://dhhs.gov/progorg/oig/modcomp/settlement.pdf)>.

<sup>55</sup> 63 Fed. Reg. 58,399 (Oct. 30, 1998).

<sup>56</sup> *Id.* at 58,400.

<sup>57</sup> *Id.*

<sup>58</sup> Pub. L. No. 97-258, 96 Stat. 978 (1982) (codified as amended 31 U.S.C. §§ 3729-3733 (1994)).

<sup>59</sup> 63 Fed. Reg. at 58,401.

<sup>60</sup> *Id.* at 58,403.

<sup>61</sup> Frederick Robinson, *Recent Health Care Fraud Enforcement Developments*, TEXAS HEALTH L., Oct. 29, 1998.

<sup>62</sup> 63 Fed. Reg. at 58,401-02.

<sup>63</sup> *Id.* at 58,403.

<sup>64</sup> *Id.*

- the government likely will require the corporation to undertake a rigorous corporate integrity program that will be closely monitored by the government;
- while investigating the disclosure, the government may find other violations and initiate action that is not covered under the voluntary disclosure program; and
- there is a significant increase in the risk of private *qui tam* suits filed under the False Claims Act.<sup>65</sup>

Thus, counsel will hesitate to voluntarily disclose conduct with the potential for such draconian repercussions and no clear promise of immunity. Nevertheless, a failure to disclose a violation almost surely will result in more severe sanctions if the government learns of the violations. Beginning in 1993, the government has made the investigation and punishment of healthcare fraud a top priority in its arsenal of civil and criminal prosecutions.<sup>66</sup> It recently has increased funding and personnel to investigate health-care violations dramatically, principally as a result of the Health Care Portability and Accountability Act of 1996.<sup>67</sup>

It is quite difficult for corporate management to know that no employee in a large corporation voluntarily will report the company's violations of law. Indeed, instigating a government investigation is a common tactic of the disgruntled or departed employee. Moreover, individuals now can receive millions of dollars for bringing a successful *qui tam* suit. Thus, many health-care companies see self-reporting as a means to minimize their civil and criminal exposure from violations of law committed by their employees.

### E. Securities and Exchange Commission

The Securities and Exchange Commission (SEC) has an informal voluntary disclosure policy — it will accord lenient treatment to companies that disclose violations and cooperate with an SEC investigation. William McLucas, former head of enforcement at the SEC, described the importance of self-disclosure to the enforcement of securities laws: “We recognize that we can’t litigate every case, we can’t audit every public company and we can’t find every miscreant. [We] try to establish an ethic or a reward for those who try to clean their house on their own volition . . . [I]t generally seems to work quite well.”<sup>68</sup>

One former top SEC enforcement officer agreed, but counseled that the government must reward firms that self-disclose their violations:

[T]he commission also appreciates the carrot has got to be a factor as well, to the extent that if a corporation discovers a problem and brings it to the attention of the commission, they get credit for it . . . And I think it has to be an important part of every enforcement program as well, because you have to recognize that in a large institution you are going to have people who go astray. I don’t care if it’s a corporation or a government agency, there are

---

<sup>65</sup> 31 U.S.C. § 3730(b).

<sup>66</sup> Deputy Attorney General Eric H. Holder, Jr., Remarks to the Am. Hospital Ass’n (Feb. 1, 1999) (transcript available at <[www.usdoj.gov/dag/speech/holderahaspeech.htm](http://www.usdoj.gov/dag/speech/holderahaspeech.htm)>). Deputy Attorney General Holder acknowledged that at times the Department’s approach to health-care fraud prosecutions has been perceived as heavy-handed. He noted that “the Department will continue to look favorably on providers that implement effective compliance programs and voluntarily report misconduct to the government.” *Id.* He also stated that “[h]ealth care fraud will continue to be one of the Department’s top enforcement priorities.” *Id.*

<sup>67</sup> Pub. L. No. 104-191, 110 Stat. 1936, 1991-2021 (1996).

<sup>68</sup> *SEC’s Top Cops Go on Record*, NAT’L L.J., July 18, 1994, at 2.

going to be people who do things that aren't in keeping with the ethic of the organization. The commission has to recognize that when a corporation takes action upon discovering a problem and brings it to their attention, they deserve credit for it.<sup>69</sup>

#### F. Consumer Product Safety Commission

In August 1995, the U.S. Consumer Product Safety Commission (CPSC) implemented an amnesty program<sup>70</sup> exempting companies from civil penalties for failure to comply with reporting obligations under the Consumer Product Safety Act.<sup>71</sup> Under the program, firms that reported potentially hazardous products to the CPSC were not subject to penalties under the Act or CPSC regulations.<sup>72</sup>

### IV. ELEMENTS OF A VOLUNTARY DISCLOSURE PROGRAM

Although the voluntary disclosure programs discussed above have much in common, each one is tailored to the industries regulated by the agency that implemented the program. Thus, FDA should adopt useful features from these programs, but it will need to add provisions that may be *sui generis* to the public health concerns posed by the FDCA. This article does not suggest model language for FDA's voluntary disclosure program. FDA should, at the earliest possible time, however, circulate a proposed voluntary disclosure program for public comment.<sup>73</sup>

The OIG at DHHS has stated that its voluntary disclosure program has not been as successful as hoped; companies are discouraged from reporting criminal violations because they fear legal actions brought by state agencies and private individuals.<sup>74</sup> A potential solution to this problem is for FDA to state in its voluntary disclosure program the steps it will take to assist companies that self-disclose to FDA with potential or filed lawsuits, such as state and local government actions, as well as private lawsuits, including product liability cases. For instance, where appropriate, FDA might file an amicus brief in support of the cooperating defendant. Another solution would be to maximize cooperation between federal and state agencies. In fact, the OIG Report recognized the need for greater coordination between state and

---

<sup>69</sup> *Id.* (comments by Gary G. Lynch, former Director of the SEC's Div. of Enforcement).

<sup>70</sup> Mark F. Foley & James F. Stern, *Products Liability: Under Its Amnesty Program, the Consumer Product Safety Commission Will Waive Penalties for Firms That Disclose Previously Unreported Product Hazards*, NAT'L L.J., Jan. 29, 1996, at B5.

<sup>71</sup> Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified as amended 15 U.S.C. §§ 2051-2084 (1994)).

<sup>72</sup> Foley & Stern, *supra* note 70, at B5.

<sup>73</sup> FDA likely would violate the Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended 5 U.S.C. §§ 551 et seq. (1994)), if it issues a Voluntary Disclosure Program without going through notice-and-comment rulemaking pursuant to 5 U.S.C. § 553. In *Chamber of Commerce v. United States Dep't of Labor*, 174 F.3d 206 (D.C. Cir. 1999), the court held that a "Directive" that set forth criteria for when employers would be inspected was issued illegally because the agency had not gone through rulemaking. The Directive provided that firms could lessen their exposure to an inspection if they participated in the agency's "Cooperative Compliance Program." The court recognized that the program did "not formally require anything: An employer is not subject to a legal penalty for failing to join" the program. *Id.* at 209. The agency's announcement that a firm's failure to join the program was deemed a rule, however, in that the policy obliged an employer "to comply or to suffer the consequences." *Id.* at 210. The court also determined that the directive was not a mere procedural rule because, on its face, it required participants to do more than merely adhere to existing law. The court also rejected the argument that the directive was a general statement of policy that was exempt from notice-and-comment rulemaking because the directive stripped the agency of discretion.

<sup>74</sup> See OIG REP., *supra* note 25, at 7.

federal officials.<sup>75</sup> This element is already part of the EPA's voluntary disclosure program.<sup>76</sup>

Many persons undoubtedly hesitate to self-report violations of the FDCA and other statutes to FDA, fearing that the self-reporting will be deemed an admission that will result in a flurry of private suits. FDA could assist companies that self-report by stating in its voluntary disclosure program that, in appropriate cases, it will allow FDA employees to testify in the lawsuits to explain the company's good faith actions.<sup>77</sup>

## V. CONCLUSION

FDA cannot expect the companies and persons it regulates to self-report violations if the agency does not define with clarity the incentives it will offer. Nor can the agency complain of inadequate resources to enforce the FDCA if the agency does not encourage persons to come forth with information about potentially illegal conduct. A successful voluntary disclosure program will help the agency, the industries regulated by FDA, and public health and safety.

---

<sup>75</sup> *See id.*

<sup>76</sup> 60 Fed. Reg. at 66,710.

<sup>77</sup> FDA's regulations set forth procedures for obtaining testimony of FDA employees in suits where FDA is not a party. 21 C.F.R. § 20.1 (1998).

