

**TESTIMONY OF GRETCHEN A. WINTER,  
BAXTER INTERNATIONAL INC.,  
TO AD HOC ADVISORY GROUP ON  
ORGANIZATIONAL GUIDELINES TO THE  
UNITED STATES SENTENCING COMMISSION  
NOVEMBER 14, 2002  
WASHINGTON, D.C.**

I am Gretchen Winter, Vice President and Counsel, Business Practices for Baxter International Inc., a position I have held for more than six years; I have been with Baxter for 13 years and working as an attorney with companies and government units for nearly 20 years. I currently serve as Vice Chair of the Ethics Officer Association Board of Directors, which has separately submitted testimony for your consideration.

In my position at Baxter, I am responsible for the company's business practices function (sometimes known as the corporate ethics function) and a member of Baxter's Corporate Responsibility Office. The testimony in this statement is being presented on behalf of our company, and we appreciate the chance to participate in this process.

I am proud to be part of the Baxter team, in a company and an industry that has a profound effect on the health and welfare of millions of individuals around the world. Our products and services are used in the treatment for thousands of patients with critical medical conditions that occur from traumatic injuries, immune disorders, kidney failure, cancer, as well as hemophilia.

We are a global health-care company with more than \$8 billion in sales and 48,000 team members in more than 100 countries worldwide. While our financial success is important, even more important to us is how we do business. At Baxter, we try to live Baxter's shared values each and every day, by acting in a completely transparent manner, engaging in dialogue with our stakeholders, by taking a progressive approach toward corporate governance and leading by example.

In my testimony today, I was asked to and will address the issues of accountability, leadership, governance, and ethical culture, specifically as reflected in Questions 1(a) through 1(d) and 6 as drafted by the Ad Hoc Advisory Group.

Let me begin with a general observation, one that echoes a point made in the Ethics Officer Association's written comments that have been separately submitted. The Organizational Guidelines (the "Guidelines") should maintain their flexible and non-prescriptive nature. This approach allows organizations of all sizes in all industries to develop company specific compliance and ethics programs that respond to the Guidelines' requirements, as well as needs that may be unique to the particular company or industry.

Question 1(a) asks:

**“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?’”**

Generally, our answer to Question 1(a) is “no.” Specific articulation of the responsibilities of the CEO, CFO, and/or other persons responsible for high-level oversight could unnecessarily, and perhaps unintentionally, limit their responsibilities to the articulated items. Such an approach could encourage too limited view of the role of high-level personnel in an effective compliance program. To the extent that further definition is desired, it seems that §8A1.2, comment 3(b) sufficiently defines the term “high-level personnel of the organization” and provides examples for organizations seeking guidance as to what type of person should take on responsibility for the program.

For example, Baxter has a comprehensive business practice program that involves a wide variety of high-level personnel of the organization. The Corporate Responsibility Office is made up of five individuals, including two senior leaders who also are corporate officers in charge of major business or functional units of the company, the General Counsel, the Vice President of Corporate Audit, and the Vice President of Business Practices. To carry out its activities on a global basis, the Corporate Responsibility Office established five Regional Business Practice Committees. The membership of the Regional Business Practice Committees is similar to that of the Corporate Responsibility Office, with senior regional business unit leaders serving as chair and vice chair and with members from business management and appropriate staff functions such as human resources, law, audit, finance, and business practices.

In sum, while the Guidelines’ current language allows flexibility in program design, the inclusion of additional illustrative examples--such as those used in the current definition in §8A1.2, comment 3(b)--could be helpful.

Question 1(b) asks:

**“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?”**

In light of court decisions such as Caremark and its progeny, legislative initiatives such as Sarbanes-Oxley, and regulatory requirements such as the NASDAQ and NYSE listing requirements, additional federal guidelines outlining board responsibilities are not necessary. However, if the as yet unstated expectation of the Ad Hoc Advisory Group and the United States Sentencing Commission is that boards of directors do have a role to play in overseeing compliance programs-and based on much of the submitted testimony, it appears that is likely to be an expectation-then that expectation should be articulated.

In Baxter’s case, the company’s board of directors oversees the company’s entire

business practice and compliance program and receives a report on the status of those programs at least once each year. The by-laws of Baxter's Board of Directors specifically give the Public Policy Committee responsibility for reviewing the policies and practices of the company to assure that they are consistent with the company's responsibility to employees, customers, and society. As part of that responsibility, the Public Policy Committee oversees the company's ethics and business practice standards for which I am responsible. I, as the Vice President of Business Practices, report to the Public Policy Committee on substantive matters and appear before the Committee at least twice each year. While greater specificity in the Guidelines about the reporting relationship between the ethics/compliance officer and the board, the title of the ethics officer, and the nature of the ethics officer's role within the organization could encourage greater focus on this issue within organizations, it is clear based on Baxter's experience that boards of directors can be engaged in the process without specific guidance through the Federal Sentencing Guidelines.

Question 1(c) asks:

**“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 ‘pervasiveness’ of criminal activity?”**

The comments made in response to Question 1(a) also apply here. The definitions highlighted in each of these items include a variety of illustrative examples, which provide both clarity and ideas for organizations seeking guidance. If the passage of time has given the Advisory Committee additional examples or reason to revise the specifics of the examples, then those changes ought to be made.

In addition, where other government organizations have issued specific guidance that could be interpreted as conflicting, the Guidelines and the guidance ought to be harmonized. For example, the Department of Health and Human Services, Office of the Inspector General, recently issued a “Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers.” Footnote 7 of that draft document states:

“The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.”

This statement may or may not reflect the views of the Ad Hoc Advisory Committee, but it is specific, detailed, and includes a rationale that enhances the understanding of the readers. Similar clarity in the Guidelines would be welcomed.

Question 1(d) asks:

**“Should §8A1.2, comment 3(k)(3), which refers to the delegation of substantial discretionary authority to persons with a ‘propensity to engage in illegal activities,’ be clarified or modified?”**

Yes. This comment should be expanded to include illustrative examples. If the Advisory Committee has collected examples of methods that organizations have effectively used to obtain knowledge of a “propensity to engage in illegal activities,” then those examples could be included here. If §8A1.2, comment 3(k) read more like the definitions in §8A1.2, comments 3(b) and 3(c) or §8C2.5, comments 2, 3, and 4, then there would be more guidance and clarity for organizations seeking to establish thorough and effective programs as required by the Guidelines.

Question 6 asks:

**“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?”**

This question suggests that the Advisory Group is looking beyond the Sentencing Commission’s current focus on criminal conduct. Because a failure to comply with laws and regulations does not always result in a criminal violation, and because many organizations’ compliance and business practice programs are values-based programs that focus on compliance with laws and regulations that do not all have criminal consequences, we believe it makes sense to expand the Guidelines to foster ethical cultures within organizations. Such an encouragement could be incorporated into the comments under §8A1.2, comment 3(k) and its sub-parts. The measurement and/or evaluation of this would have to be performed on a case-by-case basis, and the Guidelines use that kind of evaluation process elsewhere. See §8A1.2, comment 3(c).

Baxter will serve as a useful illustration. Our culture at Baxter is based on a set of seven shared values. The value of integrity is one of those values, and it requires legal and ethical conduct by all employees. It is important to remember, though, that guidelines, rules, and policies do not in and of themselves make us honest, and in and of themselves do not drive legal and ethical conduct. They only mark the pathway we should follow. Because we are individuals, we each have our own ways of thinking about guidelines and, then, according to our own moral code and our own view of “true north,” applying them. That is why it is so important that ethical decision-making be an active, dynamic, interactive, and proactive process within our respective organizations. This is critical, because each and every day, individuals at all levels of our organizations, in all corners of the world, are making ethical decisions in the course of conducting business. Baxter’s Corporate Responsibility Office, CEO or CFO will not be standing over each individual’s shoulder to direct the outcome. So

we do everything we can, through constant communication, training, and supporting tools, to be very sure that every single individual within our organization has the same “wiring” or fundamental set of values guiding their decision-making. An encouragement by the Guidelines to foster ethical cultures in all organizations would be welcomed.

Thank you for the opportunity to participate in this dialogue.