

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,¹ in response to the request for public comment issued by the United States Sentencing Commission (USSC) on December 30, 2003.² 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

¹ 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.

² 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).

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help the OIG develop its voluntary compliance guidelines for the pharmaceutical industry,³ 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);⁴ promote an "organizational culture" encouraging a commitment to compliance;⁵ satisfy new

³ 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).

⁴ Proposed Commentary to § 8B2.1.

⁵ Proposed § 8B2.1(a).

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internal reporting and more detailed oversight requirements;⁶ provide compliance training;⁷ periodically evaluate the effectiveness of their compliance programs;⁸ provide incentives to employees to follow compliance policies,⁹ in addition to enforcing compliance standards through disciplinary measures; and conduct ongoing risk assessments.¹⁰

These various changes reflect sound compliance principles that have crystallized since the initial adoption of the Organizational Guidelines, and we support their incorporation into the Guidelines.¹¹ At the same time, we hope the USSC will emphasize that - within the parameters set by this new and more rigorous framework - flexibility is still essential for companies to build compliance programs that are genuinely effective. As the USSC has explained previously, the Organizational Guidelines were designed "to encourage flexibility and independence by organizations in designing programs that are best suited to their particular circumstances."¹² Encouraging flexibility and independence is equally critical today. Without the freedom to use their best judgment - to develop customized compliance programs tailored to their individual needs and circumstances, their past experience with compliance strategies that have proved successful or disappointing, and their insights on innovations likely to strengthen their compliance efforts - companies would lack "ownership" of their compliance programs and may not feel empowered to design their programs for maximum effectiveness. The Organizational Guidelines have been "a real success story for the United States

⁶ Proposed § 8B2.1(b)(2) requires that: (1) the organizational leadership be knowledgeable about the content and operation of the compliance program; (2) the organization's board of directors be knowledgeable about the content and operation of the program, and exercise reasonable oversight over implementation and effectiveness of the compliance program; (3) specific individuals within high-level personnel have overall responsibility to oversee the compliance program; and (4) these individuals provide periodic reports on compliance matters to the organization's board. The current Guideline commentary only requires (3).

⁷ Proposed § 8B2.1(b)(4) makes compliance training a requirement, as opposed to an option, and extends the training requirement to the organization's upper levels as well as its employees and agents.

⁸ See proposed § 8B2.1(b)(5).

⁹ See proposed § 8B2.1(b)(6).

¹⁰ See proposed § 8B2.1(c).

¹¹ Recognizing that the amended Guidelines would create "heightened requirements" for an effective compliance program, the USSC asked whether the credit organizations receive for effective compliance programs should be increased from three to four points. 68 Fed. Reg. at 75359-60. Because these heightened requirements would "raise the bar" for effective compliance programs in a number of significant respects, we believe such a change is warranted. Coupling heightened requirements with a modest increase in the incentives for satisfying these requirements would be a useful step.

¹² An Overview of the Organizational Guidelines, Paula Desio, Deputy General Counsel, United States Sentencing Commission, available on the USSC website, <http://www.usc.gov>.

Sentencing Commission in its work to deter crime and encourage compliance with the law,"¹³ and the Guidelines' balance between structure and flexibility has been an important part of that success story. We believe the amended Guidelines can best stimulate ongoing improvements in companies' compliance practices if accompanied by commentary emphasizing that their revised criteria must be interpreted in the same flexible spirit that has characterized the Guidelines since their inception.

One example of why flexibility is important involves the proposed requirement to give employees "appropriate incentives to perform in accordance with [the compliance program]." ¹⁴ Companies must be able to implement this provision in a way that reinforces their efforts to make compliance an ingrained part of the organizational culture. We would be concerned with any interpretation of this requirement that mandated "bonuses" for adherence to the law and company policy, which should be a basic obligation of every company employee rather than something "above and beyond" employees' normal duties. Individual companies need the freedom to design incentive systems carefully, so as to ensure that their incentive systems do not inadvertently undermine or dilute the message that compliance with the law and company policy is expected of all employees as an ordinary part of their day-to-day responsibilities.

II. Encouraging Self-Policing

Vigorous self-policing by organizations - - the "first line of defense" in the effort to detect and prevent violations of the law - - is critical to achieving the goals of the Organizational Guidelines. The proposed amendments include two changes that would encourage self-policing, which we strongly support. We hope the USSC will also consider additional measures that would complement these changes: creating a presumption that a company that voluntarily discloses self-discovered violations has an effective compliance program; removing current Guideline language that reduces the incentive for effective compliance programs by tying the credit for an effective compliance program to a requirement for self-reporting; and working with stakeholders to address the "litigation dilemma" confronting companies that embrace self-policing.

Companies today face significant penalties for engaging in candid self-analysis and for reporting self-discovered improprieties to the Government. The USSC Ad Hoc Advisory Group's report on the Organizational Guidelines¹⁵ provides a thoughtful analysis of this problem. According to the Advisory Group, "[a] central objective of the organizational sentencing guidelines is to deter criminal conduct by creating incentives

¹³ Diana E. Murphy, The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics, 87 Iowa L. Rev. 697, 719 (Jan. 2002).

¹⁴ Proposed § 8B2.1(b)(6).

¹⁵ See Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (Oct. 7, 2003), available on the USSC website, <http://www.usc.gov>.

for voluntary compliance and by rewarding organizations that help the government discover misconduct.”¹⁶ However, the “litigation dilemma” creates countervailing incentives that can discourage vigorous self-policing. As the Advisory Group explained:

[T]he same information that an organization should use to improve its compliance and training efforts is also of potentially enormous value to those who may become involved in litigation with the organization, whether it be administrative, civil or criminal litigation. This gives rise to the “litigation dilemma” and often a justifiable reluctance by many organizations to “dig deep” for fear of creating a roadmap for litigants against it.¹⁷

In elaborating on the risks of effective compliance programs, the Advisory Group noted, for example, that “audits and investigative reports may become litigation roadmaps for potential adversaries” and even compliance training programs are “potentially riddled with peril because of the litigation dilemma.”¹⁸ Moreover, since “[u]nder present law, compliance program and audit materials are rarely confidential,” they are often subject to disclosure. “[I]f such disclosures are routinely allowed,” the Advisory Group warned, “they will undermine the law enforcement policies upon which the organizational sentencing guidelines . . . are premised: that corporate good citizenship can be induced through incentives that promote self-policing.”¹⁹ In short, the litigation dilemma “is recognized as one of the major greatest impediments to the institution or maintenance of truly effective compliance programs.”²⁰

A closely related problem addressed by the Advisory Group, which exacerbates the litigation dilemma, is that companies that voluntarily disclose suspected misconduct to the Government may be required to turn over privileged documents to the Government as a condition of cooperation. However, as the Advisory Group noted, voluntary disclosure of privileged documents may waive the privilege as to all parties who seek the disclosed documents.²¹ Consequently, even otherwise-privileged documents generated by a company’s voluntary self-policing efforts may become available to litigation adversaries and harm the company. All of these problems penalize companies for

¹⁶ Id. at 92.

¹⁷ Id. at 109.

¹⁸ Id. at 108, 116.

¹⁹ Id. at 117.

²⁰ Id. at 6.

²¹ Id. at 118.

building strong compliance programs and work against the USSC's goal of rewarding vigorous self-policing.

The USSC proposed two changes to the Guidelines currently regarding "information known by the organization" to obtain pertinent information for enforcement. The proposed amendments provide for voluntary self-policing regarding information known by the organization.²² This "all information to allow law enforcement in criminal conduct. not necessarily require self-reporting, the proposed amendments departures for strongly support these incentives for self-reporting in this

First, the proposed amendments create a presumption that an organization's compliance program is effective, but do not specify the standards for the program. The proposed amendments provide stronger incentives for organizations to create a compliance program. The proposed amendments provide a presumption that a compliance program is effective, but do not specify the standards for the program. The proposed amendments provide a presumption that a compliance program is effective, but do not specify the standards for the program.

Second, the proposed amendments provide that organizations that have an effective compliance program may be appropriate for a presumption of an effective compliance program. We agree that organizations that have an effective compliance program may be appropriate for a presumption of an effective compliance program. We agree that organizations that have an effective compliance program may be appropriate for a presumption of an effective compliance program. We agree that organizations that have an effective compliance program may be appropriate for a presumption of an effective compliance program.

²² See current § 8C2.5(g) and accompanying Commentary 12.

²³ See proposed Commentary 12 to § 8C2.5(g).

²⁴ See proposed Commentary 2 to § 8C4.1.

²⁵ See current § 8C2.5(f).

²⁶ 68 Fed. Reg. at 75359.

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self-reporting - - Government requests that the company turn over privileged documents, which may waive the privilege as to all potential litigation adversaries - - means that conditioning the credit for effective compliance programs on self-reporting diminishes the incentive for developing effective compliance programs that can prevent violations from occurring.

Finally, the USSC's Advisory Group recommended that the USSC become a "fulcrum to advance the debate [regarding the litigation dilemma] among policy makers."²⁷ Specifically, the "Sentencing Commission should consider how . . . it can advance and further the dialogue among the branches of government and interested members of the public," since "a dialogue seeking to resolve the litigation dilemma is fundamental to the full and effective operation of the organizational sentencing guidelines and public policies that they are intended to advance."²⁸ We endorse this recommendation and encourage the USSC to act on it.

III. Ethics-Based Approach to Compliance Programs

The proposed Guidelines would require that organizations exercise due diligence to prevent and detect violations of law and "otherwise promote an organizational culture that encourages a commitment to compliance with the law."²⁹ In its synopsis describing the amendments, the USSC explained that this proposal "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."³⁰ The companies in our group strongly support an ethics-based approach to compliance. Nevertheless, "ethics and values" are terms that might inject an unwarranted degree of subjectivity into Government determinations about whether a company's compliance program was effective; whether the company acted diligently to prevent and detect violations of announced legal standards is a more straightforward and objective inquiry. Consequently, we hope the USSC will emphasize the textual requirement that companies "promote an organizational culture that encourages a commitment to compliance with the law,"³¹ and make clear that companies have the flexibility to incorporate ethics-based approaches into their compliance programs in a manner best suited to their individual circumstances.

²⁷ Advisory Group Report at 129.

²⁸ Id.

²⁹ Proposed § 8B2.1(a).

³⁰ 68 Fed. Reg. at 75355.

³¹ Proposed § 8B2.1(a) (emphasis added).

IV. Misconduct By High-Level Personnel

Under the proposed amendments, high-level personnel participating in, condoning, or being willfully ignorant of an offense would create a rebuttable presumption that the organization's compliance program was ineffective, instead of the current conclusive presumption.³² We support this change. Organizations should be allowed to demonstrate that their compliance programs are effective, and to receive credit for the program if they do so, even in circumstances where an individual at a high level of the organization engaged in misconduct or malfeasance.

The USSC requested comment on: (1) whether the conclusive presumption should continue to apply in the context of large organizations; and (2) whether the rebuttable presumption should apply in the context of small organizations "in which high-level individuals within the organization almost necessarily will have been involved in the offense."³³ We believe it is unfair and counterproductive to apply the conclusive presumption to any organization. We understand the USSC's concern that even a rebuttable presumption can create special problems for small companies, and believe that eliminating the rebuttable presumption for small companies may be an appropriate step to address this concern.

V. Responsibility For Compliance Program Implementation

The proposed amendments add new language stating that "specific individual(s) within high-level personnel [*i.e.*, the compliance officer] shall be assigned direct, overall responsibility to ensure the implementation and effectiveness" of the compliance program,³⁴ whereas the current Guidelines only require that "[s]pecific individuals within high-level personnel of the organization . . . have overall responsibility to oversee compliance."³⁵

We are concerned that the proposed language could be misinterpreted to relieve company managers of their responsibilities for ensuring the implementation and effectiveness of the compliance program - - essentially making compliance efforts a discrete area that can be assigned exclusively to compliance professionals, rather than an integral part of the whole organization's culture. For a compliance program to succeed, all of the organization's operating management must embrace the program, feel a personal investment in its success, and assume accountability for its effective implementation. The compliance officer has critical duties - - providing leadership and

³² See proposed and current § 8C2.5(f).

³³ 68 Fed. Reg. at 75359.

³⁴ See proposed § 8B2.1(b)(2).

³⁵ Current Commentary to § 8A1.2.

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coordination of the compliance program, monitoring the program's performance, and keeping the company's management and board apprised of program implementation issues - - but cannot be held exclusively responsible for the overall success or failure of the program. We urge the USSC to clarify this point, emphasizing that effective compliance programs call for an organization-wide commitment involving all of the company's management.

VI. Proposed Language on "Model" Compliance Practices

The proposed amendments include language suggesting that organizations' compliance programs be measured against "model" practices. Specifically, a proposed commentary states that the precise actions required for an effective compliance program depend partly on "compliance practices and procedures that are generally accepted as standard or model practices for businesses similar to the organization."³⁶ By contrast, the current Guidelines provide that failure to follow "applicable industry practice" weighs against the finding of an effective compliance program.³⁷

Measuring compliance programs against industry practice is an important means to assess effectiveness. However, since industry guidelines describing "model" practices are often aspirational documents purposely designed to go beyond applicable industry standards - - to promote new approaches that would advance the state of the art in the compliance arena - - requiring compliance with these models is an unwarranted step that could actually discourage their creation. These aspirational models provide an important impetus for improvements in industry compliance practices, and should not be discouraged by making them mandatory. Industry groups may hesitate to develop model guidelines if they fear that the guidelines will be transformed into legal requirements, and there is no basis for a presumption that a company's compliance program is not effective unless it represents a "model" program. Instead, a company's adoption of model compliance practices should create a presumption that its compliance program is effective. We believe the "model" language in the proposed commentary to § 8B2.1 could be counterproductive, and should therefore be deleted. To advance the USSC's goals, industry groups should be encouraged to develop guidelines describing and promoting model compliance practices, and companies that adopt these model practices should be affirmatively rewarded for doing so.

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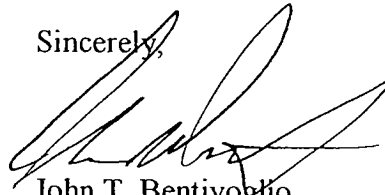
³⁶ Proposed Commentary 2(A) to § 8B2.1 (emphasis added.)

³⁷ Current Commentary to § 8A1.2.

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We hope that these comments will be useful to the USSC. We appreciate your consideration of these comments, and appreciate all of your efforts in this critical area.

Sincerely,

A handwritten signature in black ink, appearing to read "John T. Bentivoglio", written over the word "Sincerely,".

John T. Bentivoglio
Arnold & Porter LLP
(202-942-5508)

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