

COVID 19 SPECIAL EDITION N°2

April 17, 2020

A MESSAGE FROM THE SECRETARY GENERAL OF ETHICS



Dear ETHICS members – Welcome to the second Special Edition of ETHICS In Action – COVID 19. The first edition was well received and we had over 92 ETHICS members and guests join us in the follow-up Webinar which was held on April 14th. We want to thank our speakers, Roeland Van Aelst and Piergiorgio Pepe for their excellent presentations.

This Special Edition of ETHICS In Action addresses issues relating to the most important asset that a company has – its employees. Upcoming Special Editions will cover third party intermediary risks, the new EU temporary antitrust framework relating to the COVID 19 crisis as well as sales force management & compensation issues during the pandemic. We hope you find this edition interesting and we look forward to welcoming you to our next webinar.

THE NEXT ETHICS COVID 19 WEBINAR WILL TAKE PLACE ON APRIL 28th AT 16h00 CET. IT WILL FOCUS ON EMPLOYEE ISSUES RELATED TO THE CURRENT PANDEMIC CLARISSE AILLET WILL SEND OUT INVITATIONS NEXT WEEK.

COVID 19 - BALANCING EMPLOYEE SAFETY ISSUES EMPLOYEE TESTING & EMPLOYEE VOLUNTEERS DURING THE CRISIS

BALANCING EMPLOYEE SAFETY DURING THE COVID 19 PANDEMIC WITH HCO AND PATIENT NEEDS - Most of our companies have instructed their administrative, management and sales teams to work from home during this crisis. However:

- Many workers who are involved in critical manufacturing and supply chain functions are still on the job ensuring that pharmaceutical products and medical devices are produced and delivered on time to HCOs with critical patient needs.
- Most manufacturing and supply chain work areas were not designed for "social distancing".
- Shortages of masks, gloves and other personal protective equipment may make it difficult to protect employees from each other as well as from customers, suppliers and third parties with whom they must interact.

Clearly, employee safety must be a top ethical and compliance priority for companies. However, HCOs are in dire need of certain products. To their credit, most employees understand this and have stepped-up to the challenge. Nevertheless, companies must take exceptional measures to ensure on-site employee safety and security.

Given the current emergency, Ethics and Compliance Officers are among the professionals having an important role to play in helping corporate management, human resources and legal teams balance employee safety and the urgent requirements of HCOs, the medical profession and patients in order to avoid serious errors and missteps in the coming weeks and months.

Points to consider:

- 1. Should my company temporarily shut-down certain manufacturing and/or logistics sites which present high COVID 19 infection risks so that they can be re-configured or sanitized to improve worker safety?
- 2. Have employee COVID 19 protocols been put into place and clearly explained so that workers understand how to protect themselves?
- 3. Have workers been provided with a minimum of personal protection equipment and is my company attempting to purchase more and perhaps better equipment? Are employees being kept informed about these efforts?
- 4. Is there an employee health component to whistleblower reporting systems and are there management teams in place who can react quickly to address any reported COVID 19 health risks?
- 5. Are there some employees who are at greater risk if they contract COVID 19 and who should, therefore, not be asked to come to work during this situation?
- 6. What is the company's policy regarding employees who contract COVID 19 on the job? How does this policy tie in with local legal and health requirements?
- 7. How will data privacy / protection requirements be managed with respect to points 5 and 6 above?
- 8. Which authorities should be notified if an employee contracts COVID 19?
- 9. What remedial steps should be taken if an employee becomes infected at a particular location (implementing expanded social distancing at the site, site cleaning and disinfection, temporary shut-down of the site)?
- 10. In which situations should a company issue a press release?

EMPLOYEE COVID 19 TESTING

New rapid COVID 19 test kits are being developed and will become available in the near future. It may be possible for companies to acquire sufficient quantities of these kits over time to regularly test their employees and get immediate results.

Points to consider:

- 1. If COVID 19 testing of employees is introduced by my company, how will it be conducted? Will it be mandatory? Is this permitted by law in all concerned jurisdictions?
- 2. If an employee is tested positive what procedures will be put into place to deal with that employee and other employees at the site at which the employee works?
- 3. How will tracing be done to identify other employees or third parties who may have been contaminated by the infected employee?
- 4. How will the above information be disseminated and to whom?
- 5. How will the information be stored and protected?

EMPLOYEE VOLUNTEERS – Due to the enormous pressure placed on national health systems and their staffs many company HCPs as well as some non-HCPs have volunteered to work in hospitals during this pandemic. Companies are coming up with various ways of dealing with these situations. However, corporate policies need to be put into place rapidly in order to avoid missteps that could cause problems in the future.

Points to consider:

- 1. Should all company employees be authorized to volunteer or only employees with specific qualifications? Should they be encouraged to do so?
- 2. On what basis should requests for volunteering be denied (for example, HCPs currently supervising an on-going clinical trial cannot volunteer or only a specified number of company HCPs will be allowed to volunteer).
- 3. Should the company have the right to accept or refuse a posting to the particular hospital or institution at which the HCP wishes to perform volunteer services (for example, if that hospital is a customer)?
- 4. Should there be a time limit for the authorized volunteer period, with the possibility of extension by the company and / or the HCO making use of the volunteers?
- 5. Will the HCP be paid his or her salary by the company during the volunteer period? If so, could it be considered a grant or donation to the HCO?
- 6. Has documentation been prepared with HR and the legal department for signature by each HCP volunteer and the HCO institutions in question covering such things as:
 - a. The legal status of the volunteer during detachment period,
 - b. The length of the detachment period,
 - c. Who is responsible for supervising the volunteer,
 - d. Who is liable for errors or malpractice,
 - e. Who is responsible if the HCP falls ill or has an accident and are such events covered by the company's health plan,
 - f. Are there other company insurance issues that need to be checked,
 - g. What compensation, if any, is to be paid to the HCP by the company and/or the HCO institution during the detachment period,
 - h. Should the company issue press releases regarding the detachment and will the message be specific regarding a particular detached employee or general (perception is important),
 - i. Is the employee permitted to go on-line, speak to the press or otherwise disclose his or her status as a detached employee of the company and, if so, what can they say or not say,
 - j. Is the company permitted to terminate the detachment at any time and require the employee to return to the company and resume their normal duties?

If you have ideas, experiences or compelling stories which could help your colleagues and that you would like to share with other ETHICS members relating to the impact of COVID 19 on ethics and compliance, please let us know by contacting the ETHICS In Action editor, John McLoughlin, at john.mcloughlin.ethics@gmail.com

THE PASSING OF CLAUDE LE PEN



It is with great sadness that we inform our readers that Professor Claude Le Pen, a good friend of ETHICS, passed away on April 6, 2020 after a long illness. Professor Le Pen was an economist who, from 2004 to 2012, was President of the French College of Health Economists. He was also Co-Director of the Economic Masters program at Paris Dauphine University and a consultant with IMS HEALTH/IQVIA France. As many of you will recall, Professor Le Pen was one of our speakers at last year's General Assembly.

GLOBAL HEALTHCARE WEBINARS RELATING TO COVID 19

These webinars, which are organized by GHC LLC, offer special discount rates to ETHICS members. To register, click on the links indicated below.

US FCPA AND GLOBAL ANTICORRUPTION UPDATE FOR PHARMA & MED DEVICE Including Comments on Global Ethics and Compliance Challenges in Responding to the COVID-19 Pandemic – Peter Dieners of Clifford Chance is one of the presenters

Thursday, April 23, 2020

http://www.pharmaaudioconferences.com/pcaudio20200423/index.html

CHALLENGES POSED BY ALTERNATIVE BRANDED PROMOTION AND PROACTIVE ACTIVITIES BY THE FIELD PERSONNEL IN RESPONSE TO THE COVID-19 PANDEMIC

Thursday, April 30, 2020 – Stephen Nguyen-Duc, ETHICS Strategic Committee Co-Chair, is one of the presenters

http://www.pharmaaudioconferences.com/pcaudio20200430/index.html