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VIA HAND DELIVERY

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Organizational Guidelines
C/o Office of Public Affairs
United States Sentencing Commission
Suite 2-500 South Lobby
One Columbus Circle, N.E.
Washington, D.C. 20202

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

Dear Mr. Jones:

On behalf of the 18 pharmaceutical companies we represent,[1] we are writing in response to the Request For Public Comment recently issued by the United States Sentencing Commission's Advisory Group on Organizational Guidelines.

As noted in the Request For Public Comment, the work of the Advisory Group will focus primarily on the application of the criteria for an effective compliance program listed in Chapter 8 of the Sentencing Guidelines (the Organizational Guidelines) and their effect on the Organizational Guidelines as a whole. The development of effective compliance programs and the ways in which Government can foster effective programs

[1] These companies are: Abbott Laboratories, Alcon Laboratories, Inc., Allergan, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Boehringer Ingelheim Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline, Immunex Corporation, Johnson & Johnson, Eli Lilly and Company, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc, Pharmacia Corporation, Schering-Plough Corporation, and Wyeth Pharmaceuticals.

are critically important subjects to which the companies in our group have devoted considerable attention, and we are pleased that the Advisory Group has been formed to study these subjects and develop recommendations for improvements.

By way of background, the group of pharmaceutical companies we represent have substantial experience with voluntary measures to promote compliance with the numerous regulatory regimes governing their activities, and a long-standing commitment to compliance. That commitment is reflected both in individual companies' compliance efforts, and in collective efforts to improve compliance practices. The members of the group, together with a number of other companies, have been meeting semi-annually for the past three years to exchange information and insights on "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. Subsequently, we met with the Inspector General to discuss pharmaceutical compliance issues and prepared a follow-up submission outlining our suggestions on promoting pharmaceutical compliance goals. While our efforts have focused on the development of effective compliance programs within the health care industry specifically, we believe they have broader applicability to corporate compliance programs in other industries and hope our comments can be of assistance to the Advisory Group as it embarks on its work.

The Organizational Guidelines are designed to provide "just punishment, adequate deterrence, and incentives for organizations to maintain internal mechanisms for preventing, detecting, and reporting criminal conduct."[2] Our comments focus on key issues that can enhance the achievement of these goals, with particular emphasis on bolstering incentives for companies to adopt and maintain effective compliance programs.

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A. Enhancing Compliance Program Effectiveness Through Flexibility

Under the Organizational Guidelines, an effective compliance program (one that "has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct") must satisfy seven specified criteria.[3] As the Sentencing Commission has explained in its overview of the Organizational Guidelines:[4]

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[2] U.S. Sentencing Guidelines, Chapter 8, Introductory Commentary.

[3] U.S. Sentencing Guidelines, § 8A1.2., Application Note 3(k).

[4] An Overview of the Organizational Guidelines, Paula Desio, Deputy General Counsel, United States Sentencing Commission, available on the Sentencing Commission's website, http://www.ussc.gov.

> The organizational guidelines criteria [for an effective compliance program] embody broad principles that, taken together, describe a corporate "good citizenship" model, but do not offer precise details for implementation. This approach was deliberately selected in order to encourage flexibility and independence by organizations in designing programs that are best suited to their particular circumstances.

(Emphasis added.)

This is a critical principle that we encourage the Advisory Group to re-emphasize in its recommendations to the Sentencing Commission. The seven criteria currently outlined in the Organizational Guidelines provide a sound framework for compliance programs, while preserving the flexibility necessary for individual companies to design customized programs that can be genuinely effective, and enabling the Government to take full advantage of the assets companies can bring to bear on the compliance mission. Pharmaceutical companies, for example, have a wealth of past experience with compliance measures; an in-depth understanding of how compliance efforts can succeed or fail within individual companies; a corps of dedicated compliance personnel who have worked for years to identify "best practices" for promoting compliance; and a capacity for innovation that can fuel progress in the compliance arena. Companies in the defense industry and in many other industries that have focused on effective compliance strategies have developed these same kinds of assets -- and companies have been able to use these assets precisely because of the flexibility afforded by the Organizational Guidelines.

Designing effective compliance programs is an art rather than a science. "Evidence-based" compliance guidelines do not exist at this point, and good judgment will always be necessary because effective compliance programs must be customized to fit individual companies.[5] While there is a broad consensus that the seven-element framework outlined in the Organizational Guidelines provides a sound foundation for an effective compliance program, there are innumerable "micro-level" decisions that go into designing and structuring compliance programs: the "precise details for implementation" that the Sentencing Commission wisely refrained from mandating. These include, for example, decisions about whether the company should create a "stand-alone" compliance

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[5] As a former Justice Department official observed some time ago, "[n]othing will quite so clearly demonstrate empty formalism or lack of conviction than a program that includes irrelevancies adopted untested and unscreened from the program of other companies with quite different problems." John H. Shenefield, Compliance Programs as Viewed from the Antitrust Division, 48 Antitrust L.J. 73, 74 (1979).

officer position or can best enhance the compliance officer's stature by placing the position within an office such as the general counsel's office; the type of auditing and monitoring activities best suited to identifying deficiencies and potential improvements in the company's compliance structure; the ways in which compliance standards can be communicated to employees most effectively; and the type of documentation requirements that enhance the compliance program rather than sapping its vitality. With respect to these kinds of decisions, companies need a clear message that they have the freedom to exercise their best judgment: that they can and should design compliance programs tailored to the specific needs, structure, and organizational culture of the individual company, using both their creativity and the lessons learned from their past experience. By avoiding a "command and control" approach that crowds out the exercise of judgment, Government can fully harness the private sector's experience, expertise, and energy.

A flexible approach also encourages innovation, allowing companies to improve their compliance programs on an ongoing basis as they learn more both from their own experience and from new research studies designed to identify compliance program features that enhance effectiveness. Over time, these research efforts should help to provide an empirical foundation for conclusions about how companies generally, or companies within particular industries specifically, can best design effective compliance programs. But the relatively recent emergence of this research field underscores the fact that Government micro-management of compliance programs is a premature strategy that would bring an unfortunate halt to innovation in the compliance laboratory.

In short, the goal of promoting effective compliance programs can best be advanced by re-emphasizing the flexible approach currently reflected in the Organizational Guidelines. Avoiding barriers to innovation and giving companies the freedom to use all of their experience, insights, and initiative to design better compliance programs has been a successful strategy for furthering the goals of the Organizational Guidelines, and any retrenchment from that model would be unwarranted. In the decade since the Organizational Guidelines became effective, they have been "a real success story for the United States Sentencing Commission in its work to deter crime and encourage compliance with the law"[6] - - and the balance between structure and flexibility struck by the Guidelines has been an essential part of that success story.

B. Encouraging Self-Policing

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

As a Member and Vice Chair of the Sentencing Commission noted in a recent article:[7]

> [T]he Commission is . . . working to improve its cooperative relationship with the Department of Justice . . . and . . . various enforcement agencies to ensure that the value of effective compliance programs is more fully recognized and that organizations are encouraged to regularly test and evaluate the effectiveness of their compliance structures without fear that deficient results will be used to punish them.

These efforts to ensure that organizations are not penalized for vigorous self-policing are critical to the goal of providing "incentives for organizations to maintain internal mechanisms for preventing, detecting, and reporting criminal conduct," and we encourage the Advisory Group to focus on this issue as it seeks to craft recommendations for improving the Organizational Guidelines. For example, the Advisory Group may wish to develop recommendations for clarifying the provisions in the Organizational Guidelines on cooperation with Government authorities,[8] to ensure that "cooperation" is not interpreted in a manner that could undermine the goal of promoting effective compliance programs.

Reducing the disincentives for vigilant self-policing is important because the Government invests substantial resources in enforcement activities, but needs the private sector as a committed partner in these efforts. In the health care field, for example, the Department of Health and Human Services Office of Inspector General alone will receive $150-$160 million for health care anti-fraud activities in fiscal year 2003.[9] But large enforcement budgets only go so far in a $1.4 trillion sector of the economy.[10] Ultimately, the suppression of health care fraud depends on voluntary efforts by health care

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[7] John R. Steer, Changing Organizational Behavior -- The Federal Sentencing Guidelines Experiment Begins to Bear Fruit, 1291 PLI/Corp 131, 153 (Feb. 2002).

[8] U.S. Sentencing Guidelines, § 8C2.5(g) ("Self-Reporting, Cooperation, and Acceptance of Responsibility") (providing sentencing credit if the organization "fully cooperated in the investigation" of the offense by the Government). Application Note 12 to this provision states that cooperation "should include the disclosure of all pertinent information known by the organization" and that "[a] prime test of whether the organization has disclosed all pertinent information is whether the information is sufficient for law enforcement personnel to identify the nature and extent of the offense and the individual(s) responsible for the criminal conduct."

[9] 2002 WL 373620 (F.D.C.H.)(testimony of Inspector General Janet Rehnquist).

[10] Centers for Medicare and Medicaid Services, National Health Expenditure Projections 2001-2011 (estimating national health care spending for 2001 as $1.4238 trillion), http://www.hcfa.gov/stats/NHE-Proj.

companies and their employees: the parties engaged in the day-to-day operations that make them ideally positioned to serve as the first line of defense in the battle to prevent and detect misconduct. The point is equally applicable to other industries. Government contractors, for example, are in the best position to serve as the first line of defense against Government contract fraud; by taking on this mission, they prevent and detect misconduct to a degree that could never be achieved by external policing.

Recognizing the societal benefits from self-policing, and spurred in part by the influence of the Organizational Guidelines, a number of Government agencies have taken steps to credit companies for adopting strong compliance programs. And yet self-policing companies still face greater exposure than companies that leave policing efforts to the Government.

Candid self-analysis can create serious risks for a company. It can generate a body of documents that, when taken out of context, could be used to harass the company with vexatious private litigation; invite the filing of qui tam suits that may prevent the company from enjoying the benefits of a voluntary disclosure under the Organizational Guidelines[11] or under the civil False Claims Act;[12] and undermine the company's ability to defend itself in litigation.[13] Self-critical analysis may create a documentary "roadmap" that can be used against a company: a roadmap that only exists because of the company's own voluntary efforts to detect and prevent problems. Moreover, companies that voluntarily disclose suspected misconduct to the Government have often been required to turn these documents over to the Government as a condition of cooperation. By doing so, a company threatens its ability to protect privileged or potentially privileged documents in the event of private litigation.[14] All of this puts a company that engages in voluntary self-policing efforts at a distinct disadvantage compared to a company that never embraced voluntary compliance.

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11 U.S. Sentencing Guidelines, § 8C2.5(g).

12 31 U.S.C. § 3729(a).

13 In fact, even seemingly low-risk activities like compliance training seminars can harm a company. For example, in one case a company facing a class-action suit was required to turn over notes taken by employees during training programs on anti-discrimination laws, which the plaintiffs used to prove that company managers had discriminatory attitudes. Stender v. Lucky Stores, Inc., 803 F. Supp. 529 (N.D. Cal. 1992).

14 See, e.g., Westinghouse Electric Corp. v. Republic of the Philippines, 951 F.2d 1414 (3d Cir. 1991) (privileged documents voluntarily disclosed to the Justice Department and the SEC were discoverable by the plaintiffs in a civil suit); In re Steinhardt Partners, L.P., 9 F.3d 230 (2d Cir. 1993) (privileged documents voluntarily disclosed to the SEC were discoverable by civil litigation adversaries).

Given its mandate, the Advisory Group is uniquely positioned to address this problem and bring about a reduction in the disincentives for self-policing. Perhaps most importantly, the Advisory Group can recommend to the Sentencing Commission that it embrace the self-evaluative privilege - - which is fundamental to the success of the effort to spur effective compliance programs - - and work to build support for this privilege throughout the Government. By encouraging Justice Department representatives and other Government enforcement officials to refrain from seeking documents that only exist because of voluntary efforts at self-scrutiny, the Sentencing Commission can dampen fears that companies will be penalized for voluntary self-policing and disclosure, and thereby bolster these efforts. Similarly, the Sentencing Commission can increase voluntary self-policing efforts and voluntary disclosures by encouraging Government agencies to refrain from seeking documents covered by the attorney-client and work product privileges. As noted earlier, one way to communicate this message would be to add clarifying text or commentary to the Organizational Guidelines provisions on cooperation with Government authorities, to ensure that they compliment the closely-related provisions designed to foster effective compliance programs. Guideline language making clear that "cooperation" does not require steps that would undermine the adoption or maintenance of strong compliance programs would directly reduce the disincentives for self-policing, and it could also spur Government enforcement officials to re-examine practices that penalize self-policing.

Self-policing efforts by private companies are an essential adjunct to the Government's own enforcement efforts. But today, companies are cautioned that despite the benefits of compliance programs "a host of contravening considerations" should make them "pause before blindly jumping on the compliance program bandwagon."[15] By working to reduce the "host of contravening considerations" that can place companies with strong compliance programs in a worse position than their peers, the Advisory Group can fortify this critical first line of defense against corporate misconduct.

C. Promoting Effective Compliance Programs Through Clear Rules

In an important guidance memorandum issued in 1998, the Department of Justice specified the factors that must be considered in evaluating potential False Claims Act charges against health care providers.[16] Among other things, these factors include: (1) "Notice to the Provider" (whether the provider had "actual or constructive notice . . .

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[15] Michael E. Clark and Solomon L. Wisenberg, Problems With Compliance Programs: Living on the Horns of a Dilemma, 3 Health Care Fraud & Abuse Newsletter 5 (Sept. 2000).

[16] Memorandum from Deputy Attorney General Eric H. Holder, Jr. to All United States Attorneys, All First Assistant United States Attorneys, All Civil Health Care Fraud Coordinators in the Offices of United States Attorneys, and All Trial Attorneys in the Civil Division, Commercial Litigation Section, Guidance on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998).

of the rule or policy upon which a potential case would be based"); and (2) "The Clarity of the Rule or Policy" (whether it is "reasonable to conclude that the provider understood the policy").

These related factors are equally important in the context of criminal sentencing, and their relevance extends beyond the health care area. The clarity of the rules a company is expected to follow is relevant both to culpability -- the "just punishment" goal of the Organizational Guidelines -- and to a company's ability to establish an effective compliance program that deters and detects misconduct. The whole concept of compliance programs is premised on a fundamental assumption: that there are known rules with which to comply. When the rules themselves are unclear, companies cannot translate a sincere commitment to complying with the law into an effective compliance program. Most importantly, this makes it difficult for companies to develop policies that provide meaningful guidance to their employees, which is a bedrock condition for any effective compliance program. In addition, a lack of clarity can make it difficult for companies to apply the self-reporting provisions in the Organizational Guidelines, which seem to presume that conduct violating the law is readily recognizable as such. [17]

Given the importance of these issues to the application of the Organizational Guidelines and the achievement of their goals, we encourage the Advisory Group to study the possibility of incorporating criteria similar to those set out in the Justice Department's False Claims Act guidance in the Guidelines.[18] Recognition of these factors could help both to ensure more appropriate sentencing decisions, and to encourage Government agencies to provide the clear guidance organizations need to develop effective compliance programs. This is actually the simplest and least costly way to deter legal violations by organizations, because most companies want to comply

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[17] U.S. Sentencing Guidelines, § 8C2.5(f) (providing that the credit for an effective compliance program does not apply "if, after becoming aware of an offense, the organization unreasonably delayed reporting the offense to appropriate governmental authorities"); § 8C2.5(g)(granting credit to an organization partly based on whether it reported the offense to appropriate governmental authorities "within a reasonably prompt period after becoming aware of the offense"). Application Note 10 to Section 8C2.5 provides that "no reporting is required by [the self-reporting proviso in 8C2.5(f)] if the organization reasonably concluded, based on the information then available, that no offense had been committed." However, it would be useful to make clear that the then-available "information" includes not just factual information about the conduct in question, but information from the relevant Government agency about the type of conduct constituting an offense.

[18] Although incorporating these criteria might seem unnecessary on the theory that apparently-legal conduct would not result in prosecution or conviction in the first place, this is not always the case. See, e.g., United States v. Whiteside, 285 F.3d 1345, 1353 (6th Cir. 2002)(reversing criminal convictions where "competing interpretations of the applicable law [are] far too reasonable to justify these convictions") (citation and internal quotations omitted).

with the law and will do so given notice of its requirements.[19] The substantial expenditures involved in after-the-fact investigations are an avoidable cost when greater clarity would have prevented the conduct under investigation in the first place. Notice of the rules governing a company's activities is central to achieving the goals of the Organizational Guidelines, and warrants explicit recognition in the Guidelines.

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The Advisory Group has undertaken an important mission, and we hope that these comments will be useful to it in analyzing the possibilities for improving the Organizational Guidelines and furthering their underlying goals. We would be happy to address any questions you may have, and would welcome the opportunity for further exchange about these issues.

Sincerely,

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[19] As the Department of Labor has observed in connection with its enforcement mission, "[r]egulations that are easy to understand promote voluntary compliance" because "[m]ost employers comply with workplace regulations if given the information they need." 65 Fed. Reg. 73408 (Nov. 30, 2000).