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October 11, 2002

Michael Courlander
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500
Washington, DC 20002-8002

Re: August 21, 2002 Request for Public Comment

Dear Mr. Jones:

On behalf of the American Chemistry Council ("Council"), we appreciate the opportunity to respond to the Advisory Group on Organizational Guidelines to the United States Sentencing Commission ("Advisory Group") regarding its August 21 request for comments on specific questions related to its review of Chapter Eight of the U.S. Sentencing Guidelines ("*Organizational Guidelines*"). We also appreciate the Advisory Group's invitation to participate in the public hearing scheduled for November 14, 2002, and by this letter request the opportunity for a Council representative to testify at that hearing. As requested by the Advisory Group, we will submit written testimony by October 30.

The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make our lives better, healthier and safer. The Council is committed to compliance and good corporate governance through Responsible Care®, common sense advocacy designed to address major public policy issues, and extensive research and product testing. The business of chemistry is a $460 billion-a-year enterprise and a key element of our nation's economy. It is the nation's #1 exporting sector, accounting for 10 cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other industry.

Before we turn to the specific questions raised in the Advisory Group's August 21 notice, we suggest, as a general matter, that the work of the Advisory Group should be guided by the following principles:

- The *Organizational Guidelines* should continue to be understood and evaluated in the criminal sentencing context -- that is, the jurisdictional scope of the Sentencing Commission -- and

should not be expanded to address more general policy matters, such as general ethical issues.

- The evaluation of the *Organizational Guidelines* and any proposed changes to them should be based on objective evidence and a demonstrable need for those changes by those who implement and use the *Guidelines*.

- The *Organizational Guidelines* should remain capable of being implemented by organizations of any size or sector, and should not become a compilation of "best practices" that many small or medium-sized organizations may not be capable of implementing.

- The *Organizational Guidelines* should not be revised to provide general guidance on designing, implementing or auditing compliance systems. There is a vast quantity of such guidance already available in the marketplace, and it is not the function of the Sentencing Commission to provide such general educational assistance.

We elaborated on these points in our May 20, 2002 comments to the Advisory Group, which are attached to these comments. We also encourage the Advisory Group, in the future, to seek public comment through the Federal Register. It is likely that many potentially interested parties, particularly small and medium-sized businesses, were not aware of the Advisory Group's August 21 posting on the Sentencing Commission's website.

Question 1

The Advisory Group asked for comment as to whether a number of the *Organizational Guidelines* criteria for an effective compliance program (§ 8A1.2, comment 3(k)(1-7)) should be clarified or expanded. As a general matter, we do not believe that the criteria should be expanded or made more detailed. The *Organizational Guidelines* were established to outline factors to be considered in making sentencing decisions, not establish to enforceable standards for compliance programs. As a practical matter, these criteria have come to be viewed as principles for an effective compliance assurance system. Their present level of generality properly leaves it to implementing organizations to fashion the system that best fits their operations, structure and culture. Their generality also allows sentencing courts to apply the criteria on a case-by-case basis.

- Specifying the responsibilities of particular functions (e.g., CEO or CFO), expanding the definitions of "high level personnel," or providing additional comments on what is intended by "specific individual(s) within high-level personnel of the organization" would decrease the flexibility that is currently an outstanding feature of the *Organizational Guidelines*.

- The *Organizational Guidelines* should not provide detail on the responsibilities of boards of directors or equivalent governance bodies in overseeing compliance programs. First, not all organizations, particularly smaller ones, have such governance bodies. Second, the *Organ-*

izational Guidelines already embody the principle that compliance programs should be supervised by "high level" personnel. Third, the issue of director (or equivalent) responsibilities is obviously a topic of considerable federal legislative, regulatory and self-regulatory attention.

Suggesting specific corporate governance responsibilities at the sentencing level could create conflicts with the requirements just created by Congress in the Sarbanes-Oxley Act of 2002 and being implemented or considered by various regulatory and self-regulatory bodies that have primary responsibilities for corporate governance, such as the Securities & Exchange Commission, the New York Stock Exchange and the National Association of Securities Dealers.[1] While many organizations subject to the *Organizational Guidelines* are not publicly traded companies, the same governance issues are currently being considered carefully within such companies, and the Advisory Group should proceed cautiously to avoid creating unnecessary conflicts in this area.

- The flexibility in §8A1.2, comment 3(k)(4) regarding internal communication should be maintained. The use of "e.g." and "or" in this comment provide organizations several options in communicating compliance standards and procedures to employees. For example, not every organization will find that a formal training program is the most effective communications strategy.

- The Advisory Group seeks comment on whether § 8A1.2, comment 3(k)(5), concerning implementing a reporting system without fear of retribution be made more specific to encourage: (i) whistleblowing protection: (ii) a privilege or policy for good faith self-assessment and corrective action; (iii) the creation of a neutral ombudsman office for confidential reporting; or (iv) some other means of encouraging reporting without fear of retribution.

    - More specificity regarding whistleblower protection is not necessary. We agree that whistleblowers must be completely protected from acts of retribution. However, the *Organizational Guidelines* already clearly state that internal reporting should be without fear of retribution. Further, many statutes already provide specific whistleblower protections.[2] Adding more specific whistleblower provisions in the *Organizational Guidelines*

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[1] *See, e.g.*, "SEC, NY Attorney General, NYSE, NASD, NASAA Reach Agreement on Reforming Wall Street Practices" (Oct. 3, 2002) www.sec.gov/news/press/2002-144.htm (announcing joint effort to conclude investigations regarding analyst research and IPO allocations and to formulate industry-wide rules and structural reforms to govern in these areas); New York Stock Exchange, Corporate Governance Rule Proposals (submitted to SEC Aug. 15, 2002) (proposing requirements for independent corporate directors, creation of audit committees comprised of independent directors, shareholder approval of equity compensation plans, and adoption of corporate governance standards and code of business conduct and ethics).

[2] *See, e.g.*, Age Discrimination in Employment Act, 29 U.S.C. § 623; Occupational Safety and Health Act, 29 U.S.C. § 660; Job Training and Partnership Act, 29 U.S.C. § 1574; Safe Drinking Water Act, 42 U.S.C. § 300(f)-(j); Surface Transportation Act, 49 U.S.C. § 31105. A compilation of whistleblower laws can be found at www.whistleblowerlaws.com.

might create conflicts with existing substantive laws, be duplicative, or even create loopholes that might result in less protection.

- The Sentencing Commission cannot create a privilege for self-assessments or corrective action. Evidentiary privileges in federal courts are the province of the Federal Rules of Evidence Advisory Committee and Congressional review process.[3] In state courts, such privileges are generally established by either the judiciary or legislature.[4] However, as we note below in response to Question 5, it would be helpful if the *Organizational Guidelines* recognized that organizations should not be required to waive their legally-recognized privileges in order to be deemed to have "cooperated" with government authorities.

- A neutral "ombudsman" is not necessary to an effective compliance assurance program. Indeed, many effective compliance programs are those that are well-integrated into the organization and which senior management is directly supervising. Insisting that a neutral ombudsman is a necessary element of any effective compliance program may create the implication that the real responsibility for compliance oversight lies with an ombudsman, not management, and that management is not to be trusted. It would also be a very burdensome provision for many, if not most, small and medium-sized organizations.

- It is not necessary to increase the emphasis on auditing and monitoring in the *Organizational Guidelines*. These components are already clearly mentioned, and increasing the emphasis on them could incorrectly imply that they are more important than other elements of a compliance program. Further, a great deal of guidance already exists on how to create auditing programs and conduct audits.

- The discussion of discipline in § 8A.1.2, comment 3(k)(6) should not be expanded to include details such as making compliance an element of employee performance evaluations. Linking compliance to employee performance or compensation – while perhaps attractive at first blush -- raises many complicated human resources and labor relations issues. There are a variety of views on the appropriateness of such strategies. Therefore, such a complicated proposal should not be included as a basic element of an effective compliance assurance program.

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[3] *See generally*, 28 U.S.C. §§ 2072-74; I WIGMORE ON EVIDENCE § 6.3 (Tillers rev. 1983 & Supp. 2001-2002).

[4] *See generally,* WRIGHT & GRAHAM, FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 5422 & n.49 (1980 & Supp. 2002).

Question 2

The *Organizational Guidelines* should not be revised to provide for an increased criminal penalty for organizations that do not implement an effective compliance program.

- To the extent that compliance programs are not required by law, this approach would be using the *Organizational Guidelines* to create a new offense with its own penalties. Only Congress has the authority to create new offenses.[5]

- The *Organizational Guidelines* already have provisions for upward adjustments of criminal penalties for organizations that tolerated the offense or where high level personnel participated in the offense or were willfully ignorant of the offense. *See, e.g.*, § 8C2.5(2). To separately penalize an organization for not having a compliance program would be double-counting in light of these provisions. Further, not having a formal compliance system is not equivalent to tolerating or being willfully ignorant of criminal conduct.

- Not every element of the *Organizational Guidelines* that directs a downward adjustment is accompanied by a "mirror image" upward adjustment. Mandating matching upward and downward adjustments for each element would imply a wholesale review of the entire *Organizational Guidelines*.

Question 3

With the exception of a clarification of the meaning of "cooperation" addressed below in Question 5, the Organizational Guidelines do not have to be revised to encourage auditing, monitoring and self-reporting. Our members recognize the importance of these activities and would be conducting them even in the absence of the *Organizational Guidelines*. Further, the *Organizational Guidelines* clearly direct that such activities are an essential element of an effective compliance program, and we are not aware of anything in the *Organizational Guidelines* that currently creates a barrier to such activities. Lastly, it is not the function of the Sentencing Commission to address whatever disincentives to auditing might be posed by third-party litigation.

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[5] Where Congress does require organizations to implement compliance programs or controls, as it has in the recent Sarbanes-Oxley legislation, it may be appropriate to impose penalties for the failure to comply with those specific requirements.

Question 4

The Advisory Group asks a series of questions about the potential obstacles faced by small or medium-sized businesses in implementing effective compliance programs. Many of these questions (e.g., those related to how often small and medium-sized implement effective compliance programs) will likely require significant empirical research. Whatever obstacles such businesses face will not be lessened by increasing the level of detail or complexity in the *Organizational Guidelines*. Further, attempting to create unique provisions in the *Organizational Guidelines* for small and medium-sized businesses would require the Sentencing Commission to be able to discern which obstacles are unique to such businesses and to draw arbitrary lines between which businesses would "qualify" for any unique provisions and which would not.

Question 5

The Advisory Group asks whether § 8AC2.5, comment 12, or § 8C4.1 (which provide respectively for a downward adjustment for "cooperation" with or "substantial assistance" to authorities) should be clarified to state that waiver of existing legal privileges is not necessary in order to qualify for these reductions. We agree that waiving existing legal privileges should not be a factor in determining whether an organization has cooperated with or provided substantial assistance to the authorities.

- Allowing organizations to maintain their existing legal privileges will keep a current incentive for organizations to conduct the auditing, monitoring, investigations and self-reporting that the *Organizational Guidelines* recognize are essential to an effective system to prevent, detect and correct suspected misconduct.

- An organization's degree of cooperation with or assistance to the authorities should not be measured against the extent to which the organization waives or gives up legitimate legal rights.

- Privileges exist for the purpose of encouraging candid communication. Enshrining a principle that would require waiving the privilege may inhibit the candid exchanges the privilege is supposed to promote. This could also potentially conflict with provisions of the *Organizational Guidelines* that encourage internal investigations and the protection of employees who report suspected wrongdoing.

- This modification would be appropriate because it would not change existing legal privileges or establish new ones. Just as the *Organizational Guidelines* should not be a platform for establishing new substantive legal obligations, so should they not be used to diminish existing legal protections.

Question 6

The Advisory Group asks whether the *Organizational Guidelines* should be used to encourage organization to foster "ethical cultures" to ensure compliance with the "intent" of the law as opposed to "technical compliance." Our members certainly support ethical conduct by organizations, and recognize that encouraging organizations to create an "ethics infrastructure" that goes "beyond compliance" with criminal law is a laudable goal. However, that is not the function of the Sentencing Commission.

The principal function of the Commission is to promulgate "detailed guidelines prescribing the appropriate sentences for offenders convicted of federal crimes." U.S. Sentencing Commission, Guidelines Manual, Ch. 1, Pt. A, p. 1 (November 2000). In Section 805(a)(5) of the Sarbanes-Oxley Act of 2002, Congress specifically directed the Commission to ensure that the Organizational Guidelines "are sufficient to deter and punish criminal misconduct." The Commission should not to expand its role outside of the sentencing context and into general issues of corporate social responsibility or ethics that are not directly regulated by the federal criminal laws.

Individuals and organizations are convicted and sentenced because of specific violations of specific statutory provisions. They cannot be convicted or sentenced because they may in some manner be generally unethical or lack integrity, or because they may have violated the intent but not the letter of the law. Thus, the threat of increased criminal penalties should not be used to "encourage" organizations to revise their compliance assurance systems into "ethics programs." The focus of the *Organizational Guidelines* should remain on systems that assure compliance with legal requirements, not ethics programs that may focus on important questions in a wider domain. This is particularly true given that there is no agreed-upon set of ethical criteria against which organizations can be measured and that can be the basis for setting criminal penalties.

We look forward to participating in the hearings on November 14. If you have any questions about these comments, please contact me at 202-736-8111, or my colleague Chris Bell at 202-736-8118.

Sincerely,

David T. Buente

cc: James Conrad
(American Chemistry Council)

Attachment

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May 20, 2002

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Re: Request for Public Comment

Dear Mr. Jones:

On behalf of the American Chemistry Council ("Council"), we appreciate the opportunity to respond to the request for comments of the Advisory Group on Organizational Guidelines to the United States Sentencing Commission on the nature and scope of its activities as it reviews Chapter Eight ("Sentencing of Organizations") of the U.S. Sentencing Guidelines ("*Organizational Guidelines*"), with particular attention to the criteria for compliance assurance systems.

The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make our lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and extensive health and environmental research and product testing. The business of chemistry is a $460 billion-a-year enterprise and a key element of our nation's economy. It is the nation's #1 exporting sector, accounting for 10 cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other industry.

We agree that the Advisory Group should, at the outset, clarify the nature and scope of its activities. We believe that the Advisory Group should be guided by the following principles:

- The *Organizational Guidelines* should continue to be understood and evaluated in the criminal sentencing context -- that is, the jurisdictional scope of the Sentencing Commission -- and should not be expanded to address more general ethical issues.
- The evaluation of the *Organizational Guidelines* and any proposed changes to them should be based on objective evidence and a demonstrable need for those changes by those who implement and use the *Guidelines*.
- The *Organizational Guidelines* should remain capable of being implemented by organizations of any size or sector, and should not become a compilation of "best practices" that many smaller organizations may not be capable of implementing.

We elaborate on these points below. We also encourage the Advisory Group, in the future, to seek public comment through the Federal Register. It is likely that many interested parties were not aware of the Advisory Group's posting on the Sentencing Commission's website.

I. The Organizational Guidelines Should Continue To Focus On Criminal Conduct

The principal function of the Commission is to promulgate "detailed guidelines prescribing the appropriate sentences for offenders convicted of federal crimes."[1] The purpose of the *Organizational Guidelines* is to "further the basic purposes of criminal punishment: deterrence, incapacitation, just punishment, and rehabilitation." Id. In particular, the *Organizational Guidelines* are "designed so that the sanctions imposed upon organizations and their agents, taken together, will provide just punishment, adequate deterrence, and incentives for organizations to maintain internal mechanisms for preventing, detecting, and reporting criminal conduct."[2] Therefore, the role of the *Organizational Guidelines* is to address the specific issue of criminal noncompliance with legal requirements and not to expand into general issues of corporate social responsibility or ethics that are not directly regulated by criminal law.

Some of the suggestions raised in the comments submitted to the Commission in response to the Federal Register notice that led to the formation of the Advisory Group[3] would have the Commission expand its charter beyond its authority to address violations of criminal law. For example, requiring an "integrity and ethics based system," however admirable, is not necessarily related to preventing, detecting or reporting criminal conduct. Some commenters are beginning to erroneously refer to "ethics and compliance programs" as if the two concepts are interchangeable or identical. Criminal conduct is defined in a discrete set of federal statutes. Individuals and organizations are convicted and sentenced because of specific violations of specific statutory provisions. They are not convicted or sentenced because they may in some manner be unethical or lack integrity – even if that is the case.

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[1] U.S. Sentencing Commission, Guidelines Manual, Ch. 1, Pt. A, p. 1 (November 2000).
[2] USSG Ch.8 intro. comment.
[3] 66 Fed. Reg. 48306, (September 19, 2001).

The focus of the Commission should remain on systems that assure compliance with legal requirements, not ethics programs that focus on important questions in a wider domain. This is particularly true given that, unlike the defined realm of criminal offenses, there is no agreed-upon set of ethical criteria against which organizations can be measured. Encouraging organizations to create an "ethics infrastructure" that goes beyond compliance with criminal law is a laudable goal. However, the presence or absence of such an ethical infrastructure should not have consequences in the very serious context of sentencing those convicted of crimes.

For example, one commenter urged that the *Organizational Guidelines* be revised to "move this world from 'obeying the law because I have to' to 'doing what is right because I want to,'" recommending that "violations of ethical standards carry penalties similar to the violation of regulatory standards." This comment implies that the Commission has the authority to recommend punishment for acts that have not violated the law. This is asking the Commission to go beyond its mandate and do what only Congress can do. Issues raised by other commenters also go beyond the legal authority of the Commission, such as evaluating the impact of "qui tam" legislation on compliance assurance systems.

The *Organizational Guidelines* are used by courts to sentence those convicted of crimes. Therefore, proposed changes to the *Organizational Guidelines* should always be assessed in terms of how they would be used in the very serious context of sentencing in a court of law. However, almost all of the comments submitted to the Commission thus far treat the *Organizational Guidelines* as a guidance manual or educational tool on how to implement effective compliance systems, and do not discuss how these changes would be implemented in the sentencing context. For example, drawing upon some of the suggestions in the comments submitted to the Commission, should an organization's criminal sentence be adjusted if it:

- has a compliance assurance system that focuses on preventing, detecting and correcting criminal conduct, but does not address "ethics" generally;
- has a compliance officer, but does not have an "ethics officer" who does not have "at least three university level, full – term courses in ethics;" or
- has a system for confidential internal reporting of potential or actual misconduct (e.g., a 1-800 "hotline"), but does not have a "neutral ombudsman?"

In each case, we believe the answer is "no." The current *Organizational Guidelines* properly focus on effective systems directed at preventing criminal behavior.

In the 10+ years since they were first issued, the *Organizational Guidelines* have clearly taken on a significant secondary role as an inspiration and template for the development of effective corporate compliance programs. These programs in turn have frequently grown into, or been merged with, more general programs designed to foster ethical behavior and that extend beyond notions of law-abidance.

This is a good development, whether or not foreseen by Congress or the Commission. But it is not the function that Congress or the Commission intended the *Organizational Guidelines* to accomplish. Nor should the *Organizational Guidelines* be expanded now to encompass these broader but ultimately irrelevant purposes. It is a happy development that the *Organizational Guidelines* are being integrated with aspirational ethics programs. It would be wrong, however, for organizations now to be punished more severely for not having taken these "leading," "best practice" steps The threat of increased criminal penalties should not be used to "encourage" organizations to upgrade their compliance assurance systems into "ethics programs." The *Organizational Guidelines* have considerable consequences in criminal sentencing. Therefore, it is appropriate that they set out general principles and be free of extraneous detail so that they are adaptable to a wide range of organizations. They should also avoid vague aspirational directions that are not directly related to detecting and preventing crime.

II. Proposed Changes To The Organizational Guidelines Should Be Based On Objective Evidence

The process of evaluating and proposing changes to the *Organizational Guidelines* should be based on facts rather than unsupported theory. The factual inquiry should focus on how compliance systems based on the *Organizational Guidelines* have been implemented and performed. Thousands of organizations have invested substantial resources and time implementing compliance systems based on the *Organizational Guidelines*. Organizations will generally feel compelled to overhaul these systems to conform to any changes in the *Organizational Guidelines*, again at potentially significant cost. Therefore, the *Organizational Guidelines* should not be lightly changed, and any change should be supported by facts, including a demonstrated need by the community of organizations implementing them.

The factual inquiry should focus on the performance of organizations that have implemented compliance systems based on the *Organizational Guidelines*. The alleged criminal or unethical activities that currently are high-visibility issues in the media, courts and Congress are not necessarily directly relevant to the Advisory Group's task. General public or political concern about crime or ethics is not evidence that the *Guidelines* are not working or that they need improvement, though it might indicate that more widespread implementation of the *Guidelines* would be beneficial. The issue for the Advisory Group is whether the *Organizational Guidelines* work when they are implemented. We are not aware of any evidence indicating that sentences under the current guidelines have been too lenient, or that current criminal cases have resulted, despite the existence of compliance programs meeting the *Guidelines'* criteria, that would have been prevented if the organization also had an ethics program in place.

As the Commission noted in the Federal Register notice, the "organizational guidelines have had a tremendous impact on the implementation of compliance and business ethics programs over the past ten years."[4] We are unaware of evidence in the docket created for this mat-

[4] 66 Fed. Reg. 48307.

ter, Congressional testimony, or judicial opinions, indicating that the Organizational Guidelines do not work when they are implemented in good faith.. The comments in the docket do not identify any deficiencies in the *Organizational Guidelines* that need to be corrected, or any difficulties that courts or organizations have had in implementing them. Unless its work uncovers compelling evidence that there is a problem to be solved, the Advisory Group should be cautious in recommending changes. Material changes to the *Organizational Guidelines* should only be considered after a showing that the *Organizational Guidelines* are flawed or defective, and that there is a demand in the implementing community for the changes.

III. The Organizational Guidelines Must Remain Practical And Generally Applicable To All Organizations In All Sectors

The *Organizational Guidelines* properly set forth the essential steps that any organization must take to have an "effective program to prevent and detect violations of law." These criteria should remain applicable to all organizations, public or private, large or small, in all industrial and service sectors. Given the diversity of organizations and subject matter covered by compliance programs, the Commission should not attempt to prescribe additional criteria for compliance programs which are not at the same level of general applicability as the current *Organizational Guidelines*.

Any proposed changes to the requirements of the *Organizational Guidelines* should take into account the small and medium-sized organizations that constitute the vast majority of U.S. businesses. The current *Organizational Guidelines* offer the flexibility needed to allow organizations of all sizes and types to implement effective compliance programs. This is not a theoretical concern. The Commission's own statistics reveal that in fiscal year 2000, approximately 87% of organizations sentenced under Chapter 8 employed fewer than 200 persons, a figure that was 94% in fiscal year 1999.[5] In fiscal year 2000, approximately 65% of the sentenced organizations employed fewer than 50 individuals, a value that was almost 80% in fiscal year 1999.[6] Increasing the requirements or detail in the *Guidelines* may create a model that cannot be practically implemented by many small and medium-sized organizations. For example, most organizations are not likely to have the resources to have an "ethics officer," a "compliance officer," and a "neutral ombudsman."

The "best practices" of the most sophisticated companies should not become the model for what all organizations, no matter how small or limited in resources, must do to avoid serious consequences in the criminal justice system. Any time a change to the *Organizational Guidelines* is proposed, the Advisory Group should always consider whether a small business could implement the change and whether it might actually discourage the widespread implementation of compliance assurance systems by such organizations. The "leading edge" organizations that

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[5] *Sourcebook of Federal Sentencing Statistics*, Table 54 (U.S. Sentencing Commission 1999 and 2000).
[6] Id.

have already implemented "best practices" do not need changes to the *Organizational Guidelines* to continue down that path. On the other hand, organizations with fewer resources should be implementing effective compliance assurance systems based on the principles in the existing *Organizational Guidelines*, but should not be potentially subject to increased criminal penalties if they cannot attain a "best practices" level. Indeed, "raising the bar" might have the undesirable effect of discouraging many organizations from attempting to implement effective compliance assurance systems.

The Advisory Group should also take into account the proliferation of sector-specific and public and private sector guidance documents on compliance assurance programs. This is not to say that all of these documents should be incorporated into the *Organizational Guidelines*. To the contrary, the *Organizational Guidelines* should remain generic, applicable to all organizations. The Advisory Group should recognize that a vast literature on compliance assurance systems is available to the user community and that the *Organizational Guidelines* do not have to be revised to address all conceivable compliance assurance system issues.

Many federal agencies have been developing guidance on compliance assurance systems tailored to specific legislative programs. For example, the Department of Health and Human Services ("HHS") has launched a number of compliance assurance program initiatives, including:

- *Model Compliance Plan for Clinical Laboratories,* 62 Fed. Reg. 9435 (March 3, 1997).
- *Compliance Program Guidance For Medicare+Choice Organizations,* 64 Fed. Reg. 61893 (November 15, 1999).
- *Draft Compliance Program for Individual and Small Group Physician Practices,* 65 Fed. Reg. 36818 (June 12, 2000).

In all, HHS has issued compliance program guidance for nine healthcare industry sectors.[7] HHS bases these programs on the Sentencing Guidelines, but tailors them to specific sectors because it "recognizes that there is no 'one size fits all' compliance program."[8] HHS continues to develop tailored compliance program guidance, recently soliciting comments on compliance programs for the ambulance[9] and pharmaceutical industries.[10]

HHS is not alone among federal agencies in developing detailed guidance. For example:

- The Securities and Exchange Commission recently announced a list of factors, including the existence of internal compliance programs and procedures, that it will take into account in deciding whether to prosecute a matter. *Report of Investigation Pursuant to Section 21(a) of*

[7] 66 Fed. Reg. 31246, 31247, n.3 (June 11, 2001).
[8] 65 Fed. Reg. at 36819.
[9] 65 Fed. Reg. 50204 (Aug. 17, 2000).
[10] 66 Fed. Reg. 31246 (June 11, 2001).

the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Co-operation to Agency Enforcement Decisions, (SEC, October 23, 2001).

- The U.S. Department of Justice has developed general prosecutorial policies that take into account an organization's compliance assurance systems and has also developed such policies for particular types of crimes. *Federal Prosecution of Corporations* (U.S. DoJ, June 16, 1999); *Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance* (U.S. DoJ, July, 1991).
- The U.S. Customs Service has established compliance programs, such as one encouraging those engaged in international trade to implement programs to comply with the so-called "drawback" customs requirements, 19 C.F.R. § 191.191 *et. seq.*, and an "importer compliance monitoring program," 66 Fed. Reg. 38344 (July 23, 2001).
- The Occupational Safety and Health Administration ("OSHA") has devoted considerable resources to compliance programs, issuing sector-specific guidance such as the *Framework for a Comprehensive Health and Safety Program in Nursing Homes* (U.S. Dept. of Labor/OSHA, January 3, 2001).
- Though the *Organizational Guidelines* do not cover environmental crimes, the U.S. Environmental Protection Agency has provided guidance on what constitutes an effective environmental management system aimed at complying with the law. See, e.g., *Compliance – Focused Environmental Management Systems – Enforcement Agreement Guidance* (U.S. EPA, January 2000); *Incentives for Self – Policing, Discovery, Correction and Prevention of Violations*, 65 Fed. Reg. 19618 (April 11, 2000); *Code of Environmental Management Principles for Federal Agencies*, 61 Fed. Reg. 54062 (October 16, 1996).

In some situations, guidance established by federal agencies has extended to enforceable regulations on compliance assurance systems, such as the detailed, systems-oriented, process safety management regulations promulgated by OSHA.[11]

The private sector has also produced prodigious guidance on designing, evaluating and implementing compliance assurance systems. The past decade has seen an explosion of literature, trade press, conferences, guidance and educational material on not only compliance assurance systems, but also on the more general topic of ethics and integrity programs. This is reflected in the comments the Commission received from organizations such as the Coalition for Ethics and Compliance Initiatives, the Ethics Resource Center and the Alliance for Health Care Integrity.

The growth of interest in compliance assurance systems and ethics programs has not been limited to the United States. For example:

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[11] 29 C.F.R. § 1910.119.

- In 2000, the Organization of Economic Cooperation and Development ("OECD"), to which the U.S. belongs, published its revised its *OECD Guidelines for Multinational Organizations*, which establish a "code of conduct" on a range of issues, including labor, bribery, occupational safety and environmental.
- A coalition of private sector and non-governmental organizations has created *Social Accountability 8000*, which applies management systems principles to labor and social issues and is typically implemented in conjunction with accredited third-party auditors to verify conformance.
- The International Labor Organization ("ILO") this year published its *Guidelines on Occupational Health and Safety Management Systems.*
- A number of guidance documents have been developed on implementing systems to identify and meet environmental goals and obligations. These include the International Organization for Standardization's ISO 14001 environmental management systems standard (which has been implemented by over 1,000 facilities in the U.S. and 30,000 world-wide) and a number of sector-specific guidance documents such as the American Chemistry Council's Responsible Care® program and the American Forest & Paper Association's Sustainable Forestry Initiative.

Multi-national organizations that wish to achieve consistent and acceptable levels of conduct world-wide are looking to these and other documents to assist them implement systems that will be effective in the U.S. and abroad. Adding detail to the *Organizational Guidelines* could create conflicts with these other efforts, particularly for multi-national organizations that are developing comprehensive world-wide compliance assurance systems.

This brief review of the landscape on compliance assurance systems reveals that the implementing community does not suffer from an absence of guidance on implementing effective compliance assurance programs. Therefore, the Advisory Group should determine if there is a "market need" for the Commission to provide even more. Indeed, the Advisory Group should consider the potential impact of increasing the level of detail contained in the *Organizational Guidelines* on these various initiatives. Specific guidance on compliance programs has already been developed and continues to be refined in public and private, tailored to the needs and interests of specific areas of regulation. Adding detail to the *Organizational Guidelines* could create conflicts with these other efforts, leading to practical implementation problems.

Thank you for this opportunity to comment on the *Organizational Guidelines*. We look forward to continuing to work with the Advisory Group on these issues. If you have any questions about these comments, you may contact me at 202-736-8111 or my colleague Christopher Bell at 202-736-8118.

Sincerely

David T. Buente

cc: James W. Conrad, Jr. (American Chemistry Council)