

violations of law; and (2) otherwise promote an *organizational culture that encourages a commitment to compliance with the law.*" (emphasis supplied).

By this statement about culture, along with its emphasis on the role of the organization's leadership, the Ad Hoc Advisory Group recognizes that the carrot and stick approach goes only so far. A compliance program is about self-governance, and an entity must use the same leadership and process management to achieve compliance that it uses to achieve any other strategic initiative. Leadership is about values, not law.

Is legal self-governance ("compliance"), possible without a commitment to ethical self-governance? That is, will a focus on legal compliance alone be sufficient?

We think not, because rules-based systems have tended to invite behavior that seeks to subvert the spirit of those rules while honoring their letter. We have seen in recent years companies attempting to "game the system" and the never-ending pursuit of loopholes and devices designed to avoid legal requirements without overtly violating them. In addition, compliance, absent an allegiance to ethics, is truly about nothing more than doing the minimum required to comply with the basic requirements. Past precedent demonstrates that culture grounded in values and ethics has more sustainable success in establishing and maintaining higher standards of conduct than a culture that merely "encourages compliance."

The emphasis on doing what is right arises from the fact that corporate reputation, as well as an individual leader's reputation, is now more at the center of public scrutiny. And it appears that businesses are increasingly recognizing that reputation is a valuable asset to be preserved, protected, and reinforced. But it is also an asset that can be damaged under the weight of negative public perception and especially judgment of ethical impropriety. Programs that address both ethics and law serve to nurture these valuable reputations by fostering cultures in which employees appreciate the gravity of their decisions and the actions they take. These well-informed decisions and actions, then observed by all who come in contact with the company--investors, customers, suppliers, consumers, etc.--garner greater trust, which may lead to preserving and, perhaps even improving, a company's reputation. The necessary condition, then, for enjoying a valuable and enduring reputation is that those who come in contact with the company believe they can trust it; but they can only trust if on a consistent basis the company does that which is right by them and others. Therein lies the centrality of reputation.

The Ad Hoc Group report also recognizes that ethics and compliance are intertwined. As the Commission notes in the proposed amendment, the "organizational culture" addition is:

intended to reflect the emphasis on ethics and values incorporated into recent legislative and regulatory reforms, as well as the proposition that compliance with all laws is the expected behavior within organizations. (Fed. Reg. Vol.68, No. 249, 75340 at 75355

(Dec. 30, 2003)).

Discussions of ethics and its role in organizational culture permeate much of the Advisory Group's report. Indeed, according to the report, "values-based" compliance programs already appear to be the norm among member organizations surveyed by the Ethics Officer Association. The Ad Hoc Group also recognizes that "law compliance" is a subset of general ethical behavior. (Report at 40) "Culture," by definition, is shared values (Ad Hoc Report at 52) and, as we have pointed out above, laws are an expression of values, and legal violations are often failures of ethics.

The Defense Industry Initiative on Business Ethics and Conduct, an organization founded by 32 members of that industry, reached a similar conclusion and, as a result, included in its statement of purpose:

DII's essential purpose is to combine the common dedication of its Signatories to a culture and practice of ethics and right conduct in all business with the U.S. Defense Department and with others.

Nevertheless, the Ad Hoc Group expressly intends to limit ethical assessments by courts, prosecutors and parties, stating only that "determinations of whether a particular organization has adopted a good 'set of values'" or appropriate 'ethical standards' are 'subjects which may be very difficult, if not impossible, to evaluate in an objective, consistent manner." (Report at 55).

This conclusion wrongly supposes, we believe, that the courts may lack the judgment found in the other branches of the government and self-regulating bodies. Neither Congress, in The Sarbanes-Oxley Act, nor the SEC in approving the listing standards of the NYSE and Nasdaq shied away from the concept of ethics. Under those laws, and many others that we discuss below, courts will and have grappled with these subjects.

While ethics can seem to be an abstraction that calls for relative, somewhat subjective value judgments, there is actually a far more grounded, practical definition. Ethics is, simply, the shared values and norms that define how people interact. Principally, ethics is how people treat each other. Very often, ethics is explicitly expressed as positive law; at all times, ethics informs the positive law. They are inexorably intertwined.

Our concern with the proposed language and its underlying rationale, therefore, is that it both "sells the courts short" and does not comport with these more recent statutes and regulations. As a result, it could lead to *inconsistent enforcement* of both the letter and spirit of those laws.

Consequently, we believe the current environment presents a singular opportunity to establish a general requirement for *promoting a culture of ethics and compliance*, as



opposed to merely a culture of compliance. We believe this is not only an achievable goal, but moreover sends a strong signal that compliance with legal minimums will not be the standard by which sentencing courts will evaluate behavior, but instead virtue and values do indeed matter. Only through reference to fundamental legal *and ethical* principles will the Commission be able to properly discourage actions that while technically legal, undermine the spirit of the law.

Indeed, the criteria currently proposed by the Commission to determine whether an organization has promoted a culture of compliance with the law may just as easily be used to assess whether the organization has promoted a culture of compliance with law *and ethics*. Courts and prosecutors may then use the standards currently espoused in the proposed amendments for promoting a culture of compliance to just as easily measure an organization's commitment to promoting a culture of ethics and compliance. This allows for an analysis of how well the organization promotes ethics without requiring an analysis of how ethical an organization is.

Without a commitment to ethics, the Commission runs the risk of its guidelines fostering the same types of corporate cultures that allowed individuals to seek out "loopholes" in the law that led to many of the recent corporate crises. By including ethics in §8B2.1.(a)(2), the Commission not only retains intellectual consistency, but it will be implementing both the words and spirit of recent legislation and regulations.

### THE PRECEDENT FOR ETHICS

The notion of at least some government oversight of business ethics is a well-established one. And courts and prosecutors are both equipped and willing to engage in at least some assessment of ethical behavior. Indeed, much of the criminal law and the analysis of criminal behavior in the courtroom relies on an assessment of a defendant's motive. Every day, courts and juries examine motive, comparing it against the community's values (*i.e.*, its ethical framework) to determine how well or mal-intentioned the defendant's actions were. This values-based (or ethics-based) determination informs the culpability decision and ultimately, the sentence meted out. Moreover, the basic tenets of tort law are based on ethics. Before the advent of standards of strict liability, which effectively compensate harm based on notions of causation and, ultimately, who can afford to pay the compensation, tort law had as its foundation the precept of duty. Duty is simply the assigned moral obligation to behave in a certain way--an obligation interpreted and assigned by judges and which ultimately established the common law of torts.

There is also a long history of all three branches of government encouraging, if not explicitly mandating, at least some focus on ethics in business. Indeed, among Congress's objectives in passing the federal securities laws in the early 1930s was the promotion of honest securities markets. By passing these laws, Congress sought "to substitute a philosophy of full disclosure for the philosophy of caveat emptor and thus to achieve a high standard of business ethics in the securities industry." And since their passage, the courts have broadly construed the securities laws over the years to achieve

this stated purpose.

Of course, ethics is not limited to the securities laws. Many federal laws are founded on ethical principles and require at least some recognition of those principles in applying the laws to the facts of any particular case.

And in government procurement, by both statute and regulation, the executive branch is required to assess an organization's ethics on a regular basis. Pursuant to both the Office of Federal Procurement Policy Act of 1974 and the Federal Acquisition Regulation (FAR), some of the factors to be considered in determining whether a prospective contractor is a "responsible source" include whether it has adequate financial resources; the ability to comply with delivery and performance schedule; a satisfactory performance record; and a satisfactory record of *integrity and business ethics*.

Even the common law is rife with examples of ethics finding their way into the legal analysis. One example is the tort of interference with contract stating that, when the courts have yet to approve or disapprove of a certain practice, "[r]ecognized standards of *business ethics* and business customs and practices are pertinent" in determining whether interference with a contract was improper

Moreover, as the Advisory Group and Commission recognized, Congress and regulators have been even more than willing to prescribe at least some focus on ethics within organizations. For example, codes of ethics for senior executives of publicly traded companies are now essentially mandated by law and regulation, and Nasdaq and NYSE-listed companies must have codes of ethics for all employees.

In addition, the Department of Health and Human Services Office of Inspector General requires pharmaceutical manufacturers have written policies and procedures and recommends that they "develop a general corporate statement of ethical and compliance principles that will guide company operations." *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, Office of Inspector General, Department of Health and Human Services, Fed. Reg. Vol. 68, No. 86, 23731 at 23733 (May 5, 2003).

And lately, responding to the sense of frustration felt by the public, even the courts have willingly entered the ethics debate, indicating a fundamental shift in the manner in which they view ethics as part of the judicial process. This has manifested itself in several ways. First, as a greater emphasis on ethics in analysis, including in *U.S. v. Andreas*, 216 F.3d 645, (7th Cir. 2000) and *Haberman v. S.E.C.*, 205 F.3d 1345 (8th Cir. 2000) (unpublished disposition).

This is not to say that there should be no limitations on the courts' ability to assess ethical standards and conduct. The point of judicial analysis of an organization's commitment to ethics and law should be to assess whether the organization has effectively promoted them and not whether they have achieved some standardized culture of ethical and legal compliance. That is, courts should not assess *how ethical an*



organization is, but *how hard* it has tried.

Moreover, we believe that there is little risk that a court would choose to engage in the exercise of assessing an organization's ethics. This is especially so when the principles applicable at law (*i.e.*, the Chapter 8 guidelines) provide ample guidance toward the appropriate analysis: whether the organization has effectively *promoted* a culture of ethics and compliance. Indeed, as recently as last October, Judge Pollack declined to engage in the exercise of assessing an organization's ethical behavior, stating that "[t]he plaintiffs in the above-captioned putative class actions would have this Court punish breaches of business ethics by principles applicable at law which did not at the time apply to such conduct." However, the implication is that, had such "principles applicable at law" applied at the time, Judge Pollack would have engaged in the appropriate analysis. *In re Merrill Lynch & Co., Inc. Research Reports Securities Litigation*, 289 F.Supp.2d 416, 418 (SDNY. 2003).

And perhaps most remarkable to date has been the recent landmark settlement response – with the enforceability of the court's permanent injunction – to one of the largest securities frauds ever to occur in the United States. In *SEC v. Worldcom*, Judge Rakoff noted:

The permanent injunction also requires the company to provide a large segment of its employees with specialized training in accounting principles, public reporting obligations, and *business ethics*, in accordance with programs being specially developed for the company by New York University and the University of Virginia. At the behest of the Corporate Monitor, the Court also obtained from the new Chief Executive Officer a sworn "*Ethics Pledge*," requiring, on pain of dismissal, a degree of transparency well beyond S.E.C. requirements. The company has since required its senior management to sign a similar pledge, and has plans to obtain similar pledges from virtually all employees.

*S.E.C. v. Worldcom, Inc.*, 273 F.Supp.2d 431, S.D.N.Y.,2003 (emphasis added).

In sum it is our considered opinion that as long as the guidelines focus on compliance and do not explicitly include an ethical component, the discussion will remain about that which is required to do and not that which is right to do. A more prudent course, and one more consistent with the activities of the other branches of government and of industry itself, is to foster a culture based on both compliance and ethics. Only in that way will we help build a system in which both compliance and virtue are their own rewards.

Consequently, we believe the Commission should make the following changes to the proposed amendments:

§8B2.1(a)(2)

"otherwise promote an organizational culture that encourages a commitment to ethics and the law."

§8B2.1(b)

"Due diligence and the promotion of an organizational culture that encourages a commitment to ethics and compliance with the law."

§8B2.1(b)(1)

"The organization shall establish ethics and compliance standards and procedures to prevent and detect violations of law."

LRN would like to again thank the Commission for this opportunity. We hope that our comments will help inform the Commission's considerations.





March 1, 2004

United States Sentencing Commission  
One Columbus Circle, N.E.  
Suite 2-500  
Washington, D.C. 20002-8002

Attn: Public Affairs

LRN is pleased to have the opportunity to respond to the United States Sentencing Commission's request for public comment on its proposed amendments to Chapter Eight of the United States Sentencing Guidelines regarding effective compliance programs. LRN commends the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines for its insightful report and recommendations. We further commend the Commission for addressing in the proposed amendments the important issues raised by the Advisory Group.

For over ten years, it has been LRN's privilege to work with hundreds of organizations, both large and small, on legal, compliance, and ethics issues. During this time, we have gained a better understanding of the relationship between ethics and compliance, and more broadly, the relationship between corporate cultures and compliance. We have also gained insight into how organizations best communicate not only the legal and regulatory requirements of their business, but also respect for the law more broadly, as well as their values and standards. And we have had the opportunity to witness and participate in what we believe could well turn out to be a sea change in the approach to addressing these critical issues.

We are observing an emerging trend in the development of effective compliance programs, and we believe this trend is a positive one. In particular we are observing that in communicating their values and providing employees with the knowledge and information they need to succeed and thrive, they are emphasizing both ethics and legal

LRN, Inc.

1100 Glendon Avenue, Suite 700  
Los Angeles, CA 90024-3503  
Telephone 310.209.5400  
Facsimile 310.209.5401  
[www.lrn.com](http://www.lrn.com)

The Legal Knowledge Company™

compliance. Indeed, attention to ethics within organizations now takes many forms, from bringing to life codes of conduct through education and other means by which they are woven into the very fabric of the organization, to structuring education curricula in which law and the ethics are taught together. The goal of such programs is to not only comply with the law, but to instill in the organization's members an atmosphere of trust and a sense of mutual respect and benefit.

We offer the following comments to provide context to the current corporate environment – one characterized by what we observe to be intense skepticism and a lack of trust from the public. It is our belief that the Commission has a historic opportunity to do more than dictate prescriptive rules of compliance, but instead embrace both the letter and the animating spirit of the recent reforms.

### **organizational ethics are essential to legal compliance**

We strongly endorse adoption of the Ad Hoc Group's recommendations, except as stated below, and greatly appreciated the thoroughness, thoughtfulness and insight of their report. The report states that "the Advisory Group is not aware of any empirical evidence that the widespread movement to adopt compliance programs has resulted in the institution of *effective* compliance programs" (Report at 35), but nevertheless acknowledges that the state of the art for compliance programs has advanced, and the Sentencing Commission's organizational guidelines should reflect that advance. (Executive summary at 3). We offer comments to further that goal, suggesting that the Guidelines require programs that instill ethical behavior in allegiance to standards that animate the Guidelines in addition to legal compliance with the Guidelines.

The highly publicized ethical scandals that began to crescendo in 2001 showed that companies with "paper compliance programs," but no true ethical culture, collapse quickly as unethical conduct is revealed. The scandals that led to the recent reforms, while violating the law, were reflective of a broader ethical failure that was even more troubling than the actual legal violations.

Prosecutors frequently struggled to identify the appropriate laws and charges. The positive law had not kept up with the ability of highly proficient, yet ethically untethered individuals and organizations to find loopholes. Nearly all agreed, however, that the conduct was so egregious as to breach norms of ethical behavior. A collective cry arose that "there ought to be a law."

In response, several laws, as well as regulations and new rules for self-governing organizations, such as the stock exchanges, were passed. The aim of nearly all of these was to address the shortcomings extant in the positive law; namely, its failure to address conduct that was, while unethical, not necessarily illegal. At the federal level, both the legislative and executive branches have acted to redress those shortcomings.

The animating principles and foundational precepts of the rule of law originate



from shared, common values. Businesses that embrace the letter and spirit behind the law inspire and uphold a higher standard of conduct in allegiance to these shared values. This higher standard considers the consequences of actions beyond their immediate outcome to consider the ultimate impact. This higher standard also acknowledges that everything is not relative and subject to equivocation and “clever pleading”; there are fundamental truths and values that should be adopted and championed simply because they are the right thing to do.

The judiciary, through the Commission, now has the opportunity to take its proper place beside its co-branches of government in ensuring ethics plays a key role in the lawful conduct of all organizations.

The Commission has, in its proposed changes to the Guidelines, taken the bold step of recognizing the vital role organizational culture plays in establishing and maintaining an effective compliance program. In that regard, the Commission has proposed that an organization must "(1) exercise due diligence to prevent and detect violations of law; and (2) otherwise promote an *organizational culture that encourages a commitment to compliance with the law.*" (emphasis supplied).

By this statement about culture, along with its emphasis on the role of the organization's leadership, the Ad Hoc Advisory Group recognizes that the carrot and stick approach goes only so far. A compliance program is about self-governance, and an entity must use the same leadership and process management to achieve compliance that it uses to achieve any other strategic initiative. Leadership is about values, not law.

Is legal self-governance (“compliance”), possible without a commitment to ethical self-governance? That is, will a focus on legal compliance alone be sufficient?

We think not, because rules-based systems have tended to invite behavior that seeks to subvert the spirit of those rules while honoring their letter. We have seen in recent years companies attempting to “game the system” and the never-ending pursuit of loopholes and devices designed to avoid legal requirements without overtly violating them. In addition, compliance, absent an allegiance to ethics, is truly about nothing more than doing the minimum required to comply with the basic requirements. Past precedent, as discussed more fully later in this document, demonstrates that culture grounded in values and ethics has more sustainable success in establishing and maintaining higher standards of conduct than a culture that merely “encourages compliance.”

The creation of an organizational culture that does what's right is not a project, but an ongoing perennial investment. Adherence to the rule of law and strict conformity with compliance obligations is necessary, but not sufficient to create such a culture. Even in areas where there is no technical violation of the law, there is a critical distinction, as Justice Potter Stewart observed, between that which one has a right to do and that which is right to do.

The emphasis on doing what is right arises from the fact that corporate reputation, as well as an individual leader's reputation, is now more at the center of public scrutiny. And it appears that businesses are increasingly recognizing that reputation is a valuable asset to be preserved, protected, and reinforced. But it is also an asset that can be damaged under the weight of negative public perception and especially judgment of ethical impropriety. Programs that address both ethics and law serve to nurture these valuable reputations by fostering cultures in which employees appreciate the gravity of their decisions and the actions they take. These well-informed decisions and actions, then observed by all who come in contact with the company--investors, customers, suppliers, consumers, etc.--garner greater trust, which may lead to preserving and, perhaps even improving, a company's reputation. The necessary condition, then, for enjoying a valuable and enduring reputation is that those who come in contact with the company believe they can trust it; but they can only trust if on a consistent basis the company does that which is right by them and others. Therein lies the centrality of reputation.

The Ad Hoc Group report also recognizes that ethics and compliance are intertwined. As the Commission notes in the proposed amendment, the "organizational culture" addition is:

intended to reflect the emphasis on ethics and values incorporated into recent legislative and regulatory reforms, as well as the proposition that compliance with all laws is the expected behavior within organizations. (Fed. Reg. Vol.68, No. 249, 75340 at 75355 (Dec. 30, 2003)).

Discussions of ethics and its role in organizational culture permeate much of the Advisory Group's report. Indeed, the report recognizes that ethics is central to organizational culture and thus an effective compliance program. According to the report, "values-based" compliance programs already appear to be the norm among member organizations surveyed by the Ethics Officer Association (Ad Hoc Report at 52). The Ad Hoc Group also recognizes that "law compliance" is a subset of general ethical behavior. (Report at 40) "Culture," by definition, is shared values (Ad Hoc Report at 52) and, as we have pointed out above, laws are an expression of values, and legal violations are often failures of ethics.

The Defense Industry Initiative on Business Ethics and Conduct, an organization founded by 32 members of that industry, reached a similar conclusion and stated as its purpose:

DII's essential purpose is to combine the common dedication of its Signatories to a culture and practice of ethics and right conduct in all business with the U.S. Defense Department and with others. The defense industry Signatories are united in the commitment to adopt and implement principles of business ethics and conduct that acknowledge and address their organizational responsibilities under federal procurement policy and law, thereby contributing to the National Defense.



Further, they each accept the responsibility to create an organizational culture in which ethics is paramount, and compliance with federal procurement laws is a strict obligation. The DII's essential strength lies in sharing best practices to maintain the highest ethical standards, encouraging employees to ethical conduct, and requiring compliance in the course of its business activities. The DII, while not a lobbying organization, is an advocate of its principles to the defense industry, to the Government and to the Public.

Nevertheless, the Ad Hoc Group expressly intends to limit ethical assessments by courts, prosecutors and parties, stating only that "determinations of whether a particular organization has adopted a good 'set of values'" or appropriate 'ethical standards' are 'subjects which may be very difficult, if not impossible, to evaluate in an objective, consistent manner." (Report at 55).

This conclusion wrongly supposes, we believe, that the courts may lack the judgment found in self-regulating bodies and other branches of the government. Neither Congress, in The Sarbanes-Oxley Act, nor the SEC in approving the listing standards of the NYSE and Nasdaq shied away from the concept of ethics. Under those laws, and many others that we discuss below, courts will and have grappled with these subjects.

While ethics can seem to be an abstraction that calls for relative, somewhat subjective value judgments, there is actually a far more grounded, practical definition. Ethics is, simply, the shared values and norms that define how people interact. Principally, ethics is how people treat each other. Very often, ethics is explicitly expressed as positive law; at all times, ethics informs the positive law. They are inexorably intertwined.

Our concern with the proposed language and its underlying rationale, therefore, is that it both "sells the courts short" and does not comport with these more recent statutes and regulations. As a result, it could lead to *inconsistent enforcement* of both the letter and spirit of those laws.

Consequently, we believe the current environment presents a singular opportunity to establish a general requirement for *promoting a culture of ethics and compliance*, as opposed to merely a culture of compliance. We believe this is not only an achievable goal, but moreover sends a strong signal that compliance with legal minimums will not be the standard by which the sentencing courts will evaluate behavior, but instead virtue and values do indeed matter. Only through reference to fundamental legal *and ethical* principles will the Commission be able to properly discourage actions that while technically legal, undermine the spirit of the law.

Indeed, the criteria currently proposed by the Commission to determine whether an organization has promoted a culture of compliance with the law may just as easily be used to assess whether the organization has promoted a culture of compliance with law *and ethics*. Courts and prosecutors may then use the standards currently espoused in the

proposed amendments for promoting a culture of compliance to just as easily measure an organization's commitment to promoting a culture of ethics and compliance. This allows for an analysis of how well the organization promotes ethics without requiring an analysis of how ethical an organization is.

Without a commitment to ethics, the Commission runs the risk of its guidelines fostering the same types of corporate cultures that allowed individuals to seek out "loopholes" in the law that led to many of the recent corporate crises. By including ethics in §8B2.1.(a)(2), the Commission not only retains intellectual consistency, but it will be implementing both the words and spirit of recent legislation and regulations.

### THE PRECEDENT FOR ETHICS

The notion of at least some government oversight of business ethics is a well-established one. And contrary to the Advisory Group's assertion, courts and prosecutors are both equipped and willing to engage in at least some assessment of ethical behavior. Indeed, much of the criminal law and the analysis of criminal behavior in the courtroom relies on an assessment of a defendant's motive. Every day, courts and juries examine motive, comparing it against the community's values (*i.e.*, its ethical framework) to determine how well or mal-intentioned the defendant's actions were. This values-based (or ethics-based) determination informs the culpability decision and ultimately, the sentence meted out. Moreover, the basic tenets of tort law are based on ethics. Before the advent of standards of strict liability, which effectively compensate harm based on notions of causation and, ultimately, who can afford to pay the compensation, tort law had as its foundation the precept of duty. Duty is simply the assigned moral obligation to behave in a certain way--an obligation interpreted and assigned by judges and which ultimately established the common law of torts.

There is also a long history of all three branches of government encouraging, if not explicitly mandating, at least some focus on ethics in business. Indeed, among Congress's objectives in passing the federal securities laws in the early 1930s was the promotion of honest securities markets. By passing these laws, Congress sought "to substitute a philosophy of full disclosure for the philosophy of caveat emptor and thus to achieve a high standard of business ethics in the securities industry." *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 151, 92 S.Ct. 1456, 31 L.Ed.2d 741 (1972) (footnote omitted). And since their passage, the courts have broadly construed the securities laws over the years to achieve this stated purpose. *See Davenport v. A.C. Davenport & Son Co.*, 903 F.2d 1139, C.A.7 (Ill.), 1990 ("The fundamental purpose of section 10(b) and rule 10(b)(5) is to achieve a high standard of business ethics. This purpose is taken seriously and is broadly construed").

Of course, ethics is not limited to the securities laws. Many federal laws are founded on ethical principles and require at least some recognition of those principles in applying the laws to the facts of any particular case. *See, e.g., Vulcan Engineering Co., Inc. v. Fata Aluminium, Inc.*, 278 F.3d 1366 Fed Cir. C.A.Fed. (Mich.), 2002, Feb. 5,



2002. ("The rules of patent infringement are rules of *business ethics*, and require prudent commercial actions in accordance with law")(emphasis added).

And in government procurement, by both statute and regulation, the executive branch is required to assess an organization's ethics on a regular basis. Pursuant to both the Office of Federal Procurement Policy Act of 1974 and the Federal Acquisition Regulation (FAR), some of the factors to be considered in determining whether a prospective contractor is a "responsible source" include whether it has adequate financial resources; the ability to comply with delivery and performance schedule; a satisfactory performance record; and a satisfactory record of *integrity and business ethics*. 41 U.S.C. § 403(7)(Supp.2001); 48 C.F.R. § 9.104-1(a)-(d).<sup>1</sup>

Even the common law is rife with examples of ethics finding their way into the legal analysis. One example is the tort of interference with contract. *See* Restatement (Second) of Torts § 767 cmt. i (1977) (stating that, when the courts have yet to approve or disapprove of a certain practice, "[r]ecognized standards of *business ethics* and business customs and practices are pertinent" in determining whether interference with a contract was improper) (emphasis supplied). *See also, Saglioccolo v. Eagle Ins. Co.*, 112 F.3d 226, (6<sup>th</sup> Cir. 1997) (citing the Restatement with approval); *Morrow v. FBS Ins. Montana-Hoiness Labar, Inc.*, 749 P.2d 1073, 1076 (Mont.1988) (Montana Supreme Court cited approvingly to the Restatement (Second) of Torts, § 767 at 38-39 (1977), as a correct statement of the law in Montana on proper or improper motive.); *Ackerson v. Ackerson*, 895 F.2d 1416 (Table) C.A.9 (Mont.),1990 (unpublished opinion) (noting that the Restatement in Comment 1 concludes that "when there is room for different views, the determination of whether the interference is improper or not is ordinarily left to the jury, to obtain its common feel for the state of community mores and for the manner in which they would operate upon the facts in question").

Another example is the tort of economic duress. The tort finds its basis in business ethics. "The rationale underlying the principle of economic duress is the imposition of certain minimal standards of *business ethics* in the market place." *Centric Corp. v. Morrison-Knudsen Co.*, 731 P.2d 411, 413 (Okla.1986).

Moreover, as the Advisory Group and Commission recognized, Congress and regulators have been even more than willing to prescribe at least some focus on ethics within organizations. For example, codes of ethics for senior executives of publicly traded companies are now essentially mandated by law and regulation<sup>2</sup>, and Nasdaq and NYSE-listed companies must have codes of ethics for all employees.

In addition, the Department of Health and Human Services Office of Inspector General requires pharmaceutical manufacturers have written policies and procedures and

<sup>1</sup> We also note that most government employees at the local, state, and national level are subject to various ethics requirements, including statutory ethical duties found in ethics-in-government legislation.

<sup>2</sup> The Securities and Exchange Commission requires that companies have and disclose codes of ethics for certain senior executives or disclose why they do not have such codes.

recommends that they "develop a general corporate statement of ethical and compliance principles that will guide company operations." According to the OIG, the purpose of such a code is to "function in the same fashion as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within an organization." *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, Office of Inspector General, Department of Health and Human Services, Fed. Reg. Vol. 68, No. 86, 23731 at 23733 (May 5, 2003).

And lately, responding to the sense of frustration felt by the public, even the courts have willingly entered the ethics debate, indicating a fundamental shift in the manner in which they view ethics as part of the judicial process. This has manifested itself in several ways. First, as a greater emphasis on ethics in analysis:

- "The facts involved in this case reflect an inexplicable lack of *business ethics and an atmosphere of general lawlessness* that infected the very heart of one of America's leading corporate citizens." *U.S. v. Andreas*, 216 F.3d 645, (7th Cir. 2000) (referring to agricultural conglomerate Archer Daniels Midland Co.) (emphasis added).
- "Rejecting [defendant's] assertions, the SEC viewed his felonious conduct as a serious breach of his obligation to maintain high standards of business ethics, a threat to the integrity of the securities market, and undermining federal taxing power... We find no basis to set aside the SEC's findings and conclusions, and therefore affirm." *Haberman v. S.E.C.*, 205 F.3d 1345 (8th Cir. 2000) (unpublished disposition).

This is not to say that there should be no limitations on the courts' ability to assess ethical standards and conduct. The point of judicial analysis of an organization's commitment to ethics and law should be to assess whether the organization has effectively promoted them and not whether they have achieved some standardized culture of ethical and legal compliance. That is, courts should not assess *how ethical* an organization is, but *how hard* it has tried.

Moreover, we believe that there is little risk that a court would choose to engage in the exercise of assessing an organization's ethics. This is especially so when the principles applicable at law (*i.e.*, the Chapter 8 guidelines) provide ample guidance toward the appropriate analysis: whether the organization has effectively *promoted* a culture of ethics and compliance. Indeed, as recently as last October, Judge Pollack declined to engage in the exercise of assessing an organization's ethical behavior, stating that "[t]he plaintiffs in the above-captioned putative class actions would have this Court punish breaches of business ethics by principles applicable at law which did not at the time apply to such conduct." However, the implication is that, had such "principles applicable at law" applied at the time, Judge Pollack would have engaged in the appropriate analysis. *In re Merrill Lynch & Co., Inc. Research Reports Securities Litigation*, 289 F.Supp.2d 416, 418 (SDNY. 2003).



And perhaps most remarkable to date has been the recent landmark settlement response – with the enforceability of the court's permanent injunction – to one of the largest securities frauds ever to occur in the United States. In *SEC v. Worldcom*, Judge Rakoff noted:

In the instant lawsuit, however, the Securities and Exchange Commission (the "Commission"), with the full cooperation of the company's new management and significant encouragement from the Court-appointed Corporate Monitor (Richard C. Breeden, Esq.), has sought something different:

- not just to clean house but to put the company on a new and positive footing;
- not just to enjoin future violations but to create models of corporate governance and internal compliance for this and other companies to follow;
- not just to impose penalties but to help stabilize and reorganize the company and thereby help preserve more than 50,000 jobs and obtain some modest, if inadequate, recompense for those shareholder victims who would otherwise recover nothing whatever from the company itself.

The permanent injunction also requires the company to provide a large segment of its employees with specialized training in accounting principles, public reporting obligations, and *business ethics*, in accordance with programs being specially developed for the company by New York University and the University of Virginia. At the behest of the Corporate Monitor, the Court also obtained from the new Chief Executive Officer a sworn "*Ethics Pledge*," requiring, on pain of dismissal, a degree of transparency well beyond S.E.C. requirements. The company has since required its senior management to sign a similar pledge, and has plans to obtain similar pledges from virtually all employees.

*S.E.C. v. Worldcom, Inc.*, 273 F.Supp.2d 431, S.D.N.Y.,2003 (emphasis added).

In sum it is our considered opinion that as long as the guidelines focus on compliance and do not explicitly include an ethical component, the discussion will remain about that which is required to do and not that which is right to do. A more prudent course, and one more consistent with the activities of the other branches of government and of industry itself, is to foster a culture based on both compliance and ethics. Only in that way will we help build a system in which both compliance and virtue are their own rewards.

Consequently, we believe the Commission should make the following changes to the proposed amendments:

## §8B2.1(a)(2)

"otherwise promote an organizational culture that encourages a commitment to ethics and the law."

## §8B2.1(b)

"Due diligence and the promotion of an organizational culture that encourages a commitment to ethics and compliance with the law."

## §8B2.1(b)(1)

"The organization shall establish ethics and compliance standards and procedures to prevent and detect violations of law."

LRN would like to again thank the Commission for this opportunity. We hope that our comments will help inform the Commission's considerations and would welcome an opportunity to testify before the Commission to further amplify our perspective.

Sincerely,



Dov Seidman  
Chairman and Chief Executive Officer





S O U T H E R N  
M E T H O D I S T  
U N I V E R S I T Y <sup>SM</sup>

*Maguire Center for Ethics and Public Responsibility*

February 13, 2004

The Honorable Judge Diana M. Murphy, Chair  
U.S. Sentencing Commission  
One Columbus Circle NE, Suite 2-500  
Washington DC 20002-8002

Dear Judge Murphy,

I have read Robert Olson, Stuart Gilman, and Michael Hoffman's thoughtful letter, bill mark-up, and justification with respect to proposed amendments to the FSGO. They deserve your most careful reading and consideration.

It is vital to address the authors' recommendation that Guidelines stress society's aspirations for a supportive organizational culture and good ethical environment, beyond mere compliance. The founding fathers recognized this. We should too. This amendment must set noble goals as well as legalistic minimums.

Thank you for your time and consideration.

Sincerely,

Richard O. Mason, Director  
The Cary M. Maguire Center for Ethics  
and Public Responsibility  
and Carr P. Collins Distinguished Professor  
214.768-3145  
[rmason@mail.cox.smu.edu](mailto:rmason@mail.cox.smu.edu)

ROM:lt

CC: Robert J. Olson, PhD, Principal Consultant  
Stuart Gilman, PhD, President  
Michael Hoffman, PhD, Executive Director

*ETHICS CENTER ADVISORY BOARD*

Mrs. Ruth Sharp Altshuler  
*Dallas philanthropist*  
Mr. Henry C. Beck Jr.  
*Henry C. Beck Co.*  
Mr. Bob Buford  
*The Buford Foundation*  
Mr. John Castle  
*Dallas attorney*  
Dr. John Connolly  
*Texas School Coalition*  
Mrs. Jeanne Tower Cox  
*Dallas philanthropist and civic leader*  
Mr. Charles G. Cullum  
*Charles Cullum Investments*  
Mr. Ward L. Huey Jr.  
*Belo Corp.*  
Mr. Vester T. Hughes Jr.  
*Hughes & Luce L.L.P.*  
Mr. Ray L. Hunt  
*Hunt Consolidated Inc.*  
Hon. Lee F. Jackson  
*Dallas County Judge/Commissioners Court*  
Dr. Bobby B. Lyle  
*Lyc0 Energy Corporation*  
Mr. Cary M. Maguire  
*Maguire Oil Co.*  
Rev. William K. McElvaney  
*Perkins School of Theology, Emeritus*  
Dr. Ruth Morgan  
*SMU Provost Emerita*  
Dr. Mike Moses  
*Dallas Independent School District*  
Mr. Erle Nye  
*TXU Corporation*  
Bishop William B. Oden  
*United Methodist Church*  
Mrs. Betty Osborne  
*Harry Bock Co.*  
Ms. Caren Prothro  
*Dallas Foundation*  
Major General Hugh G. Robinson  
*The Tetra Group Inc.*  
Dr. Charles C. Sprague  
*Southwestern Medical Foundation*  
Rt. Rev. James M. Stanton  
*Episcopal Diocese of Dallas*

*Ex officio members*

Dr. R. Gerald Turner  
*SMU President*  
Dr. Ross C. Murfin  
*SMU Provost*  
Dr. Richard O. Mason  
*Director of the Maguire Center*  
SMU Student Representative

January 28, 2004

The Honorable Jude Diana M. Murphy, Chair  
U.S. Sentencing Commission  
One Columbus Circle NE, Suite 2-500  
Washington DC 20002-8002

Dear Judge Murphy,

We congratulate you, your fellow commissioners, and your staff for drafting the Proposed Amendments and making them available for public comment. We know that the process has involved considerable time and resources. The result, however, has been amendments to the Guidelines that will make them more relevant to the new millennium.

Yet we're concerned that they are not as germane and significant as they could be. Indeed, if the goal was to go "beyond compliance," they disappoint by not going as far as numerous other governmental bodies, such as the SEC and Congress, have done already. As they stand now, the Proposed Amendments:

- fail to support the integration of "ethics" into compliance programs,
- sidestep an opportunity to re-define "effectiveness" in a substantive way, and
- neglect to reconsider the purview of an ethics and compliance program in the current environment of corporate malfeasance.

In our opinion, the Proposed Amendments need to reflect the proposition that ethics is the heart of law.

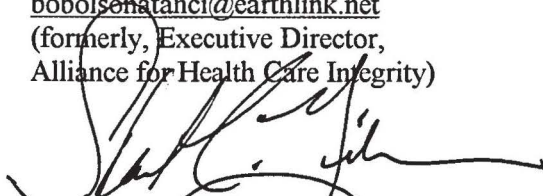
We respectfully offer our suggested changes to the Proposed Amendments with an accompanying justification (please see enclosures). It is our hope that you will consider them in the spirit in which they are offered—a mutual concern for enhancing the public good. We will also be contacting members of Congress in the same spirit. If there's anything we can do to assist the Commission in further understanding these suggested changes—or obtaining documents in support of them—please do not hesitate to contact us.

This process for amending the Federal Sentencing Guidelines for Organizations presents an exciting opportunity, one that will probably not come again for another ten years. We urge the Sentencing Commission to retain its *leadership role* in preventing corporate malfeasance by including the changes we've suggested in the final amendments.

Sincerely,



Robert J. Olson, PhD, Principal Consultant  
MetaEthics  
714.307.6400  
[bobolsenatahci@earthlink.net](mailto:bobolsenatahci@earthlink.net)  
(formerly, Executive Director,  
Alliance for Health Care Integrity)



Stuart Gilman, PhD, President  
Ethics Resource Center  
202.737.2258  
[Stuart@Ethics.org](mailto:Stuart@Ethics.org)



Michael Hoffman, PhD, Executive Director  
Center for Business Ethics at Bentley College  
781.891.2981  
[mhoffman@bentely.edu](mailto:mhoffman@bentely.edu)



# JUSTIFICATION for Suggested Changes to Proposed Amendments to FSGO

*It is questionable whether a compliance program can be truly effective  
if it does not have an ethics component.*

- - - Diana E. Murphy<sup>i</sup>

The changes we have suggested to the Proposed Amendments to the FSGO can be divided into three general categories: Omission of Ethics, Expansion of Ethics and Compliance Program Purview, and Measurement of Program Effectiveness. For each of these categories, we will provide a justification for the suggested changes.

## **Omission of Ethics**

There is no mention of “ethics” in the Proposed Amendments *even though*

- ethics was discussed extensively in the Advisory Group’s Recommendations for Proposed Amendments, primarily in relation to the new developments in the arenas of compliance, ethics, and corporate governance with which the Advisory Group was trying to “synchronize” its recommendations (though *not* in the amendments and commentary it actually recommended);
- ethics figures largely in the “new developments” mentioned by the Advisory Group. For example, the SEC, Sarbanes-Oxley Act of 2002, and the NYSE all encourage or require their constituents to move beyond a compliance-based program to an ethics/values/integrity-based program for the prevention of fraud, waste, and abuse. In addition, the FASB has recently proposed a rule that would change its approach from rule-based to principle-based. All of these “new developments,” although they preceded the Proposed Amendments, are bolder, more innovative, and consistent with best practices, than the Proposed Amendments;
- ethics is the real tenor of “organizational culture” as enunciated in the Proposed Amendments. The concept of “organizational culture” that is apparently substituted for “ethics” simply begs the question of how an organization gets “beyond compliance” and how it measures whether its culture “promotes compliance with law.” An organization can strengthen its compliance program by enforcing more compliance with law ever more rigorously (and penalties for noncompliance), but in doing so it risks turning itself into a police state. Alternatively, it can situate compliance in ethics inasmuch as the laws that are the object of compliance are already grounded in ethical principles. To do otherwise only reinforces what William Widen in a recent article in *The Business Lawyer* refers to as “technical compliance”<sup>ii</sup>—or the Office of the Inspector General calls a “paper program”;
- ethics is no more “fuzzy” than the law. Both require interpretation, ethics within the organization as business decisions are made, and law in the judicial system by attorneys (and at much greater cost to the organization and public). Furthermore, the reluctance to refer to ethics in the Proposed Amendments seems to be based, in part, on the mistaken notion that by doing so they obviate the need for “...prosecutors to litigate and judges to determine whether an organization has a ‘good set of values’ or ‘appropriate ethical standards.’”<sup>iii</sup> This is simply not the case. Prosecutors and judges would still have to make

a separate determination about the effectiveness of the organizational culture in promoting compliance with law. In contrast, they could determine the effectiveness of the organization's *ethics-compliance program* based on

- 1) the existence of a statement of ethical principles and the integrated ethics-compliance interventions taken by the organization to realize them (and, thus, achieve compliance with the letter *and* the spirit of the law) and/or
- 2) the resulting, tested/ observed changes in knowledge, attitudes/ values/beliefs/norms, and short-term practices among employees and, consequently, the organization.

The latter is preferable, of course, because due diligence is only a tenth of the battle—the proof is in the pudding. Furthermore, prosecutors and judges would have to do no more than they are already doing with regard to evaluating an compliance programs. That is, they would simply

- 1) ask for documentation that explains the program,
- 2) compare the program against existing model standards, and
- 3) then assess the extent to which the organization has effectively implemented its program.

Each of these steps fits with current and proposed approaches to measuring compliance program effectiveness.

- ethics could be integrated into the Proposed Amendments *without breaking new ground* for the Sentencing Commission, thereby raising questions about its mission. That ground was broken with the original, 1991 guidelines when the Sentencing Commission shifted its attention from looking solely at the crime, its perpetrators, and the organization as a whole—to looking at ways to prevent the occurrence of crime. Compliance programs went part of the way (but, given the epidemic of corporate in the last several years, clearly not far enough); ethics goes the rest of the way. The integration of ethics into compliance programs only enhances those programs and increases their effectiveness.

The time is ripe for the Sentencing Commission to maintain its leadership in the prevention of corporate crime by giving ethics its rightful place in the Proposed Amendments.

### **Expansion of Ethics and Compliance Program's Purview**

If we've learned anything in the last several years about prevention of corporate crime, it is that ethics and compliance programs need to drill deeper and climb higher in the organization.

When they do not, the result is often what Widen describes with respect to Enron:

The cultural problem revealed by Enron ultimately is not subject to correction by teaching lawyers more accounting, fine tuning rules governing the use of "gatekeepers" in corporate matters, or requiring and expecting more from independent directors, though all these measures would help in a small way. The problem is that corporate and legal culture has lost all sense of right and wrong. Norms and business behavior have evolved so that compliance with the positive law is the so-called standard of ethical conduct—a role for which positive law is ill-suited.<sup>iv</sup>

For this reason, we have suggested changes to the Proposed Amendments that expand the ethics and compliance program into all levels and functions of the organization (total internal market penetration, if you will), particularly the decisions made by officers and directors.



For example, we recommend that

- the Ethics and Compliance Officer be a *real* officer of the corporation with full rights and responsibilities in all executive decisions.
- this individual have academic and/or certificated training in both ethics and law (though she need not have a PhD in ethics or a JD in law).
- the Sentencing Commission consider including language in the commentary to the proposed “auditing and monitoring amendment” that suggests an “ethical impact report” for all major strategy and financial decisions. Many an Enron could have been prevented if an ethical impact report would have laid bare *in a documented fashion* the potential violations of ethical principles and law *before* a decision was made to go forward.

Finally, the effectiveness of an ethics and compliance program is not only measured in terms of the channels and messages it uses for communicating with employees; it is also effective in terms of the ways and extent to which it institutionalizes itself. In fact, if the literature is right, the latter may be much more significant than the former. One way to institutionalize itself is the command-and-control structure that sets up the program, designs its policies and procedures, and communicates them to the organization. The other—and far more effective—is the participatory structure that seeks the participation of employees, managers, officers, and directors (and other stakeholders, as appropriate) in the design, implementation, and evaluation of the program. Models for this latter structure include The Conference Model, Future Search, and Whole System Change. Thus, if an ethics and compliance program is going to be truly effective, it will need to become simply the way the organization goes about its business.

### Measurement of Program Effectiveness

- The Proposed Amendments fail to enunciate any real measures of program effectiveness. Instead, they add more due diligence criteria, which, in the final analysis, cannot distinguish between a “paper program” and a truly effective program (one that follows the letter of the law and one that captures its spirit). Even the highlighting of the Health Care Compliance Association’s criteria<sup>v</sup> does little to advance the discussion since these criteria simply measure more refined aspects of due diligence. Knowing whether something occurred or how many of it occurred, however, is not the same as knowing the impact and outcome of that occurrence.
- The Proposed Amendments, then, ignore written and verbal testimony that delineated strategies for measuring impact, that is, changes in knowledge, attitudes/values/beliefs/norms, and short-term practices. At the very least, these might include pre-and post-testing of training sessions and periodic, self-reported surveys of all employees on key, organizational risk and protective factors for fraud, waste, and abuse. It would not be sufficient, for example, to know that a self-described attorney went to law school (or, to represent another common measure, liked it a lot); we’d want to know that she had passed both law school and the bar exam.
- There are methodologically sound ways, contrary to the opinions expressed in the document,<sup>vi</sup> to measure the effectiveness of ethics-compliance intervention—and even to relate these impact measures to the desired outcomes, namely, the prevention of fraud, waste, and abuse. Program evaluators and behavioral scientists would prove very helpful in this endeavor. At the very least, they could identify proxy measures that are strongly correlated with the incidence of various types of corporate corruption. It is never enough to say that just because we provided compliance training to 3,000 employees that the training

had any impact on them—or achieved the organizational goals of preventing violations of law.

---

<sup>i</sup> Diana E. Murphy, “The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics,” *Iowa Law Review* 87 (2002): 716.

<sup>ii</sup> William H. Widen, “Enron at the Margin,” *The Business Lawyer* 58 (May 2003): *passim*.

<sup>iii</sup> Advisory Group on Organizational Guidelines (AGOG), “Recommendations for Proposed Amendments for Federal Sentencing Guidelines for Organizations” (October 27, 2003): 54.

<sup>iv</sup> Widen 962-3.

<sup>v</sup> AGGO 76ff.

<sup>vi</sup> AGOG 35ff.



**PART B – REMEDYING HARM FROM CRIMINAL CONDUCT, AND  
PREVENTING AND DETECTING VIOLATIONS OF THE LAW**

**1. REMEDYING HARM FROM CRIMINAL CONDUCT**

\* \* \*

**2. PREVENTING AND DETECTING VIOLATIONS OF LAW**

**§8B2.1 Effective Programs to Prevent and Detect Violations of Law**

(a) To have an effective program to prevent and detect violations of law, for purposed of subsection (f) of §8C2.5 (Culpability Score) and subsection (c)(1) of §8D1.4 (Recommended Conditions of Probation – Organizations), an organization shall—

- (1) Exercise due diligence to prevent and detect violations of law; and
- (2) otherwise promote and organizational culture that encourages a commitment to the ethical principles that inform compliance with law

Such program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting violations of law, as well as promoting an organizaitonal culture committed to ethical principles, that is, one that demonstrates commitment to ethical principles and compliance with law. The failure to prevent or detect instant offense leading to sentencing does not necessarily mean that the program is not generally effective in preventing and detecting violations of law, as well as in promoting an organizational culture committed to ethical principles.

(b) Due diligence and the promotion of an organizational culture that encourages a commitment to compliance with law and the ethical principles that inform law within the meaning of subsection (a) minimally require the following steps:

- (1) The organization shall establish ethics and compliance standards and procedures to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles.
- (2) The organizational leadership shall be knowledgeable about the content, and operation, and effectiveness of the program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles.

The organization's governing authority shall be knowledgeable about the content, ~~and operation,~~ and effectiveness of the program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles, and shall exercise reasonable oversight with respect to the implementation and effectiveness of the program to prevent and detect violations of the law, as well as to promote an organizational culture committed to ethical principles.

Specific individual(s) within ~~high~~ executive-level personnel of the organization shall be assigned direct, full-time, overall responsibility to ensure implementation and effectiveness of the program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles. Such individual(s) shall be given adequate resources and authority to carry out such responsibility, including full participation in all major executive decisions, and shall report on the implementation and effectiveness of the program to prevent and detect violations of law, as well as in promoting an organizational culture committed to ethical principles, directly to the governing authority or an appropriate subgroup of the governing authority.

- (3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through exercise of due diligence, has a history of engaging in violations of law or other conduct inconsistent with an effective program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles.
- (4)(A) The organization shall take reasonable steps to institutionalize its ethics and compliance program by
  - (i) using model practices in organizational and systems change and
  - (ii) communicating ~~communicate~~ in a practical manner its ethics and compliance standards and procedures, and other aspects of the program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles, to the individuals referred to in subdivision (B) by conducting effective training programs that include but are not limited to subjects such as ethical and legal decision making, and otherwise disseminating information, appropriate to such individual's respective roles and responsibilities, with special emphasis on the organization's executive team.



(B) The individuals referred to in subdivision (A) are the members of the governing authority, the organizational leadership, the organization's employees, and, as appropriate, the organization's agents.

(5) The organization shall take reasonable steps—

(A) to ensure that the organization's program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles, is followed, including use of monitoring and auditing systems that

(i) -are designed to prevent and detect violations of law and ethical principles that inform law, and

(ii) function at all levels and in all functions of the organization, including, but not limited to, the executive and governing authority level;

(B) to evaluate at least annually periodically the effectiveness of the organization's program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles; and

(C) to have a system whereby the organization's employees and agents may report or seek guidance regarding potential or actual violations of law without fear of retaliation, including mechanisms to allow for anonymous reporting.

(6) The organization's program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles, shall be promoted and enforced consistently through appropriate incentives, such as including compliance with law and commitment to ethical principles as a major component in performance reviews, to perform in accordance with such program and disciplinary measures for engaging in violations of law and for failing to take reasonable steps to prevent or detect violations of law, as well as to promote an organizational culture committed to ethical principles.

(7) After a violation of law or ethical principles that inform law has been detected, the organization shall take reasonable steps to respond appropriately to the violation of law or ethical principles that inform law and to prevent further similar violations of law or ethical principles that inform law, including making any necessary modifications to the organization's program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles, and to the organization's business practices, as necessary.



- (c) In implementing subsection (b), the organization shall conduct at least annually ongoing risk assessment and take appropriate steps to design, implement, or modify each step set for the in subsection (b) to reduce violations of law or ethical principles that inform law identified by the risk assessment.

### Commentary

#### Application Notes:

1. Definitions. For purposes of this guideline:

“Ethics and cCompliance standards and procedures” means standards of conduct, such as a code of ethics or statement of values, and internal control systems that are reasonably capable of reducing the likelihood of violations of law and ethical principles that inform law.

“Governing authority” means (A) the Board of Directors, or (B) if the organization does not have a Board of Directors, the highest level governing body of the organization.

“Organizational leadership” means (A) ~~executive~~high-level personnel of the organization; (B) ~~executive~~high-level personnel of a unit of the organization; and (C) substantial authority personnel. The terms “~~executive~~high-level personnel of the organization” and “substantial authority personnel” have the meaning given those terms in the Commentary to §8A1.2 (Application Instructions – Organizations). The term “~~executive~~~~executive~~-level personnel of a unit of the organization” has the meaning given that term in the Commentary to §8C2.5 (Culpability Score).

“Effective” means not only the count resulting from specific program activities, but also (A) the impact (measured changes in knowledge, attitudes/values/beliefs, and/or short-term practice) of those activities and (B) the outcome of those activities (actual reductions in violations of law or ethical principles that inform law—or well-documented proxies for those violations).

Except as provided in Application Note 4(A), “violations of law” means violations of any law, criminal or noncriminal (including a regulation), for which the organization is, or would be, liable.

2. Factors to Consider in Meeting Requirements of Subsections (a) and (b).—

(A) In General.—Each of the requirements set forth in subsections (a) and (b) shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, the organization shall consider factors that include (i) the size of the organization, (ii) applicable government regulations,



and (iii) any ethics and compliance practices and procedures that are well-documented generally accepted as standard or model practices for businesses similar to the organization.

(B) The Size of the Organization.—

- (i) In General.—The formality and scope of actions that an organization shall take to meet the requirements of subsections (a) and (b), including the necessary features of the organization's ethics and compliance standards and procedures, depend on the size of the organization. A larger organization generally shall devote more formal operations and greater resources in meeting such requirements than shall a smaller organization.
- (ii) Small Organizations.—In meeting the requirements set forth in subsections (a) and (b), small organizations shall demonstrate the same degree of commitment to compliance with the law and commitment to ethical principles that inform law, as larger organizations, although generally with less formality and fewer resources than would be expected of larger organizations.

3. Application of Subsection (b)(2).—

- (A) Governing Authority.—The responsibility of the governing authority under subsection (b)(2) is to exercise reasonable oversight of the organization's efforts to ensure compliance with the law and ethical principles that inform law. In large organizations, the governing authority likely will discharge this responsibility through oversight, whereas in some organizations, particularly small ones, it may be more appropriate for the governing authority to discharge this responsibility by directly managing the organization's ethics and compliance efforts.
- (B) Executive High-Level Personnel.—The organization has discretion to delineate the activities and roles of the specific individual(s) within executive high-level personnel of the organization assigned overall and direct responsibility to ensure the effectiveness and operation of the program to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles; however, the individual(s) must be able to carry out their overall and direct responsibility consistent with subsection (b)(2), including the ability to report on the effectiveness and operation of the program to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles, to the governing authority, or to an appropriate subgroup of the governing authority.

In addition to receiving reports from the foregoing individual(s), the governing authority or an appropriate subgroup thereof typically should receive at least annually/periodically information on the implementation and effectiveness of the



program to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles, from the individual(s) with day-to-day operational responsibility for the program.

(C) Organizational Leadership.—Although the overall and direct responsibility to ensure the effectiveness and operation of the program to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles, is assigned to specific individuals within ~~executive~~ high-level personnel of the organization, it is incumbent upon all individuals within the organizational leadership to be knowledgeable about the content, ~~and~~ operation, and effectiveness of the program to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles, pursuant to subsection (b)(2), and to perform their assigned duties consistent with the exercise of due diligence, and the promotion of an organizational culture that encourages a commitment to ethical principles that inform the compliance with the law, under subsection (a).

4. Application of Subsection (b)(3).—

(A) Violations of Law.—Notwithstanding Application Note 1, “violations of law,” for purposes of subsection (b)(3), means any official determination of a violation or violations of any law, whether criminal or noncriminal (including a regulation).

(B) Consistency with Other Law.—Nothing in subsection (b)(3) is intended to require conduct inconsistent with any Federal, State, or local law, including any law governing employment or hiring practices.

(C) Implementation.—In implementing subsection (b)(3), the organization shall hire and promote individuals consistent with Application Note 3(C) so as to ensure that all individuals with the organizational leadership will perform their assigned duties with the exercise of due diligence, and the promotion of an organizational culture that encourages a commitment to ethical principles that inform law compliance with the law, under subsection (a). With respect to the hiring or promotion of any specific individual within the substantial authority personnel of the organization, an organization shall consider factors such as: (i) the individual’s combined academic and certificated training in ethics and/or law, as well as training in organizational change strategies and behavioral training methodologies (ii) the recency of the individual’s violations of law and other misconduct (i.e., the individual’s other conduct inconsistent with an effective program to prevent and detect violations of law, as well as to promote an organizational culture committed to ethical principles); (iii) the relatedness of the individual’s violations of law and other misconduct to the specific responsibilities the individual is anticipated to be assigned as part of the substantial authority personnel of the organization; and (iii) whether the individual has engaged in a pattern of such violations of law and other misconduct.



5. Risk Assessments under Subsection(c).—Risk assessments required under subsection (c) shall include the following:

- (A) Assessing periodically the risk that violations of law or commitment to ethical principles that inform law will occur, including an assessment of the following:
- (i) The nature and seriousness of such violations of law.
  - (ii) The likelihood that certain violations of law or commitment to ethical principles that inform law may occur because of the nature of the organization's business. If, because of the nature of an organization's business, there is a substantial risk that certain types of violations of law or ethical principles that inform law may occur, the organization shall take reasonable steps to prevent and detect those types of violations of law or ethical principles that inform law. For example, an organization that, due to the nature of its business, handles toxic substances shall establish ethics and compliance standards and procedures designed to ensure that those substances are always handled properly. An organization that, due to the nature of its business, employs sales personnel who have flexibility to set prices shall establish ethics and compliance standards and procedures designed to prevent and detect price-fixing. An organization that, due to the nature of its business, employs sales personnel who have the flexibility to represent the material characteristics of a product shall establish ethics and compliance standards and procedures designed to prevent fraud. Furthermore, an organization shall establish ethics and compliance standards and procedures designed to prevent corporate malfeasance that may result from the decisions of executive management and governing authority.
  - (iii) The prior history of an organization. The prior history of an organization may indicate types of violations of law or ethical principles that inform law that it shall take actions to prevent and detect. Recurrence of similar violations of law or ethical principles that inform law creates doubt regarding whether the organization took reasonable steps to prevent and detect violations of law or ethical principles that inform the law.
- (B) Prioritizing, periodically as appropriate, the actions taken under each step set forth in subsection (b), in order to focus on preventing and detecting the violations of law or ethical principles that inform law identified under subdivision (A) as most likely to occur and most serious.
- (C) Modifying, as appropriate, the actions taken under any step set forth in subsection (b) to reduce the risk of violations of law or ethical principles that inform law identified in the risk assessment.

(D) Assessing at least annually one or more of these characteristics of organizational culture: executive decision making process, impact and/or outcome of this process through use of an "ethics impact report," level of organizational trust, public image, relative disparity in employee compensation, bottom-line mentality and others that are well-documented in the literature.

*Background:* This section sets forth the requirements for an effective program to prevent and detect violations of law. This section responds to section 805(a)(2)(5) of the Sarbanes-Oxley Act of 2002, Public Law 107-204, which directed the Commission to review and amend, as appropriate, the guidelines and related policy statements to ensure that the guidelines that apply to organizations in this Chapter "are sufficient to deter and punish organizational criminal misconduct."

The requirements set forth in this guideline are intended to achieve reasonable prevention and detection of violations of law, both criminal and noncriminal, for which the organization would be vicariously liable, as well as to promote an organizational culture committed to ethical principles. The prior diligence of an organization in seeking to detect and prevent violations of law, as well as to promote an organizational culture committed to ethical principles, has a direct bearing on the appropriate penalties and probation for the organization if it is convicted and sentenced for a criminal offense.

\* \* \*



**JOSEPH E. MURPHY**  
A PROFESSIONAL CORPORATION  
30 TANNER STREET  
HADDONFIELD, NEW JERSEY 08033

TEL: 856-429-5355  
FAX: 856-429-0866

JEMURPHY@CSLG.COM

U.S. Sentencing Commission  
One Columbus Circle, N.E.  
Suite 2-500, South Lobby  
Washington, DC 20002

January 26, 2004

Re: Proposed Amendments to Chapter Eight

Dear Commissioners:

The United States Sentencing Commission has published and requested comments on proposed amendments to Chapter Eight of the Sentencing Guidelines relating to compliance programs. I offer the following comments as a practitioner in the compliance and business ethics field and as one with a strong interest in the success of the Sentencing Commission's efforts to promote effective compliance programs in organizations<sup>1</sup>. I previously had the opportunity to testify in the Ad Hoc Advisory Group's information gathering process and to provide other information for the Group's use prior to the submission of the proposed amendments. I would be happy to testify regarding these comments or any other matters relating to the proposed amendments, should the Commission desire such testimony during this amendment cycle.

**The proposed amendments are a positive step**

The Sentencing Guidelines have brought clarity and commitment to the field of compliance. Indeed, one can fairly mark the emergence of compliance as a discrete field to the date the Guidelines went into effect. If this is so, then it could fairly be asked, why is a change necessary? Perhaps the best answer is that the proposed amendments are not really so much of a change as they are a recognition that this field has evolved and changed over time. The proposed amendments, in effect, actually recognize the reality of industry best practices and bring the Guidelines up to date.

Moreover, these revisions serve to strengthen organizational compliance programs and drive them to be more effective. We need programs that will withstand the circumstances we have all seen in the cases, from Enron to Andersen, and from WorldCom to Parmalat. The proposed changes show excellent insight into the dynamics of compliance programs, and what it takes for them to be truly effective.

**Comments on question 4**

---

<sup>1</sup> Partner, Compliance Systems Legal Group; Vice-Chairman, Integrity Interactive Corporation; Co-editor, *ethikos*. These comments reflect my personal opinions and may not necessarily reflect the views of any organization with which I am associated.

The Commission asks for comment on four questions. These comments address one of those questions.

The challenge: Can we reach smaller organizations? Question four asks if there are factors that could encourage smaller organizations to develop and maintain compliance programs. I strongly believe the answer is “yes.” Of course, government could try the stick approach – make it mandatory, legislate or regulate it, etc. But none of these strong-arm approaches will cause companies to be creative and to take initiative in making their programs truly effective. And they will be accompanied by protests about overregulation and expensive bureaucratic requirements. The preferred approach is to provide a real incentive for companies to adopt programs – the same model that worked for larger organizations in 1991.

The Guidelines now offer all organizations the one incentive of lower fines (and avoiding forced imposition of a program through probation). In truth, however, what has meant more to companies is the prospect that prosecutors and regulators will take good corporate citizenship into account when deciding whether to prosecute any company. It is the same carrot and stick model as the sentencing process, but because this carrot occurs so much earlier in the process, and so few major companies take criminal cases to actual trials and sentencing, it is the carrot of not being prosecuted that stands out as being truly worthwhile to larger companies.

Experience shows that larger companies have been much more influenced by the Sentencing Guidelines. Partly this is because just about any large organization knows it is likely to be in the crosshairs of a prosecutor or regulator at some time and place. Perhaps even more importantly, while larger companies have their own in-house legal departments and are more likely to consider such government initiatives, smaller organizations are notorious for being focused primarily on survival and growth. While long-term wellbeing is important to all companies, short term survival and growth opportunities are the greater, sometimes all-consuming demand on the time of managers at smaller companies.

What will actually reach these smaller organizations? The best incentive is an economic one that has real-world meaning for competitive businesses. For this the most practical approach is to look to the supply chains of the larger companies that are committed to compliance and ethics programs. If the leading companies were to ask their suppliers and contractors about having compliance and ethics programs, and if this became a significant factor in winning business and benefits from these larger companies, such a change could cause a dramatic transformation of the compliance landscape.

Just to give one example, Integrity Interactive Corporation, the online compliance training company I co-founded, has grown dramatically and has instituted its own compliance program, with its own compliance officer, required employee training, and a code of conduct. In 2003 it became a member of the Ethics Officer Association. Integrity Interactive did this because it was the right thing to do, but also because we believed it was something our customers should expect of any substantial supplier.



In contrast, the company has simply not seen compliance officers from the major law firms joining the EOA, or contacting Integrity Interactive for training, or doing any of the other things that Integrity and its customers do. We have not seen stories in the compliance press about the major US law firms adopting Sentencing Guidelines-type compliance programs; even though they are as much “organizations” as the companies they advise.

If law firms and other service providers can successfully offer compliance-related services to compliance sensitive major companies without even being asked if they have compliance programs themselves, this suggests very little market incentive for others to adopt such programs.

It should be noted that many of these smaller organizations may have the type of subject-specific “programs” that were characteristic of large corporations before the Guidelines – perfunctory EEO training, signs over the copiers warning people about copyright infringement, unread labor standards fliers on a bulletin board -. but nothing that matches the management focus and rigor of the Guidelines.

How could larger companies make this change happen? I would not recommend that companies be expected to require that all of their suppliers have compliance programs, or that they be expected to police their entire supply chain. Such a demand would not be realistic, and could be an enormous distraction for companies. On the other hand, the current environment in which companies do not even ask such compliance-sensitive suppliers as their outside counsel whether they have a compliance program, is hard to justify.

Large companies could require that some suppliers in sensitive areas, such as those who handle their hazardous waste, have rigorous programs. (The risk is so high, this is likely already a common practice) But they could also just enquire of other suppliers whether they have such programs. Companies could make it clear that having such a program is a plus factor in selecting suppliers. Any indication that a compliance program at a supplier represents a competitive advantage could have a dramatic effect on this next tier of the economy. Compliance advocates in all companies look to be able to sell management on the advantages of having an effective compliance program, but usually must rely on scare tactics; imagine the impact of being part of the team that actually wins business because of the compliance program; few things could matter more.

What would be the rationale for larger companies to take this step? Perhaps the best reason is that it helps strengthen their own compliance programs and could help cut off problems at the source. For example, a supplier with a strong compliance program is less likely to offer gifts and hospitality that are unethical. It is less likely to get its customer into trouble for environmental violations or improper overseas payments. Its employees are less likely to engage in harassment which could also be attributed to its customer. And it is less likely to engage in the types of aiding and abetting in financial fraud that are alleged to have happened in the Enron case. A contractor, agent, or consultant is less

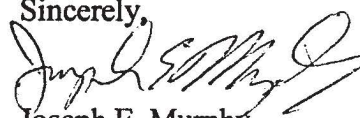
likely to aid a customer's employees in engaging in misconduct if that supplier has instituted strong procedures to ensure legal and ethical conduct.

How would this fit into the Guidelines standards? There are several options. It could be included in item 1, through the Commentary, as one of the standards and procedures a company would adopt. A reference could also be added in commentary on item 4, to the effect that to the extent it was appropriate to have compliance communications to agents, this element could be discharged by having one's agents institute programs of their own. The risk assessment discussion could note that an organization that uses third parties to perform functions for it may require that those third parties themselves adopt compliance programs. Attached is copy of the proposed Guidelines amendments with these insertions marked in.

### **Comments on the "litigation dilemma" and the Commission's role**

Finally, these Comments second a point made by the Advisory Group about the role of the Commission as a catalyst for change. The litigation dilemma identified in the Advisory Group's report needs to be examined, and policy makers need to consider how best to promote compliance consistently. It is also absolutely essential that the Department of Justice and other enforcement and regulatory arms of the government understand how important their role is in getting organizations to energize their compliance programs. If the Department were to be more public about how it takes compliance programs into account and how it measures them, this could add enormous clout to in-house compliance people. For example, if the government were publicly to consider it a sign of bad faith for a company to fail to ask its outside counsel and accountants about those legal and accounting firms' compliance programs, this could change the compliance landscape in entire sectors of the economy.

The Commission is the agency best able to foster the needed discussion in these areas, based on its unique mandate and independent position in the government. I encourage the Commission to formally undertake this mission as a catalyst for change going forward.

Sincerely,  
  
Joseph E. Murphy



The proposed revisions addressing question 4 are in black, in the Commentary.

## 2. PREVENTING AND DETECTING VIOLATIONS OF LAW

### §8B2.1. Effective Program to Prevent and Detect Violations of Law

(a) To have an effective program to prevent and detect violations of law, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (c)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

- (1) exercise due diligence to prevent and detect violations of law; and
- (2) otherwise promote an organizational culture that encourages a commitment to compliance with the law.

Such program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting violations of law. The failure to prevent or detect the instant offense leading to sentencing does not necessarily mean that the program is not generally effective in preventing and detecting violations of law.

(b) Due diligence and the promotion of an organizational culture that encourages a commitment to compliance with the law within the meaning of subsection (a) minimally require the following steps:

- (1) The organization shall establish compliance standards and procedures to prevent and detect violations of law.
- (2) The organizational leadership shall be knowledgeable about the content and operation of the program to prevent and detect violations of law.

The organization's governing authority shall be knowledgeable about the content and operation of the program to prevent and detect violations of the law and shall exercise reasonable oversight with respect to the implementation and effectiveness of the program to prevent and detect violations of the law.

Specific individual(s) within high-level personnel of the organization shall be assigned direct, overall responsibility to ensure the implementation and effectiveness of the program to prevent and detect violations of law. Such individual(s) shall be given adequate resources and authority to carry out such responsibility and shall report on the implementation and effectiveness of the program to prevent and detect violations of law directly to the governing authority or an appropriate subgroup of the governing authority.

- (3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any

individual whom the organization knew, or should have known through the exercise of due diligence, has a history of engaging in violations of law or other conduct inconsistent with an effective program to prevent and detect violations of law.

- (4)
    - (A) The organization shall take reasonable steps to communicate in a practical manner its compliance standards and procedures, and other aspects of the program to prevent and detect violations of law, to the individuals referred to in subdivision (B) by conducting effective training programs, and otherwise disseminating information, appropriate to such individual's respective roles and responsibilities.
    - (B) The individuals referred to in subdivision (A) are the members of the governing authority, the organizational leadership, the organization's employees, and, as appropriate, the organization's agents.
  - (5) The organization shall take reasonable steps—
    - (A) to ensure that the organization's program to prevent and detect violations of law is followed, including using monitoring and auditing systems that are designed to detect violations of law;
    - (B) to evaluate periodically the effectiveness of the organization's program to prevent and detect violations of law; and
    - (C) to have a system whereby the organization's employees and agents may report or seek guidance regarding potential or actual violations of law without fear of retaliation, including mechanisms to allow for anonymous reporting.
  - (6) The organization's program to prevent and detect violations of law shall be promoted and enforced consistently through appropriate incentives to perform in accordance with such program and disciplinary measures for engaging in violations of law and for failing to take reasonable steps to prevent or detect violations of law.
  - (7) After a violation of law has been detected, the organization shall take reasonable steps to respond appropriately to the violation of law and to prevent further similar violations of law, including making any necessary modifications to the organization's program to prevent and detect violations of law.
- (c) In implementing subsection (b), the organization shall conduct ongoing risk assessment and take appropriate steps to design, implement, or modify each step set forth in subsection (b) to reduce the risk of violations of law identified by the risk assessment.



Commentary

Application Notes:

1. Definitions.—For purposes of this guideline:

"Compliance standards and procedures" means standards of conduct and internal control systems that are reasonably capable of reducing the likelihood of violations of law. To the extent that an organization's culture and ability to comply with the law are affected by those third parties who provide it services, its control systems may include efforts to have such third parties adopt their own programs to prevent and detect violations of law.

"Governing authority" means the (A) the Board of Directors, or (B) if the organization does not have a Board of Directors, the highest level governing body of the organization.

"Organizational leadership" means (A) high-level personnel of the organization; (B) high-level personnel of a unit of the organization; and (C) substantial authority personnel. The terms "high-level personnel of the organization" and "substantial authority personnel" have the meaning given those terms in the Commentary to §8A1.2 (Application Instructions - Organizations). The term "high-level personnel of a unit of the organization" has the meaning given that term in the Commentary to §8C2.5 (Culpability Score).

Except as provided in Application Note 4(A), "violations of law" means violations of any law, whether criminal or noncriminal (including a regulation), for which the organization is, or would be, liable.

2. Factors to Consider in Meeting Requirements of Subsections (a) and (b).—

(A) In General.—Each of the requirements set forth in subsections (a) and (b) shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, the organization shall consider factors that include (i) the size of the organization, (ii) applicable government regulations, and (iii) any compliance practices and procedures that are generally accepted as standard or model practices for businesses similar to the organization.

(B) The Size of the Organization.—

(i) In General.—The formality and scope of actions that an organization shall take to meet the requirements of subsections (a) and (b), including the necessary features of the organization's compliance standards and procedures, depend on the size of the organization. A larger organization generally shall devote more formal operations and greater resources in meeting such requirements than shall a smaller organization.

(ii) Small Organizations.—In meeting the requirements set forth in subsections (a) and (b), small organizations shall demonstrate the same degree of commitment to compliance with the law as larger organizations, although generally with less formality and fewer resources than would be expected of larger organizations. While each of the requirements set forth in subsections (a) and (b) shall be

*substantially satisfied by all organizations, small organizations may be able to establish an effective program to prevent and detect violations of law through relatively informal means. For example, in a small business, the manager or proprietor, as opposed to independent compliance personnel, might perform routine audits with a simple checklist, train employees through informal staff meetings, and perform compliance monitoring through daily "walk-arounds" or continuous observation while managing the business. In appropriate circumstances, this reliance on existing resources and simple systems can demonstrate the same degree of commitment that, for a much larger organization, would require more formally planned and implemented systems.*

- (C) Applicable Government Regulations.—*The failure of an organization to incorporate within its program to prevent and detect violations of law any standard required by an applicable government regulation weighs against a finding that the program was an "effective program to prevent and detect violations of law" within the meaning of this guideline.*

3. Application of Subsection (b)(2).—

- (A) Governing Authority.—*The responsibility of the governing authority under subsection (b)(2) is to exercise reasonable oversight of the organization's efforts to ensure compliance with the law. In large organizations, the governing authority likely will discharge this responsibility through oversight, whereas in some organizations, particularly small ones, it may be more appropriate for the governing authority to discharge this responsibility by directly managing the organization's compliance efforts.*
- (B) High-Level Personnel.—*The organization has discretion to delineate the activities and roles of the specific individual(s) within high-level personnel of the organization assigned overall and direct responsibility to ensure the effectiveness and operation of the program to detect and prevent violations of law; however, the individual(s) must be able to carry out their overall and direct responsibility consistent with subsection (b)(2), including the ability to report on the effectiveness and operation of the program to detect and prevent violations of law to the governing authority, or to an appropriate subgroup of the governing authority.*

*In addition to receiving reports from the foregoing individual(s), the governing authority or an appropriate subgroup thereof typically should receive periodically information on the implementation and effectiveness of the program to detect and prevent violations of law from the individual(s) with day-to-day operational responsibility for the program.*

- (C) Organizational Leadership.—*Although the overall and direct responsibility to ensure the effectiveness and operation of the program to detect and prevent violations of law is assigned to specific individuals within high-level personnel of the organization, it is incumbent upon all individuals within the organizational leadership to be knowledgeable about the content and operation of the program to detect and prevent violations of law pursuant to subsection (b)(2), and to perform their assigned duties consistent with the exercise of due diligence, and the promotion of an organizational culture that encourages a commitment to compliance with the law, under subsection (a).*



4. Application of Subsection (b)(3).—
- (A) Violations of Law.—Notwithstanding Application Note 1, “violations of law,” for purposes of subsection (b)(3), means any official determination of a violation or violations of any law, whether criminal or noncriminal (including a regulation).
  - (B) Consistency with Other Law.—Nothing in subsection (b)(3) is intended to require conduct inconsistent with any Federal, State, or local law, including any law governing employment or hiring practices.
  - (C) Implementation.—In implementing subsection (b)(3), the organization shall hire and promote individuals consistent with Application Note 3(C) so as to ensure that all individuals within the organizational leadership will perform their assigned duties with the exercise of due diligence, and the promotion of an organizational culture that encourages a commitment to compliance with the law, under subsection (a). With respect to the hiring or promotion of any specific individual within the substantial authority personnel of the organization, an organization shall consider factors such as: (i) the recency of the individual’s violations of law and other misconduct (i.e., the individual’s other conduct inconsistent with an effective program to prevent and detect violations of law); (ii) the relatedness of the individual’s violations of law and other misconduct to the specific responsibilities the individual is anticipated to be assigned as part of the substantial authority personnel of the organization; and (iii) whether the individual has engaged in a pattern of such violations of law and other misconduct.
5. Application of Subsection (b)(4).— To the extent it is appropriate to provide training and otherwise disseminate information to the organization’s agents, an organization may satisfy this provision if the agent adopts its own program to prevent and detect violations of law that includes such training and dissemination of information..
6. Risk Assessments under Subsection (c).—Risk assessment(s) required under subsection (c) shall include the following:
- (A) Assessing periodically the risk that violations of law will occur, including an assessment of the following:
    - (i) The nature and seriousness of such violations of law.
    - (ii) The likelihood that certain violations of law may occur because of the nature of the organization’s business. If, because of the nature of an organization’s business, there is a substantial risk that certain types of violations of law may occur, the organization shall take reasonable steps to prevent and detect those types of violations of law. For example, an organization that, due to the nature of its business, handles toxic substances shall establish compliance standards and procedures designed to ensure that those substances are always handled properly. An organization that, due to the nature of its business, employs sales personnel who have flexibility to set prices shall establish compliance standards and procedures designed to prevent and detect price-fixing. An organization that, due to the nature of its

*business, employs sales personnel who have flexibility to represent the material characteristics of a product shall establish compliance standards and procedures designed to prevent fraud. An organization that uses third parties to perform functions for it may require that those third parties themselves adopt programs to prevent and detect violations of law.*

- (iii) The prior history of the organization. The prior history of an organization may indicate types of violations of law that it shall take actions to prevent and detect. Recurrence of similar violations of law creates doubt regarding whether the organization took reasonable steps to prevent and detect those violations of law.*
- (B) Prioritizing, periodically as appropriate, the actions taken under each step set forth in subsection (b), in order to focus on preventing and detecting the violations of law identified under subdivision (A) as most likely to occur and most serious.*
- (C) Modifying, as appropriate, the actions taken under any step set forth in subsection (b) to reduce the risk of violations of law identified in the risk assessment.*

*Background: This section sets forth the requirements for an effective program to prevent and detect violations of law. This section responds to section 805(a)(2)(5) of the Sarbanes-Oxley Act of 2002, Public Law 107-204, which directed the Commission to review and amend, as appropriate, the guidelines and related policy statements to ensure that the guidelines that apply to organizations in this Chapter "are sufficient to deter and punish organizational criminal misconduct."*

*The requirements set forth in this guideline are intended to achieve reasonable prevention and detection of violations of the law, both criminal and noncriminal, for which the organization would be vicariously liable. The prior diligence of an organization in seeking to detect and prevent violations of law has a direct bearing on the appropriate penalties and probation terms for the organization if it is convicted and sentenced for a criminal offense.*



**PRESIDENT**

**E. E. (Bo) Edwards**  
Nashville, TN

**PRESIDENT ELECT**

**Barry C. Scheck**  
New York, NY

**FIRST VICE PRESIDENT**

**Barbara E. Bergman**  
Albuquerque, NM

**SECOND VICE PRESIDENT**

**Martin S. Pinales**  
Cincinnati, OH

**TREASURER**

**Jeralyn E. Merritt**  
Denver, CO

**SECRETARY**

**John Wesley Hall, Jr.**  
Little Rock, AR

**PARLIAMENTARIAN**

**William D. Massey**  
Memphis, TN

**IMMEDIATE PAST PRESIDENT**

**Lawrence S. Goldman**  
New York, NY

**DIRECTORS**

**Hal R. Arenstein**  
Cincinnati, OH

**Steven D. Benjamin**  
Richmond, VA

**Donald A. Bosch**  
Knoxville, TN

**William H. Buckman**  
Moorestown, NJ

**Jerry J. Cox**  
Mt. Vernon, KY

**Richard A. Cremer**  
Roseburg, OR

**Joshua L. Dratel**  
New York, NY

**David A. Elden**  
Los Angeles, CA

**Priscilla E. Forsyth**  
Sioux City, IA

**Stephen R. Glassroth**  
Montgomery, AL

**Leslie Hagin**  
Seattle, WA

**Carmen D. Hernandez**  
Washington, DC

**Robert J. Hooker**  
Tucson, AZ

**Bret H. Huggins**  
Florence, AZ

**Richard S. Jaffe**  
Birmingham, AL

**William (Bill) O. James, Jr.**  
Little Rock, AR

**Kathryn M. Kase**  
Houston, TX

**Helen Leiner**  
Fairfax, VA

**Jack T. Litman**  
New York, NY

**J. Cheney Mason**  
Orlando, FL

**William D. Massey**  
Memphis, TN

**Randi McGinn**  
Albuquerque, NM

**Daniel E. Monnat**  
Wichita, KS

**E. G. (Gerry) Morris**  
Austin, TX

**William H. Murphy, Jr.**  
Baltimore, MD

**Cynthia Hujar Orr**  
San Antonio, TX

**Ellen S. Podgor**  
Tucker, GA

**Barry J. Pollack**  
Washington, DC

**Jeffery P. Robinson**  
Seattle, WA

**Marvin E. Schechter**  
New York, NY

**Robin Shellow**  
Milwaukee, WI

**Alan Silber**  
Charlottesville, VA

**Howard M. Srebnick**  
Miami, FL

**Lisa M. Wayne**  
Denver, CO

**William T. Whitaker**  
Akron, OH

**Christie N. Williams**  
Dallas, TX

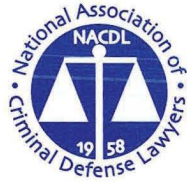
**William P. Wolf**  
Chicago, IL

**Vicki H. Young**  
San Francisco, CA

**John K. Zwertling**  
Alexandria, VA

**EXECUTIVE DIRECTOR**

**Ralph Grunewald**



# NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS

February 27, 2004

United States Sentencing Commission  
One Columbus Circle, N.E.  
Washington, DC., 20002

The purpose of this letter is to set forth on behalf of the National Association of Criminal Defense Lawyers (NACDL) our comments on the proposed amendments to Chapter 8 (Sentencing of Organizations) of the Federal Sentencing Guidelines. We ask that the Sentencing Commission consider these comments before finalizing the proposed amendments.

Possibly the most significant change is the requirement that effective compliance programs would no longer be required to attempt to detect and prevent violations of criminal law, but would now be required to attempt to detect and prevent violations of any law, criminal or non-criminal, including regulatory violations. See Application Notes 1 and 4(A) to Section 8B2.1. This proposed change conforms with a dangerous trend toward blurring the distinctions between criminal law and regulatory violations. Under the proposed changes, an organization's punishment for a criminal violation would be dependent, in part, on its implementation of programs to prevent civil administrative regulations. See Section 8C2.5(f) (an organization's culpability score would be lower if it had in place an effective program to detect and prevent "violations of law"). Criminal sanctions should be reserved for violations of criminal laws. They should not be used as a back door route to increase the penalties for regulatory non-compliance. The Sentencing Commission should resist the temptation indirectly to criminalize conduct that can be, and is, sanctioned through the administrative regulatory process.

Another proposed change in one of the criterion for an effective compliance program would change a provision that now says that the organization should use due care not to delegate substantial discretionary authority to individuals whom the organization knows, or should have known, "have a propensity to engage in illegal activities," to a new provision that states that the organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knows, or should have known, has a history of engaging in violations of law or other conduct inconsistent with an effective compliance program. Section 8B2.1(b)(3). This proposed provision and the commentary to the provision are an improvement over the present version, but should make clear that the mere fact that a person of substantial authority within the

"LIBERTY'S LAST CHAMPION"

1150 18th Street, NW ♦ Suite 950 ♦ Washington, DC 20036

Fax 202-872-8690

assist@nacdl.org

www.nacdl.org

W3003841  
202-872-8600

**EXECUTIVE DIRECTOR**  
**Ralph Grunewald**



**PRESIDENT**

**E. E. (Bo) Edwards**  
Nashville, TN

**PRESIDENT ELECT**

**Barry C. Scheck**  
New York, NY

**FIRST VICE PRESIDENT**

**Barbara E. Bergman**  
Albuquerque, NM

**SECOND VICE PRESIDENT**

**Martin S. Pinales**  
Cincinnati, OH

**TREASURER**

**Jeralyn E. Merritt**  
Denver, CO

**SECRETARY**

**John Wesley Hall, Jr.**  
Little Rock, AR

**PARLIAMENTARIAN**

**William D. Massey**  
Memphis, TN

**IMMEDIATE PAST PRESIDENT**

**Lawrence S. Goldman**  
New York, NY

**DIRECTORS**

**Hal R. Arenstein**  
Cincinnati, OH

**Steven D. Benjamin**  
Richmond, VA

**Donald A. Bosch**  
Knoxville, TN

**William H. Buckman**  
Moorestown, NJ

**Jerry J. Cox**  
Mt. Vernon, KY

**Richard A. Cremer**  
Roseburg, OR

**Joshua L. Dratel**  
New York, NY

**David A. Elden**  
Los Angeles, CA

**Priscilla E. Forsyth**  
Sioux City, IA

**Stephen R. Glassroth**  
Montgomery, AL

**Leslie Hagin**  
Seattle, WA

**Carmen D. Hernandez**  
Washington, DC

**Robert J. Hooker**  
Tucson, AZ

**Bret H. Huggins**  
Florence, AZ

**Richard S. Jaffe**  
Birmingham, AL

**William (Bill) O. James, Jr.**  
Little Rock, AR

**Kathryn M. Kase**  
Houston, TX

**Helen Leiner**  
Fairfax, VA

**Jack T. Litman**  
New York, NY

**J. Cheney Mason**  
Orlando, FL

**William D. Massey**  
Memphis, TN

**Randi McGinn**  
Albuquerque, NM

**Daniel E. Monnat**  
Wichita, KS

**E. G. (Gerry) Morris**  
Austin, TX

**William H. Murphy, Jr.**  
Baltimore, MD

**Cynthia Hujar Orr**  
San Antonio, TX

**Ellen S. Podgor**  
Tucker, GA

**Barry J. Pollack**  
Washington, DC

**Jeffery P. Robinson**  
Seattle, WA

**Marvin E. Schechter**  
New York, NY

**Robin Shellow**  
Milwaukee, WI

**Alan Silber**  
Charlottesville, VA

**Howard M. Srebnick**  
Miami, FL

**Lisa M. Wayne**  
Denver, CO

**William T. Whitaker**  
Akron, OH

**Christie N. Williams**  
Dallas, TX

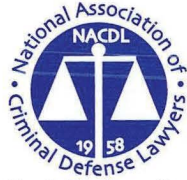
**William P. Wolf**  
Chicago, IL

**Vicki H. Young**  
San Francisco, CA

**John K. Zwerling**  
Alexandria, VA

**EXECUTIVE DIRECTOR**

**Ralph Grunewald**



# NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS

United States Sentencing Commission  
February 27, 2004  
Page 2

organization has a prior violation or violations of any law (including civil administrative regulations) is not by itself inconsistent with the existence of an effective compliance program. Rather, the organization should merely be required to consider the factors set forth in proposed Application Note 4C (recency of violation(s), relation of violation(s) to current duties and whether or not there is a pattern of prior violations) in determining whether or not including the individual within the organization's substantial authority personnel presents a significant impediment to the effectiveness of the compliance program.

Proposed Application Note 2C to Section 8B2.1 should be eliminated. In accordance with the proposed change to make effective compliance programs responsible not merely for detecting and preventing criminal violations, but regulatory violations, this proposed Application Note would make it weigh against a finding that a program is effective if any standard required by any administrative regulation is not incorporated in the compliance program. A compliance program required to preclude punishment for violations of criminal law should not need to be a comprehensive regulatory compliance program.

Subsection (f) of Section 8C2.5 currently prohibits the three-level reduction in the culpability score even if the organization has an effective compliance program, if the organization unreasonably delayed reporting the offense to governmental authorities. Section 8C2.5(g) provides a five-level decrease based on cooperation, which includes timely notification of the offense. In light of this provision, a failure of timely notification should not preclude the application of the three-level decrease.

Subsection (f) of Section 8C2.5 also currently prohibits the three level-reduction in the culpability score even if the organization has an effective compliance program, if certain high-level officials within the organization were culpable in the offense. The proposed amendments change this prohibition to a rebuttable presumption that this reduction does not apply if certain high-level officials within the organization were culpable in the offense. This is a positive change that gives discretion to sentencing judges to assess the facts on a case-by-case basis. NACDL endorses this amendment and believes it should apply regardless of the size of the organization.

The Sentencing Commission seeks comments on whether the current three-level reduction under Section 8C2.5(f) should be changed to four levels to reflect the increased requirements of an effective compliance program. NACDL opposes the

"LIBERTY'S LAST CHAMPION"

1150 18th Street, NW ♦ Suite 950 ♦ Washington, DC 20036

202-872-8600

Fax 202-872-8690

assist@nacdl.org

www.nacdl.org



**PRESIDENT**

**E. E. (Bo) Edwards**  
Nashville, TN

**PRESIDENT ELECT**

**Barry C. Scheck**  
New York, NY

**FIRST VICE PRESIDENT**

**Barbara E. Bergman**  
Albuquerque, NM

**SECOND VICE PRESIDENT**

**Martin S. Pinales**  
Cincinnati, OH

**TREASURER**

**Jeralyn E. Merritt**  
Denver, CO

**SECRETARY**

**John Wesley Hall, Jr.**  
Little Rock, AR

**PARLIAMENTARIAN**

**William D. Massey**  
Memphis, TN

**IMMEDIATE PAST PRESIDENT**

**Lawrence S. Goldman**  
New York, NY

**DIRECTORS**

**Hal R. Arenstein**  
Cincinnati, OH

**Steven D. Benjamin**  
Richmond, VA

**Donald A. Bosch**  
Knoxville, TN

**William H. Buckman**  
Moorestown, NJ

**Jerry J. Cox**  
Mt. Vernon, KY

**Richard A. Cremer**  
Roseburg, OR

**Joshua L. Dratel**  
New York, NY

**David A. Elden**  
Los Angeles, CA

**Priscilla E. Forsyth**  
Sioux City, IA

**Stephen R. Glassroth**  
Montgomery, AL

**Leslie Hagin**  
Seattle, WA

**Carmen D. Hernandez**  
Washington, DC

**Robert J. Hooker**  
Tucson, AZ

**Bret H. Huggins**  
Florence, AZ

**Richard S. Jaffe**  
Birmingham, AL

**William (Bill) O. James, Jr.**  
Little Rock, AR

**Kathryn M. Kase**  
Houston, TX

**Helen Leiner**  
Fairfax, VA

**Jack T. Litman**  
New York, NY

**J. Cheney Mason**  
Orlando, FL

**William D. Massey**  
Memphis, TN

**Randi McGinn**  
Albuquerque, NM

**Daniel E. Monnat**  
Wichita, KS

**E. G. (Gerry) Morris**  
Austin, TX

**William H. Murphy, Jr.**  
Baltimore, MD

**Cynthia Hujar Orr**  
San Antonio, TX

**Ellen S. Podgor**  
Tucker, GA

**Barry J. Pollack**  
Washington, DC

**Jeffery P. Robinson**  
Seattle, WA

**Marvin E. Schechter**  
New York, NY

**Robin Shellow**  
Milwaukee, WI

**Alan Silber**  
Charlottesville, VA

**Howard M. Srebnick**  
Miami, FL

**Lisa M. Wayne**  
Denver, CO

**William T. Whitaker**  
Akron, OH

**Christie N. Williams**  
Dallas, TX

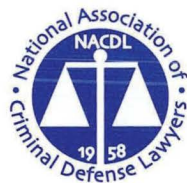
**William P. Wolf**  
Chicago, IL

**Vicki H. Young**  
San Francisco, CA

**John K. Zwerling**  
Alexandria, VA

**EXECUTIVE DIRECTOR**

**Ralph Grunewald**



# NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS

United States Sentencing Commission  
February 27, 2004  
Page 3

increased requirements as discussed above. If, however, the requirements are to increase, it would be appropriate to increase the reduction for having an effective program to four levels.

Proposed Application Note 12 to Section 8C2.5 notes that if various criteria are met, waiver of the attorney-client privilege and the work product doctrine will not be a prerequisite to a reduction in culpability for "cooperation." However, the proposed Application Note states, waiver of the attorney-client privilege and the work product doctrine may be required in order to obtain the reduction for cooperation. NACDL believes that under no circumstance should waiver of the attorney-client privilege or the work product doctrine be a prerequisite to obtaining credit for cooperation. Respect for these privileges is necessary in order for the organization frankly and candidly to determine whether there have been criminal violations, the scope of any such violations and appropriate corrective actions. An organization can cooperate with the government without waiving these privileges and should not be required to waive these privileges in order to obtain appropriate recognition for its cooperation.

Proposed Application Note 4 to Section 8C2.8 says that in determining where within the applicable range to set a fine, the court "should" consider any prior criminal record of an individual within high-level personnel. This proposed Application Note should state that the mere fact of a prior criminal record of such an individual is not necessarily relevant to where within the range to set the fine. Based on the criteria set forth in Application Note 4C to Section 8B2.1(b)(3), such a criminal record may be wholly irrelevant to whether or not the organization had an effective compliance program. In such cases, it should likewise be irrelevant to where within the applicable range the fine is set.

Proposed Application Note 2 to Section 8C4.1 states that if various criteria are met, waiver of the attorney-client privilege and the work product doctrine will not be a prerequisite to a providing "substantial assistance." However, the proposed Application Note states, the Government may determine that waiver of attorney-client privilege or work product doctrine may be necessary to ensure that a substantial assistance departure motion will be made. NACDL believes that under no circumstance should waiver of the attorney-client privilege or the work product doctrine be a prerequisite to obtaining credit for substantial assistance. Respect for these privileges is necessary in order for the organization frankly and candidly to determine whether there have been criminal violations, the scope of any such violations and appropriate corrective actions. An organization can substantially

"LIBERTY'S LAST CHAMPION"

1150 18th Street, NW ♦ Suite 950 ♦ Washington, DC 20036

Fax 202-872-8690

assist@nacdl.org

www.nacdl.org

202-872-8600

**PRESIDENT**

**E. E. (Bo) Edwards**  
Nashville, TN

**PRESIDENT ELECT**

**Barry C. Scheck**  
New York, NY

**FIRST VICE PRESIDENT**

**Barbara E. Bergman**  
Albuquerque, NM

**SECOND VICE PRESIDENT**

**Martin S. Pinales**  
Cincinnati, OH

**TREASURER**

**Jeralyn E. Merritt**  
Denver, CO

**SECRETARY**

**John Wesley Hall, Jr.**  
Little Rock, AR

**PARLIAMENTARIAN**

**William D. Massey**  
Memphis, TN

**IMMEDIATE PAST PRESIDENT**

**Lawrence S. Goldman**  
New York, NY

**DIRECTORS**

**Hal R. Arenstein**  
Cincinnati, OH

**Steven D. Benjamin**  
Richmond, VA

**Donald A. Bosch**  
Knoxville, TN

**William H. Buckman**  
Moorestown, NJ

**Jerry J. Cox**  
Mt. Vernon, KY

**Richard A. Cremer**  
Roseburg, OR

**Joshua L. Dratel**  
New York, NY

**David A. Elden**  
Los Angeles, CA

**Priscilla E. Forsyth**  
Sioux City, IA

**Stephen R. Glassroth**  
Montgomery, AL

**Leslie Hagin**  
Seattle, WA

**Carmen D. Hernandez**  
Washington, DC

**Robert J. Hooker**  
Tucson, AZ

**Bret H. Huggins**  
Florence, AZ

**Richard S. Jaffe**  
Birmingham, AL

**William (Bill) O. James, Jr.**  
Little Rock, AR

**Kathryn M. Kase**  
Houston, TX

**Helen Leiner**  
Fairfax, VA

**Jack T. Litman**  
New York, NY

**J. Cheney Mason**  
Orlando, FL

**William D. Massey**  
Memphis, TN

**Randi McGinn**  
Albuquerque, NM

**Daniel E. Monnat**  
Wichita, KS

**E. G. (Gerry) Morris**  
Austin, TX

**William H. Murphy, Jr.**  
Baltimore, MD

**Cynthia Hujar Orr**  
San Antonio, TX

**Ellen S. Podgor**  
Tucker, GA

**Barry J. Pollack**  
Washington, DC

**Jeffery P. Robinson**  
Seattle, WA

**Marvin E. Schechter**  
New York, NY

**Robin Shellow**  
Milwaukee, WI

**Alan Silber**  
Charlottesville, VA

**Howard M. Srebnick**  
Miami, FL

**Lisa M. Wayne**  
Denver, CO

**William T. Whitaker**  
Akron, OH

**Christie N. Williams**  
Dallas, TX

**William P. Wolf**  
Chicago, IL

**Vicki H. Young**  
San Francisco, CA

**John K. Zwerling**  
Alexandria, VA

**EXECUTIVE DIRECTOR**

**Ralph Grunewald**



# NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS

United States Sentencing Commission  
February 27, 2004  
Page 4

assist the government without waiving these privileges and should not be required to waive these privileges in order to obtain appropriate recognition for its substantial assistance.

Very truly yours,

Barry J. Pollack  
Co-chair, White Collar Committee  
National Association of Criminal  
Defense Lawyers

"LIBERTY'S LAST CHAMPION"

1150 18th Street, NW ♦ Suite 950 ♦ Washington, DC 20036  
Fax 202-872-8690 assist@nacdl.org

202-872-8600

www.nacdl.org



March 1, 2004

**VIA HAND DELIVERY AND ELECTRONIC MAIL**

United States Sentencing Commission  
One Columbus Circle, N.E.  
Suite 2-500  
Washington, D.C. 20002-8002  
Attention: Public Affairs

Re: Request for Public Comment by the United States Sentencing Commission  
on Proposed Amendments to Sentencing Guidelines

Dear Commissioners:

We are writing on behalf of 21 pharmaceutical companies,<sup>1</sup> in response to the request for public comment issued by the United States Sentencing Commission (USSC) on December 30, 2003.<sup>2</sup> Our comments concern the proposed amendments to Chapter Eight (the Organizational Guidelines), which describes the elements of effective compliance programs.

By way of background, the group of pharmaceutical companies we represent has substantial experience with voluntary compliance programs, and a long-standing commitment to compliance. That commitment is reflected both in individual companies' compliance efforts, and in a variety of collective efforts to improve compliance practices. Along with a number of other pharmaceutical companies, the group's members have been meeting semi-annually for the past five years to identify "best practices" for promoting compliance. Most of the group's current members also submitted comments to the Department of Health and Human Services Office of Inspector General (OIG) to

---

<sup>1</sup> These companies are: Abbott Laboratories, Alcon Laboratories, Inc., Allergan, Inc., Amgen Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals, Inc., Bayer Corporation, Boehringer Ingelheim Corporation, Bristol-Myers Squibb Company, Daiichi Pharmaceutical Corporation, Eli Lilly & Company, Fujisawa Healthcare, Inc., Genentech, Inc., GlaxoSmithKline, ICOS Corporation, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc., TAP Pharmaceutical Products Inc., and Wyeth Pharmaceuticals.

<sup>2</sup> Notice of proposed amendments to sentencing guidelines, policy statements, and commentary. Request for public comment, including public comment regarding retroactive application of any of the proposed amendments, 68 Fed. Reg. 75340 (Dec. 30, 2003).

help the OIG develop its voluntary compliance guidelines for the pharmaceutical industry,<sup>3</sup> and submitted comments responding to requests for public comment by the USSC Advisory Group on the Organizational Guidelines. We appreciate the Advisory Group's recognition of our comments. Given the seminal role that the Organizational Guidelines have played in fostering effective compliance programs, we welcome the USSC's initiative to update and refine the Guidelines' criteria.

Our previous comments to the USSC Advisory Group emphasized two key principles: (1) articulating core compliance program standards that give individual companies the flexibility necessary to create "customized" programs tailored to their unique circumstances; and (2) encouraging vigorous self-policing, by reducing the penalties associated with organizational self-analysis and self-reporting. As discussed below, we believe that the proposed amendments promote these principles and will advance the goals of the Organizational Guidelines, although in some instances revisions to the proposal can further advance these goals. Our comments also address: (1) ethics-based compliance approaches; (2) the effect of misconduct by high-level personnel on organizational sentencing; (3) responsibility for compliance program implementation; and (4) proposed language on "model" compliance practices. We hope that these comments will be of assistance to the USSC in finalizing its amendment to the Organizational Guidelines.

\* \* \*

#### **I. Enhancing Compliance Program Effectiveness by Defining Fundamental Standards that Preserve Flexibility**

The companies in our group support the proposed amendments, which would retain the seven-element framework of the existing Guidelines, while also creating a number of new obligations and broadening the required scope of effective compliance programs. For instance, the proposed Guidelines would require that companies: establish compliance programs designed to prevent and detect any violations of law or regulation (rather than violations of criminal laws, as in the current Guidelines);<sup>4</sup> promote an "organizational culture" encouraging a commitment to compliance;<sup>5</sup> satisfy new

<sup>3</sup> See 66 Fed. Reg. 31246 (June 11, 2001) (OIG notice requesting comment on the development of voluntary compliance program guidance for pharmaceutical manufacturers); 67 Fed. Reg. 62057 (Oct. 3, 2002) (draft OIG guidance and request for comment); 68 Fed. Reg. 23731 (May 5, 2003) (final OIG guidance).

<sup>4</sup> Proposed Commentary to § 8B2.1.

<sup>5</sup> Proposed § 8B2.1(a).