

Maintaining Professional Competence

Emerging Standards of Professional Responsibility for Health Care Compliance
Professionals in the Pharmaceutical, Biotech & Medical Device Industries

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Benefits of Recognizing HCC Professional Responsibilities

- Legal Reasons
 - Expectations of authorities
- Business Reasons
 - Balancing risks to achieve optimal decisions
 - Talent management, succession planning, performance management
- Personal/Professional Reasons
 - Professional advancement and development
 - A viable defense in some legal actions

What Does US HHS OIG Say about the Duties of Pharm/MDD HCC Professionals?

- The focal point for compliance activities
 - Appropriate authority
 - Experience or knowledge with relevant compliance issues
- HCC Professionals should demonstrate
 - High integrity
 - Good judgment
 - Assertiveness
 - An approachable demeanor
 - Elicit the respect and trust of company employees



“These interpersonal skills are as important as the professional experience of the compliance officer”

What Do the Legal Authorities Say About Professional Responsibilities?

- Duty of Care
- Standard of Care
- Why Should I Care?

What Do the Legal Authorities Say About Professional Responsibilities?

■ Duty of Care

- A requirement that a person act toward others and the public with the watchfulness, attention, caution and prudence that a reasonable person in the circumstances would use
- A sort of social contract that embodies the implicit responsibilities held by individuals towards others within society
- Reckless driving
- Slip and fall
- Products liability
- *Professional malpractice*

Similar to the civil law concept of *bonus pater familias*

- The conduct a normally careful and prudent person capable of conducting himself or herself with care and diligence

What Do the Legal Authorities Say About Professional Responsibilities?

■ Standard of Care

- The watchfulness, attention, caution and prudence that a reasonable person in the circumstances would exercise
 - Professionals are held to reasonable standards for members of their profession, rather than those of the general public
 - True whenever you are practicing a profession irrespective of whether you are a licensed professional

■ Adherence to the standard of care

- A viable defense against negligence actions where the professional met or exceeded the standard of care

ELIZABETH II



Bribery Act 2010

2010 CHAPTER 23

§ 7 Failure of commercial organisations to prevent bribery

...a defence for [commercial organisation] to prove that [commercial organisation] had in place adequate procedures designed to prevent persons associated with [commercial organisation] from undertaking such conduct...

Will the UK Bribery Act Create
New legal obligations for companies?
For compliance professionals?

What Do the Legal Authorities Say About Professional Responsibilities?

- Expanded use of “responsible corporate officer doctrine”
 - United States v. Park, 421 U.S. 658, 672 (1975); United States v. Dotterwich, 320 U.S. 277 (1943)
 - OIG Permissive Exclusion - 1128(b)(15)(A)(ii) of the Social Security Act
- Under Park and Dotterwich
 - “...companies have “a positive duty to seek out and remedy violations when they occur . . . and . . . a duty to implement measures that will insure that violations will not occur...”
- *“Individuals targeted may range from chairmen to mid-level compliance officers” **
- Park and Dotterweich evolved prior to adoption of extensive corporate compliance programs
- Can rigor of compliance programs, and diligence of compliance officers be a factor in defending against these claims?

*Bloomberg LP . Drug Executives May Face Prosecution Under FDA Lawyer's Drive; By Anna Edney | March 09, 2011 12:01AM ET
Eric Blumberg, deputy chief counsel for litigation at FDA. Source: FDA

Why should I care?

- Professional Responsibilities
 - Expected or imposed by the government and the law
 - Describe expected, objective standards of conduct
 - Professional recognition, development, advancement
- *US Caputo/Abtox* case Illustrates potential perils to compliance professions for failure to conform to professional responsibilities

US v. Caputo

Basic Facts

- AbTox marketed sterilizers for hospital instruments
- Riley - Chief Compliance Officer made “false” submissions to FDA to obtain market clearance
 - Withheld information on adverse events
 - Failed to properly investigate product complainants
- Marketed a *different* analyzer
 - Claimed to customers that it was cleared for marketing
 - Continued to do so even after receipt of warning letters from FDA
- Sterilizers left residue on ophthalmic instruments causing serious eye injury and blindness

Court's Findings

- The company's compliance program was a “sham”
- CCO was not independent
- CCO had no training in corporate compliance
- No proactive compliance efforts at the company emphasizing corporate ethics
- Company and CCO failed to recognize or react to known violations - hid adverse testing results from the FDA

US v. Caputo...

Quotes from the court

- “...[O]ne of only a few Chief Compliance Officers ever tried and convicted in federal court ...”
- “Corporate compliance officers are very much today’s corporate ‘fire personnel.’ They are often the company’s ‘first responders’ and must focus on proactive and reactive efforts to be effective.”
- CCO’s activities
 - “woefully and criminally inadequate.”
 - **aided and abetted illegal marketing plans,** using his expertise to “further shield and cover up offenses proven at trial”

CCO sentenced to six years in prison, and CEO to 10 years. Both required to repay hospitals \$17 M from fraudulent sales.

Caputo suggests potential perils to compliance professions for failure to conform to professional responsibilities

But What *Are* the Professional Responsibilities of Compliance Officers?

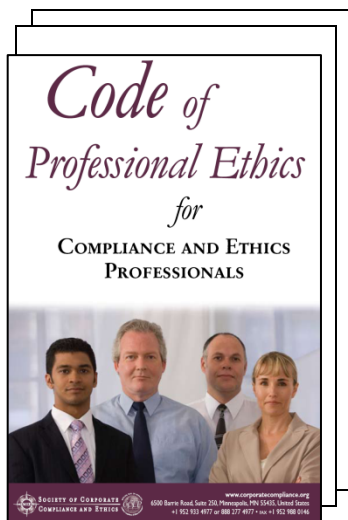
One Source –
Society of Corporate Compliance & Ethics

■ Obligations to the Public

- Abide by and promote compliance with the spirit and the letter of the law governing
- Exemplify the highest ethical standards in their professional conduct in order to contribute to the public good

■ Obligations to the Employing Organization

- Serve their employing organizations with the highest sense of integrity
- Exercise unprejudiced and unbiased judgment on their behalf
- Promote effective compliance and ethics programs



■ Obligations to the Profession

- Strive to uphold the integrity and dignity of the profession
- Advance the effectiveness of compliance and ethics programs
- Promote professionalism in compliance and ethics

Available in
English, Spanish, German,
French, Portuguese, Chinese,
Korean, Italian,
Japanese, Serbian

SCCE Code of Ethics

■ Duties to the Public

- Shall not aid, abet, or participate in misconduct.
- Shall take such steps as are necessary to prevent misconduct by their employing organizations.
- Shall exercise sound judgment in cooperating with all official and legitimate government investigations of or inquiries concerning their employing organization.
- If, in the course of their work, CEPs become aware of any decision by their employing organization which, if implemented, would constitute misconduct, the professional shall:
(a) refuse to consent to the decision; (b) escalate to the highest governing authority, as appropriate; (c) if serious issues remain unresolved after exercising "a" and "b", consider resignation; and (d) report the decision to public officials when required by law.

- Take necessary action to prevent misconduct
- Escalate disagreements to the highest governing authority, as appropriate

"CEPs should consider resignation only as a last resort, since CEPs may be the only remaining barrier to misconduct."

SCCE Code of Ethics

Duties to the Employing Organization

- Serve their employing organizations in a timely, competent, and professional manner.
 - Ensure to the best of their abilities that employing organizations comply with all relevant laws.
 - Investigate with appropriate due diligence all issues, information, reports, and/or conduct that relate to actual or suspected misconduct, whether past, current, or prospective.
 - Keep senior management and the highest governing body informed of the status of the compliance and ethics program, both as to the implementation of the program, and about areas of compliance risk.
 - Not aid or abet retaliation against any employee who reports actual, potential, or suspected misconduct, and shall strive to implement procedures that ensure the protection from retaliation of any employee who reports actual, potential, or suspected misconduct.
 - Carefully guard against disclosure of confidential information obtained in the course of their professional activities, recognizing that under certain circumstances confidentiality must yield to other values or concerns (e.g., to stop an act which creates appreciable risk to health and safety, or to reveal a confidence when necessary to comply with a subpoena or other legal process).
 - Take care to avoid any actual, potential, or perceived conflicts between the interests of the employing organization and either the CEP's own interests or the interest of individuals or organizations outside of the employing organization with whom the CEP has a relationship.
 - Disclose and ethically handle conflicts of interest and remove significant conflicts whenever possible.
 - Conflicts of interest may create divided loyalties. CEPs shall not permit loyalty to individuals in the employing organization with whom they have developed a professional or a personal relationship to interfere with or supersede the duty of loyalty to the employing organization and/or the superior responsibility of upholding the law, ethical business conduct, and this Code of Ethics.
 - Not mislead employing organizations about the results that can be achieved through the use of their [CEP's] services
-
- Diagram illustrating connections between duties:
- Investigate with appropriate due diligence all issues, information, reports, and/or conduct that relate to actual or suspected misconduct, whether past, current, or prospective. → Performance is timely, competent, and professional
 - Carefully guard against disclosure of confidential information obtained in the course of their professional activities, recognizing that under certain circumstances confidentiality must yield to other values or concerns (e.g., to stop an act which creates appreciable risk to health and safety, or to reveal a confidence when necessary to comply with a subpoena or other legal process). → Investigate alleged misconduct with diligence
 - Take care to avoid any actual, potential, or perceived conflicts between the interests of the employing organization and either the CEP's own interests or the interest of individuals or organizations outside of the employing organization with whom the CEP has a relationship. → Guard-against conflicts of interest

- Performance is timely, competent, and professional
- Investigate alleged misconduct with diligence
- Keep management informed on the program and risks
- Guard-against conflicts of interest
- Keep confidential matters confidential
- Exercise unbiased, fact-based judgment

SCCE Code of Ethics

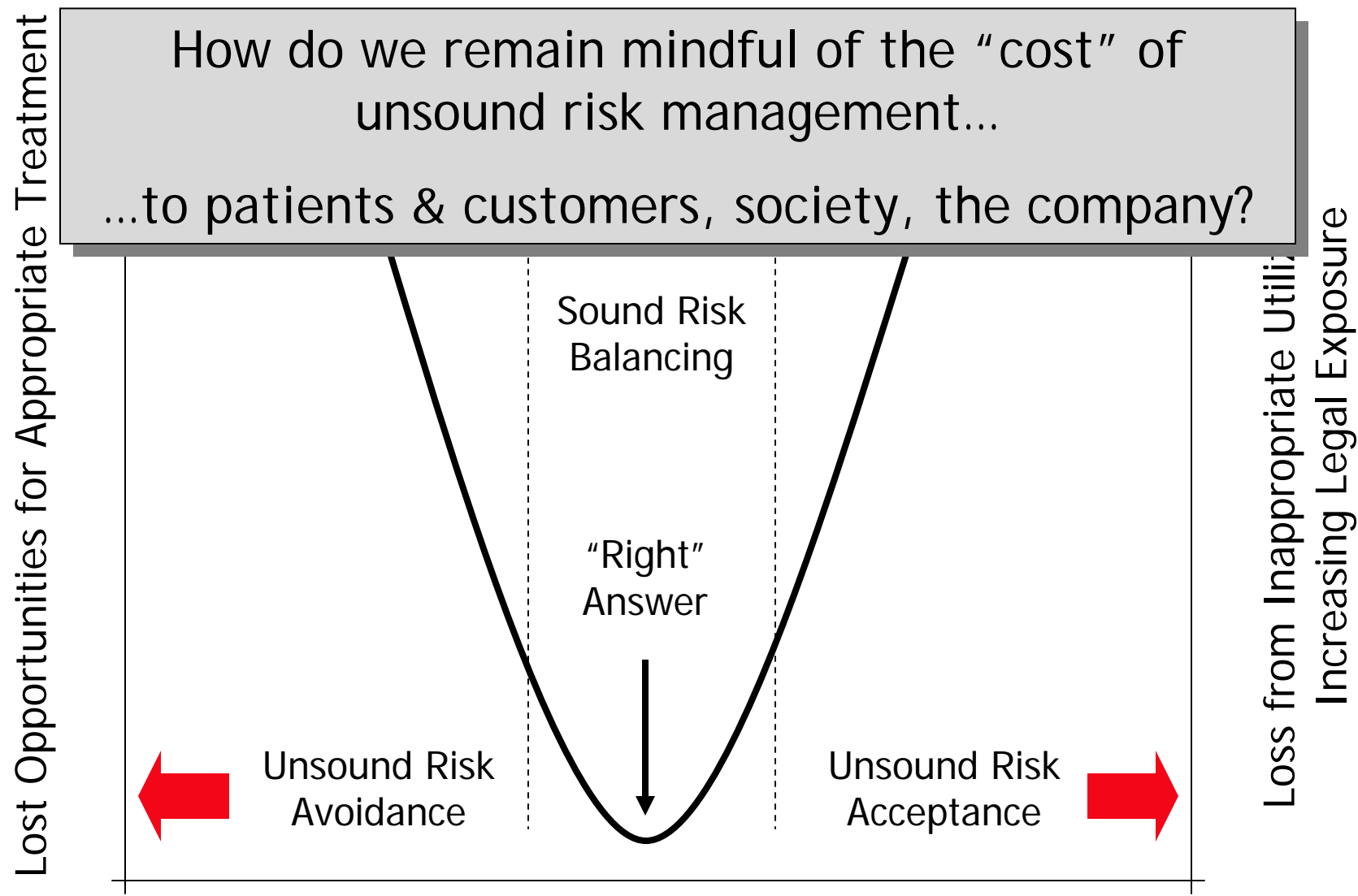
■ Duties to the Profession

- Pursue their professional activities, including investigations of misconduct, with honesty, fairness, and diligence.
- Not disclose without consent or compulsory legal process confidential information about the business affairs or technical processes of any present or former employing organization. Such disclosure could erode trust in the profession or impair the ability of compliance professionals and ethics professionals to obtain such information from others in the future.
- Not make misleading, deceptive or false statements or claims about their professional qualifications, experience, or performance.
- Not attempt to falsely damage the professional reputation of other compliance professionals.
- Maintain competence with respect to developments within the profession, including knowledge of and familiarity with current theories, industry practices, and laws

- Pursue duties with honesty, fairness, and diligence
- Maintain professional competence

Business Reasons to Recognize HCC Professional Responsibilities

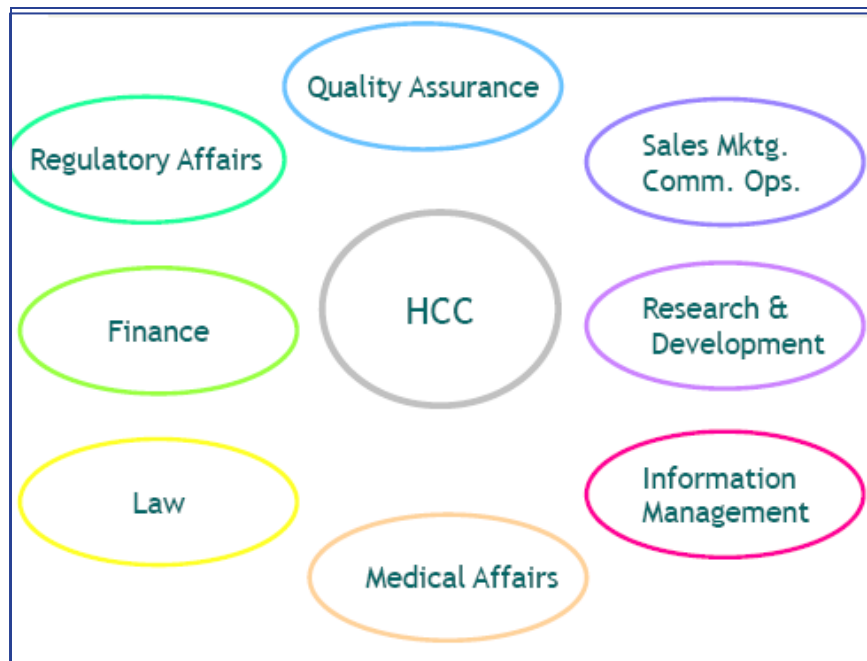
The "HCC Function*" - Illustrates Implications Unsound or Variable HCC Guidance



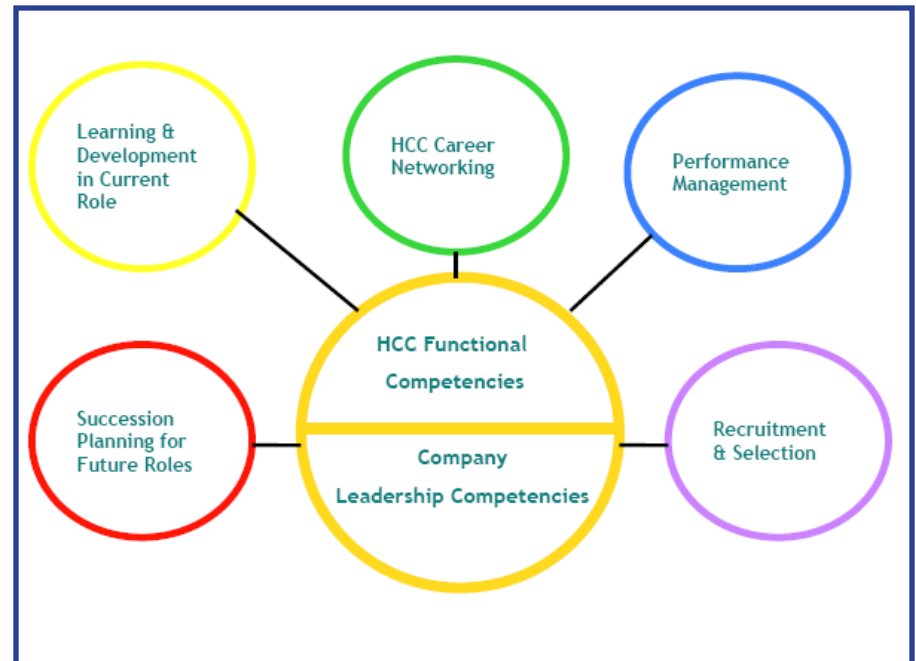
Getting Aligned, Staying Aligned

Diverse Feeder Disciplines

How do we get everyone aligned?



What Do Competencies, Talent Management & Learning Development Look Like For HCC?



■ Diverse/Variable Experience/Ability/Interests

- Compliance organizations, management/leadership
- Legal/regulatory issues
- Nature and extent of business activities and interactions with customers
- ¹⁶ External vs Internal issues

■ Leadership Competencies vs HCC Functional Competencies

- Role of professional responsibilities
- Observable behaviors
- Reinforce "good" behaviors
- Discourage "bad behaviors"

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CLOSING THOUGHTS

Professional Responsibilities are a
Strategic Imperative

Consider lessons learned from the Shakers

Did the Shakers Miss a Key Strategic Imperative?

■ The Shakers

- Beginning in the late 19th century, built 19 communal settlements with some 20,000 converts over the next century
- Widely admired for their industry and inventions
- Turnover was very high; the group reached maximum size of about 6,000 full members in 1840
- Strict believers in celibacy, Shakers maintained their numbers through conversion and adoption of orphans



As of 2011...
...only three are left

Professional responsibilities are an element of helping
to assure sustainable professional succession