Conscientious Collaboration: A Proactive Approach to Ensuring Ethical Interactions with Healthcare Professionals

Executive Summary

Medical device and pharmaceutical manufacturers depend on collaboration with doctors and other healthcare professionals (HCPs) to create and develop innovative products that help HCPs in their life-saving work. In today’s intensive enforcement environment, however, manufacturers and HCPs must also collaborate to keep their interactions ethical and free from bias and conflict of interest that can adversely influence medical decision-making. Conscientious Collaboration is Covidien’s platform through which we can discuss a proactive approach to ensuring ethical interactions with our customers and our HCP partners.

A New Era of Transparency and Accountability

Innovative new products and solutions from medical device and pharmaceutical manufacturers are an increasingly dominant part of healthcare. New products can offer doctors the opportunity to achieve better patient outcomes and often lower the cost of healthcare.

Manufacturers depend on HCPs for help conducting clinical trials and pre-market testing of products, as well as for field input, training of other HCPs, and improvements in techniques. But HCPs are also our customers, so the potential for conflicts of interest exists.

More than ever before, regulators are examining the interactions that medical device and pharmaceutical manufacturers have with doctors and other HCPs.

Covidien welcomes this focus on accountability and transparency. We believe that it will help prevent conflicts of interest that could compromise quality of care and increase healthcare costs. We believe that more accountability and transparency will lead to a better healthcare industry with higher ethical standards across the board.

At the same time, we believe that both medical device and pharmaceutical manufacturers and HCPs must take a very proactive role in shaping this new era.

Collaboration between manufacturers and HCPs can lead to innovations that help save lives and lower the cost of healthcare. HCPs are important partners for us. They have invaluable knowledge and experience in the business of providing effective patient care. Their insights can help us develop effective solutions to challenging medical problems.
The Physician Payment Sunshine Act provisions are part of the Patient Protection and Affordable Care Act of 2009. Under these provisions, medical device and pharmaceutical manufacturers in the United States must annually report to the government most payments greater than $10 until the aggregate of $100 is reached, at which point all applicable payments, including those less than $10, must be disclosed. The government will publish payment information on a public web site.

In the United States, a growing number of states – including Massachusetts and Vermont – have instituted marketing laws for medical device and pharmaceutical manufacturers, including disclosure requirements.

The United States Foreign Corrupt Practices Act of 1977 (FCPA) criminalizes payments to government officials outside the United States when intended to influence purchasing (“officials” include doctors and HCPs who are government employees). The UK Bribery Act of 2010 goes even further by making it unlawful to make payments to influence private individuals. Similar legislation is in place or under consideration in many other countries.

HCPs Under a Public Microscope

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New Rules of Engagement: Conscientious Collaboration

Today, manufacturers and HCPs must work together in a state of Conscientious Collaboration. Covidien’s Conscientious Collaboration platform includes being:

- Constantly aware of and embracing evolving ethical codes of conduct, policies and laws surrounding HCP/industry relationships
- Scrupulous about all HCP interactions
- Guided by our conscience and common sense
- Confident in our ability to be a good partner to HCPs and customers and to deliver optimal patient-focused solutions

Covidien has chosen to take a proactive approach to ensuring ethical interactions with HCPs. In developing our approach, we considered several factors:

First, we’re committed to creating and developing innovative healthcare solutions, developed in ethical collaboration with medical professionals, which enhance the quality of life for patients. We have a long, successful history of involving doctors and other HCPs in decision-making throughout our products’ lifecycles, which has enabled us to deliver innovative, effective products.

Second, we assumed that regulation would continue to evolve and intensify.

Third, we foresaw a need for compliance policies that are very specific to healthcare – policies that target the risks in the complex relationships between HCPs and medical device and pharmaceutical manufacturers.

Fourth, we recognized the value of industry codes of conduct, like those sponsored by AdvaMed and Eucomed, and became an early adopter and champion of the codes. These industry codes provide a strong foundation to build on.

Fifth, we saw that medical institutions and our customers were also struggling to protect themselves and their HCPs with appropriate conflict-of-interest policies. We saw value in being able to both lead and learn from their experiences.
**Executing Conscientious Collaboration**

Covidien’s compliance platform has four key principles built on applicable laws and industry codes:

**Separation:** All decisions regarding education and research grants are made by our Medical Affairs Department, *not* by Sales and Marketing. Led by Michael Tarnoff, MD, FACS for our Medical Devices and Supplies segments and Herbert Neuman, MD for our Pharmaceuticals segment, our various Medical Affairs organizations are structured to be independent of the profit and loss balance sheets that guide decision-making on the commercial side of our businesses. This helps ensure that decisions about support for clinical programs, research, and professional training and education are not linked to product purchase or use. This structure also serves to protect HCPs from the conflict-of-interest issues that may result when the sales organization holds this authority.

Further, all HCP interactions including consulting agreements are ultimately evaluated by independent Grants and Compliance Committees (GCCs). The GCCs review interactions with HCPs to ensure that the interactions are conducted with integrity and comply with Covidien’s Comprehensive Compliance Programs, relevant laws and regulations, and industry codes of conduct. The GCCs include representatives from Covidien’s Medical Affairs, Communications, Legal and Finance departments. Pre-authorization from the GCCs is required for all grants, consultancy arrangements and charitable donations that result in remuneration to healthcare professionals. These committees base their decision on the professional, scientific and clinical merits— not on sales volume. Policies governing Sales and Marketing interactions comply with industry codes of conduct (such as the PhRMA and AdvaMed codes) and all applicable laws.

**Transparency:** All interactions are open and disclosed to involved parties, including HCPs’ employers as appropriate.

**Documentation:** All interactions and agreements with HCPs follow established, detailed policies and are thoroughly documented. For example, consulting agreements contain details about the work product, qualifications of the consultant, timelines for deliverables and expense reimbursement.

**Fair Market Value:** Compensation to HCPs is based on reasonable and fair market value for the work delivered. This is independently assessed by the GCCs prior to execution of any contract.
Our Practices and Policies

We have created and implemented a number of practices and policies governing ethical interactions with HCPs. These include:

No Sponsored Travel and Attendance at Third-Party Congresses: In 2010, Covidien became the first large medical device company to stop direct sponsorship of HCPs’ travel and attendance at third-party congresses and conferences on a global basis. This policy change caused disappointment among some HCPs, but it has removed a significant area of risk for both Covidien and HCPs. We have chosen to focus our training resources in programs offered through our own training centers in the United States, France, China and Japan; and through partnerships with leading medical institutions and professional societies. We believe that this approach provides the greatest benefit to HCPs and patients, by focusing our training resources on safe and effective use of our products and by improving our control over program quality while mitigating the risk of conflicts of interest.

Minimally Invasive Surgical Fellowships in the United States: We recently ended direct sponsorship of minimally invasive surgical (MIS) fellowships. We decided to put the sponsorship award process into the hands of neutral organizations. One such organization is the Foundation for Surgical Fellowships (FSF). This enables us to financially support vital training while avoiding the potential for conflict of interest.

Investigator-Sponsored Research Grant Committee: We established an Investigator-Sponsored Research Grant Committee (ISR Committee) to help assess and approve HCP requests for clinical research grants through a process independent of our Sales and Marketing Department. Based in Medical Affairs, the ISR Committee is a cross-functional team that has decision-making authority over research grants requests. This process enables us to continue to support bona fide research projects, while keeping investigators, their institutions and Covidien in compliance with relevant laws, regulations, codes and policies.

Distributor Compliance Program: In many markets, Covidien sells its products through distributors. We established a formal Distributor Compliance Program and developed an International (non-U.S.) Distributor Code of Conduct to partner with our distributors to help them to understand and achieve compliance with Covidien policies. The Code outlines the expectations and standards for doing business on behalf of Covidien.

Covidien’s intent is to preserve and promote appropriate interactions with HCPs, by ensuring that all collaboration is ethical and will stand up to scrutiny. We continue to refine and improve our practices and policies, to make them more responsive and efficient for everyone involved.
Reinforcing a Corporate Culture of Compliance

Practices and policies are important, but on their own they aren't sufficient. With regulation a moving target, we can't expect everyone to be an expert on the laws. Therefore, we have worked diligently to create a corporate culture of compliance.

For example, Covidien's Guide to Business Conduct provides practical, on-the-job guidance to help our employees recognize compliance problems – including potential violations in interactions with HCPs – as they are happening. Our Comprehensive Compliance Programs and the Guide to Business Conduct are backed up with a global network of resources. We have established a clear path to help employees report problems or obtain advice. Our failure-to-report policy emphasizes that everyone has a personal responsibility to report violations. Our no-retaliation policy reduces risk and reassures those who are thinking of reporting legitimate concerns.

Our senior management team has supported our compliance program from the beginning. Their support has been vital to the program's success.

We're confident that, by collaborating closely and conscientiously with our HCPs, we can help change minds and behavior across our industry. Beyond sharing what we have done so far, we have many more ideas. For example, we would like to work with industry associations to develop "seals of approval" that identify and emphasize companies that are compliant with voluntary codes of conduct.

An Effective Partner for HCPs and Institutions

Ensuring ethical interactions with HCPs is vital to the global healthcare environment. Our goal is to continue to develop new devices and drugs that respond to the needs of the market, with the help of balanced input from HCPs and productive collaboration with them. Achieving balance is challenging, but it is critical for medical device and pharmaceutical manufacturers to make this happen.

Covidien's Conscientious Collaboration platform is our commitment to open communications about the need to ensure compliant interactions with our customers and partners. Through our policies and practices, we aim to enhance innovation and promote positive patient outcomes by preserving the ability of HCPs to partner with our Company in an ethical manner.