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October 4, 2002

VIA HAND DELIVERY

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

Re: Request for Additional Public Comment By the United States Sentencing Commission Advisory Group on Organizational Guidelines

Dear Mr. Courlander:

On behalf of the 19 pharmaceutical companies we represent, we are writing in response to the Request For Additional Public Comment recently issued by the United States Sentencing Commission's Advisory Group on Organizational Guidelines.

As we noted in responding to the Advisory Group's initial Request For Public Comment, its work involves subjects of critical importance to the companies in our group. The group of pharmaceutical companies we represent have 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 several years to identify "best practices" for promoting compliance. Last year, the group's members joined together to submit comments to the Department of Health and Human Services Office of Inspector General, which had requested public comments on its plans to develop voluntary compliance guidelines for the pharmaceutical industry. We subsequently met with the Inspector General to discuss pharmaceutical compliance issues and prepared a follow-up submission outlining our suggestions on promoting pharmaceutical compliance goals. We are now preparing comments on the draft

pharmaceutical compliance guidelines just released by the Inspector General, and hope to continue the dialogue with the Inspector General through sponsoring events such as roundtable discussions.

Developing effective strategies to prevent corporate misconduct has become a high-profile topic following the Enron collapse - - but this issue has always been critical, it will remain so once it fades from the front pages, and it deserves the careful study the Advisory Group has undertaken. This is an important task, and we hope our comments can be of some assistance to the Advisory Group as it formulates its recommendations to the Sentencing Commission for improving the Organizational Guidelines. We have addressed below most of the specific questions raised in the Advisory Group's Request For Additional Public Comment. In doing so, we have sought to highlight two key principles: (1) retaining the balance between structure and flexibility now reflected in the Organizational Guidelines, which has successfully fostered effective compliance programs by giving organizations the responsibility and freedom to develop programs tailored to their individual circumstances; and (2) enhancing the impact of the Organizational Guidelines, by reducing the existing disincentives for vigorous self-policing by organizations and full involvement in self-policing efforts by their employees.

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Question 1.a.

1. *Should the Chapter Eight Guidelines' criteria for an "effective program to prevent and detect violations of law" at § 8A1.2, comment 3(k)(1-7), be clarified or expanded to address the specific issues designated below? If so, how can this be done consistent with the limitations of the Commission's jurisdiction and statutory authority at 28 U.S.C. § 994 et seq.?*

a. *Should § 8A1.2, comment 3(k)(2), referring to the oversight of compliance programs by high-level personnel, specifically articulate the responsibilities of the CEO, the CFO and/or other person(s) responsible for high-level oversight? Should § 8A1.2, comment 3(k)(2) further define what is intended by "specific individual(s) within high-level personnel of the organization" (see also, § 8A1.2, comment 3(b)) and "overall responsibility to oversee compliance?"*

Response:

This is one of several questions that raises an overarching issue: the degree of flexibility that organizations need in order to design compliance programs that are genuinely effective. We believe the approach currently reflected in the Organizational Guidelines - - one that defines effective compliance programs in terms of seven broad criteria "deliberately selected in order to encourage flexibility and independence by organizations in designing programs that are best suited to their particular circumstances" - - was wisely chosen, and should be re-emphasized in the Advisory Group's report to the Sentencing Commission. This is true for several related reasons.

First, the Organizational Guidelines apply to a remarkably diverse group of organizations, subject to an equally diverse set of legal obligations. The organizations

covered by the Organizational Guidelines include corporations of every size in every line of business, as well as "partnerships, associations, joint-stock companies, unions, trusts, pension funds, unincorporated organizations, governments and political subdivisions thereof, and non-profit organizations." The broad, flexible criteria now articulated in the Guidelines are essential to maintain their relevance to the broad range of organizations they cover.

Second, compliance programs must be customized to fit the particular organization in order to be truly effective. In the health care field, for example, the HHS Office of Inspector General has consistently emphasized that a compliance program can only be effective if it becomes ingrained in the organization's operations and culture, which makes a "one size fits all" model unworkable. Consistent with this principle, the Organizational Guidelines wisely provide that "[t]he precise actions necessary for an effective program to prevent and detect violations of law will depend upon a number of factors," including an organization's size, the likelihood that certain offenses may occur because of the nature of its business, its prior history, and the applicable industry practice and the standards called for by any applicable governmental regulation.

This flexible and particularized approach requires each individual organization to take responsibility for assessing its own environment and risk profile: to identify all of the various industry-specific and organization-specific factors that should affect the focus and structure of its compliance program, and build a program carefully tailored to that assessment. At the same time, this approach empowers organizations to use all of their experience and creativity in crafting a compliance program - - to mobilize the assets necessary to tap the full potential of these programs. This can only occur if the compliance program is "owned" by the organization and its individual representatives: if the people who must make the program work have invested their time, energy, and expertise in its design, and feel a stake in its success. In the related context of corporate governance, for example, the committee recently charged with recommending revised standards for companies listed on the New York Stock Exchange emphasized that it sought "to empower and encourage" the directors, officers, and employees of these companies, and thus "to avoid recommendations that would undermine their energy, autonomy and responsibility."

Finally, a flexible approach is critical to encourage innovation and improvements in the compliance arena. Since the Organizational Guidelines went into effect, they have helped to spur a wide range of formal and informal efforts to identify the factors that influence the effectiveness of compliance programs, the ways to measure effectiveness, and the "best practices" to promote compliance with specific legal requirements or within specific industries. Over time, these efforts will provide a more systematic understanding of how compliance programs in particular industries, or focused on particular legal areas, can be designed and implemented most successfully. They also underscore the limits of our current state of knowledge, and the resulting need to be cautious about detailed prescriptions that could deter innovation and limit companies' ability to incorporate new information and insights into their compliance programs.

In sum, the structured but flexible approach now embodied in the Organizational Guidelines has been important in fueling progress in the compliance workshop, and remains equally important today. It deserves re-emphasis and re-affirmation.

We have elaborated on these points at some length at the outset because they are relevant to many of the Advisory Group's questions. To return to the specific question at hand, we fear that revising the Organizational Guidelines to prescribe specific responsibilities of the CEO, CFO, and others responsible for high-level oversight of compliance programs (or to further define "specific individual(s) within high-level personnel of the organization" or "overall responsibility to oversee compliance") would represent an unfortunate shift toward micromanagement. These issues are addressed appropriately in the existing Guidelines.

Decisions about the exact responsibilities of the CEO, CFO, board, and other high-level personnel charged with overseeing compliance efforts should be made in the context of a specific organization, based on a thoughtful analysis of its individual circumstances. Among other things, the compliance-related duties assigned to specific positions must be based on an industry-specific and company-specific risk profile, and must be re-evaluated and refined on an ongoing basis as the risk profile changes. For example, recent scandals involving financial and accounting misconduct may produce the impression that compliance hinges mainly on financial personnel. But that focus will likely shift with changing circumstances - - and even today, for many companies the most critical compliance efforts involve matters outside the financial sphere. In the pharmaceutical industry, for example, the many legal and ethical obligations bearing on health and safety necessarily play a central role in shaping companies' compliance programs. Because uniform "compliance job descriptions" for every organization cannot provide the flexibility necessary to accommodate these essential kinds of considerations, they will not serve the Government's interests.

Question 1.b.

b. *To what extent, if any, should Chapter Eight specifically mention the responsibility of boards of directors, committees of the board or equivalent governance bodies of organizations in overseeing compliance programs and supervising senior management's compliance with such programs?*

Response:

For any organization, a strong compliance program requires active oversight by the board and appropriate board committees (or equivalent governing bodies and their committees), and reporting systems that provide all of the organization's top leadership with the information needed for effective oversight. As discussed above (in response to question 1.a.), we therefore suggest adding language to the Organizational Guidelines expressly recognizing these principles.

These issues have recently gained considerable attention, particularly in connection with preventing financial misconduct in publicly-traded companies. Measures to strengthen the role of directors and officers in certain aspects of compliance oversight have been adopted by Congress (with the enactment of the Sarbanes-Oxley Act), by exchanges such as the New York Stock Exchange (which recently adopted revised listing standards concerning corporate governance matters, now pending approval by the SEC), and by individual companies. We do not mean to suggest that the Guidelines need revision to reflect these recent measures: they apply to a subset of organizations, and the Guidelines

already anticipate new developments affecting compliance practices in specific sectors. Among other things, the Guidelines establish a presumption that an organization with an effective compliance program will incorporate and follow "applicable industry practice" and "the standards called for by any applicable government regulation." Similarly, a member of the Sentencing Commission's staff explained at the Commission's 1995 symposium on the Organizational Guidelines that:

> [T]he definition of an effective compliance program should be viewed as somewhat "elastic" - - in other words, able to accommodate a range of compliance approaches with the ultimate focus of the definition being to encourage companies to devise programs that actually work.
>
> This . . . has an important implication. It means that as certain compliance practices become recognized for their effectiveness, companies should . . . "read them into" the guideline requirements even if the guidelines do not explicitly require these practices.

Thus, the existing Guideline provisions on effective compliance programs are not static. They call for compliance programs to reflect changes both in applicable industry practice (including the industry's recognition of compliance practices that have proved effective) and in standards required by applicable government regulations - - whether these developments relate to board oversight or other matters. This is a sound approach, which suggests that language spelling out detailed responsibilities for boards (or equivalent bodies) and their various committees is not necessary. Nor would detailed corporate governance prescriptions be appropriate, given the diverse group of organizations covered by the Organizational Guidelines and their different types of governance structures.

Question 1.c.

c. *Should modifications be made to §8A1.2, comment 3(b) (defining "high-level personnel" and §8A1.2, comment 3(c) (defining "substantial authority personnel")? Should modifications be made to §8C2.5, comments 2, 3, or 4, relating to offenses by "units" of organizations and "persuasiveness" of criminal activity?*

Response:

Sections 8A1.2 and 8C2.5 recognize that large companies often contain several business units and that the leaders of these business units may hold great authority to act on behalf of the organization. Out of necessity, decision-making authority and accountability are often dispersed widely among such business units. The Guidelines also acknowledge the difference between pervasive and relatively isolated organizational conduct. We believe that comment 4 of Section 8C2.5 should further clarify the distinction between pervasive and non-pervasive conduct among the business units of an organization. Specifically, comment 4 should articulate that if conduct is not pervasive among business units, the conduct of one business unit should not be imputed to other business units.

Question 1.e.

c. *Should § 8A1.2, comment 3(k)(4), regarding the internal communication of standards and procedures for compliance, be more specific with respect to training methodologies? Currently § 8A1.2, comment 3(k)(4) provides:*

> *The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, **e.g.**, by requiring participation in training programs **or** by disseminating publications that explain in a practical manner what is required. (Emphasis added).*

The use of the "e.g." can be interpreted to mean that "training programs" and "disseminating publications" are illustrative examples, rather than necessary components, of "communicating effectively." The use of "or" can be interpreted to mean that "training programs" and "disseminating publications" are alternative means for satisfying the "communicating effectively" requirement.

Should the preceding language be clarified to make clear that both training and other methods of communications are necessary components of "an effective" program? If so, should the term "disseminating publications" be replaced by more flexible language such as "other forms of communications?"

Response:

As discussed earlier, we believe the flexibility offered by the Guidelines' existing language on effective compliance programs serves a number of important purposes, and any retrenchment from that approach would be unfortunate. While the companies in our group do use both training programs and other methods (such as written materials) to communicate their compliance standards and procedures to employees, adding language to the Organizational Guidelines mandating the use of training programs plus other methods of communication would be ill-advised. In addition, while "other forms of communication" (apart from written materials) can be valuable, the Guidelines' current language, citing illustrative examples of communication strategies, already gives companies the flexibility to use other forms of communication. Consequently, we do not believe any changes in this language would be necessary or desirable.

Question 1.f.

d. *Should § 8A1.2, comment 3(k)(5), concerning implementing and publicizing a reporting system that fosters reporting without fear of retribution, be made more specific to encourage: (i) whistleblowing protections; (ii) a privilege or policy for good faith self-assessment and corrective action (e.g., 15 U.S.C. § 1691(c)(1) (1998)); (iii) the creation of a neutral or ombudsman office for confidential reporting; or (iv) some other means of encouraging reporting without fear of retribution?*

Response:

As currently written, comment 3(k)(5) states that the organization must have taken reasonable steps to achieve compliance with its standards, citing as an example "by having in place and publicizing a reporting system whereby employees . . . could report criminal conduct by others within the organization without fear of retribution." We believe that a mechanism allowing employees to report suspected misconduct without fear of retribution is fundamental to a strong compliance program (and that, mechanisms aside, employees deserve the assurance that the company does not countenance retaliation for reporting wrongdoing in any circumstance). However, the current Guideline language already encourages companies to create mechanisms for employees to report misconduct without fear of retribution, and we do not believe the Guidelines should be amended to prescribe the specific type of mechanism companies should adopt. Companies need the discretion to make this decision based on thoughtful judgments about what will work best given their individual circumstances.

With regard to a privilege or policy for good faith self-assessment and corrective action, and the creation of a neutral/ombudsman office for confidential reporting, we believe that offering employees these kinds of protections may be valuable in enhancing a compliance program. Again, however, they should not be mandated, and it is important to understand that there are limits on a company's ability to extend these protections to its employees. Employees cannot be given an unqualified assurance of confidentiality if their reports may be discoverable in litigation, or required by the Government as a condition of the company cooperating with the Government; similarly, a company can assure employees that good faith self-assessment and corrective action will not result in inappropriate employment sanctions (provided that the company itself has some assurance that this will not be viewed as "non-cooperation" by government enforcement officials, or subject the company to collateral sanctions such as suspension or debarment), but a fear of employment sanctions is not always the principal deterrent to good-faith self-assessment and corrective action since employees also have confidentiality concerns. The ability to offer these kinds of assurances to employees could remove barriers to employee reporting and thereby enhance the effectiveness of compliance programs, and we hope the Advisory Group will adopt recommendations designed to mitigate the underlying problems that limit companies' ability to provide such assurances. However, the Organizational Guidelines should not require or encourage companies to make promises they cannot keep.

Question 1.g.

e. *Should greater emphasis and importance be given to auditing and monitoring reasonably designed to detect criminal conduct by an organization's employees and other agents, as specified in § 8A1.2, comment 3(k)(5), including defining such auditing and monitoring to include periodic auditing of the organization's compliance program for effectiveness?*

Response:

Organizations can make the auditing and monitoring component of their compliance programs most effective given the freedom and encouragement to design it thoughtfully. The types of "systems audits" of a company's compliance program referenced in the Advisory Group's question can offer a powerful tool for evaluating the program's effectiveness, diagnosing deficiencies, and engineering improvements. We do not mean to

suggest that these systems audits (or any other specific technique for auditing and monitoring) should be referenced in mandatory-sounding language in the Guidelines. The key principle is that organizations should be free to adopt an auditing and monitoring approach (or a combination of approaches) best suited to their specific needs, and to alter their auditing and monitoring strategy as factors such as their experience, changes in industry practice, or new research results suggest the potential for improvements. While we believe this principle is already reflected in the existing Guideline provisions, it may be helpful to add language specifying that systems audits of the organization's compliance program represent one example of an auditing and monitoring technique that organizations may find appropriate to their needs.

Question 1.h.

f. *Should § 8A1.2, comment 3(k)(6), be expanded to emphasize the positive as well as the enforcement aspects of consistent discipline, e.g., should there be credit given to organizations that evaluate employees' performance on the fulfillment of compliance criteria? Should compliance with standards be an element of employee performance evaluations and/or reflected in rewards and compensation?*

Response:

The criteria described in Section 8A1.2, comments (k)(1)-(k)(7) are minimum requirements for an effective compliance program. Comment (k)(6) currently provides that the organization's compliance standards "must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense" and that (while the adequate discipline of individuals responsible for offense is a necessary component of enforcement) the appropriate form of discipline will be case-specific. This is an appropriate minimum requirement. We strongly endorse the idea of adopting carefully-designed programs to evaluate the performance of appropriate categories of employees on their fulfillment of job-related compliance criteria, or to give special recognition to employees who have made an outstanding contribution to the organization's compliance efforts. However, these kinds of measures should not become minimum requirements for all of the organizations covered by the Organizational Guidelines, without which they will be deemed to have ineffective compliance programs.

Questions 3 and 5.

2. *How can the Chapter Eight Guidelines encourage auditing, monitoring, and self-reporting to discover and report suspected misconduct and potential illegalities, keeping in mind that the risk of third-party litigation or use by government enforcement personnel realistically diminishes the likelihood of such auditing, monitoring and reporting?*

3. *Should the provision for "cooperation" at § 8C2.5, comment 12, and/or the policy statement relating to downward departure for substantial assistance at § 8C4.1, clarify or state that the waiver of existing legal privileges is not required in order to qualify for a reduction either in culpability score or as predicate to a substantial assistance motion by the government? Can additional incentives be provided by the*

Chapter Eight Guidelines in order to encourage greater self-reporting and cooperation?

Response:

We have grouped these questions together because they both raise an issue central to achieving the goals of the Organizational Guidelines: how the existing disincentives for vigorous self-policing can be reduced. Reducing these disincentives is important because the Government can magnify the impact of its own enforcement activities by enlisting the full support of private sector organizations and their employees: the parties ideally positioned to serve as the first line of defense in the effort to prevent and detect misconduct.

As the Advisory Group's questions recognize, self-policing activities such as auditing, monitoring and self-reporting can create serious risks for a company - - risks that, unfortunately, do diminish the likelihood of auditing, monitoring, and reporting. Among other things, vigilant self-policing can create a documentary "roadmap" that can be used against a company: a roadmap <u>that only exists because of the company's voluntary efforts to detect and prevent legal violations</u>. Moreover, when companies that make voluntary disclosures to the Government are required to turn these documents over to the Government as a condition of cooperation, they jeopardize their ability to protect privileged or potentially privileged documents in the event of private litigation. All of this penalizes voluntary self-policing efforts: it puts the "good citizen" corporation at a disadvantage compared to a company that never embraced voluntary compliance; thwarts the goals of the Organizational Guidelines; and undermines the privately-funded "first line of defense" that Government enforcement agencies should seek to bolster.

To help rectify these problems, we strongly support the idea of adding language to the Guidelines clarifying that "cooperating" with the Government and providing "substantial assistance" to the Government do not require the disclosure of privileged documents - - or any documents that the organization generated by <u>bona</u> <u>fide</u> voluntary self-policing activities. While this is a modest reform that would not eliminate the existing disincentives for voluntary self-policing, it would help to reduce these disincentives and ensure that the Guideline provisions on cooperation and substantial assistance do not undermine the goal of fostering effective compliance programs.

In addition, the Advisory Group can recommend that the Sentencing Commission educate Government enforcement personnel about the importance of the self-evaluative privilege in spurring self-policing, and work to build Government-wide support for this privilege. By encouraging Government enforcement officials to refrain from seeking documents <u>that only exist because of voluntary efforts at self-scrutiny</u>, the Sentencing Commission can strengthen "good citizen" corporations by reducing the risk that they will be penalized for voluntary self-policing. Similarly, the Sentencing Commission can bolster effective compliance programs by encouraging Government agencies to refrain from seeking documents covered by the attorney-client and work product privileges. While the Sentencing Commission cannot proscribe practices that penalize self-policing, it can sponsor educational or research programs that could produce a better understanding of this problem and prompt Government enforcement officials to re-examine counterproductive practices. Given the Sentencing Commission's leadership role in promoting voluntary

compliance, it is uniquely positioned to fortify this critical first line of defense against corporate misconduct.

Question 6.

4. *Should Chapter Eight of the Sentencing Guidelines encourage organizations to foster ethical cultures to ensure compliance with the intent of regulatory schemes as opposed to technical compliance that can potentially circumvent the purpose of the law or regulation? If so, how would an organization's performance in this regard be measured or evaluated? How would that be incorporated into the structure of Chapter Eight?*

Response:

The companies in our group view their compliance programs as part of a broader commitment to legal and ethical conduct, and consistently emphasize that commitment to their employees. However, it would be inappropriate - - and unworkable - - for the Organizational Guidelines to make the adoption of an "ethics-based" approach a criterion for judging the effectiveness of a compliance program. Such a modification in the Guidelines would either produce cosmetic changes in compliance programs (e.g., changing the compliance officer's title to "ethics and compliance officer," sprinkling new references to "ethics" here and there in compliance policies), or it would require more problematic and contentious changes. For example, we understand that one comment has suggested that an "effective" program must include an ethics officer who completed at least three university courses in ethics; for many organizations, such a requirement may be impractical or have doubtful utility. In addition, the idea that organizations should be required to adopt programs designed "to ensure compliance with the intent of regulatory schemes as opposed to technical compliance" is fraught with difficulties. This approach could essentially punish organizations (through increased sentences) for failure to comply with the "intent" of a regulatory scheme, and it fails to recognize that organizations and individuals alike should be able to rely on the actual written regulations as the "best evidence" concerning the intent of a regulatory scheme - - that Government regulatory agencies have a responsibility to translate the regulatory intent into specific, clearly-written rules that eliminate guesswork about how organizations and individuals can discern the intent of the regulatory scheme and conform their conduct accordingly.

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We hope that these comments will be useful to the Advisory Group in developing recommendations for improving the Organizational Guidelines and preparing its report to the Sentencing Commission. We would also appreciate the opportunity for a representative of our group to testify at the Advisory Group's November 14, 2002 public hearing. Please feel free to contact either of the undersigned concerning this request. Thank you for your consideration, and for all of your efforts in this critical area.

Sincerely,

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