

Master Thesis Topic: Elbows out in the race for market access: Does regulatory uncertainty (e.g., EU AI ACT) affect the prevalence of unethical pro-organizational behavior in the medical technology sector?

Brief Overview:

Regulatory uncertainty in the context of medical device technology relates to the lack of a clear regulatory approval process medical device manufacturers undergo, before being able to market/distribute the device to third parties (Stern, 2022). According to Stern (2017), regulatory uncertainty has been linked with factors like delay in market entry (first-mover disadvantages) and lower rates of innovative device commercialization. Consequently, if regulatory uncertainty leads to disadvantages for manufacturers, it can be argued that manufacturers will engage in acts to limit disadvantages, for instance “manufacturers may deliberately select language so as to avoid making medical claims that would require premarket review in order to get products to market faster or at a lower cost.” (Stern, 2022). Given the new EU AI ACT, medical device manufacturers need to demonstrate regulatory compliance with both the Medical Device Regulation (MDR) and the AI ACT. Thus, it is important to investigate the impact of such new regulation within the medical device space, specifically if manufactures will engage in behaviors that are pro-organizational yet could be deemed as unethical. For instance, omitting information from their AI products to avoid regulatory scrutiny of the EU AI Act in order to stay innovative and achieve speedy regulatory compliance.

Using the concept of Unethical Pro-Organizational behaviors (UPB) – that is “where companies engage in practices that are intended to promote the effective functioning of the organization and in the process circumvent core societal values, norms, laws, or standards of proper conduct” (Steele et al., 2023, Umphress and Bingham, 2011) -, the research aims to examine the prevalence, types and contributing factors in the medical technology sector.

Exemplary Research Question:

- What is the prevalence of unethical pro-organizational behavior in the medical technology sector? Specifically, “business-related UPB which consists of activities that directly contribute to the realization of the organization’s economic interest objectives, and relational-related UPB which consists of behaviors dealing with relationships with stakeholders” (Jing et al., 2021).
- What types of unethical pro-organizational behavior are medical device manufacturers likely to engage in, to achieve regulatory compliance with the EU AI Act and the MDR?
- Does regulatory uncertainty, specifically the (EU AI Act) lead to unethical pro-organizational behavior like business related /relational related UPB?

Research Design:

Using adapted surveys developed on unethical pro-organizational behavior, the proposed research includes a quantitative survey based on the UPB literature first introduced by Umphress and Bingham, 2011, as outlined by (Liu & Qiu, 2015) sent to manufacturers in the EU, US and China.

Application Process: Interested master students should send a short motivation email, CV, and grade report to edmund.balogun@tum.de & martin.fladerer@tum.de.

Relevant literature:

CIPD, CEBMa, & ANU (2019). Unethical behaviour in the workplace: A rapid assessment of the research literature (Research Report).

European approach to artificial intelligence (2024). <https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence>.

European Commission. (2023b). EU-U.S. Terminology and Taxonomy for Artificial Intelligence (Shaping Europe's digital future, Issue. <https://digital-strategy.ec.europa.eu/en/library/eu-us-terminology-and-taxonomy-artificial-intelligence>

European Commission. Guidance - MDCG endorsed documents and other guidance https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

Gogoll, J., Zuber, N., Kacianka, S., Greger, T., Pretschner, A., & Nida-Rümelin, J. (2021). Ethics in the software development process: from codes of conduct to ethical deliberation. *Philosophy & Technology*, 34(4), 1085-1108.

Jing, W., Shi, W., Liu, G., & Zhou, L. (2021). Moving beyond initiative: the reconceptualization and measurement of unethical pro-organizational behavior. *Frontiers in Psychology*, 12. <https://doi.org/10.3389/fpsyg.2021.640107>

Liu, Y., & Qiu, C. (2015). Unethical Pro-Organizational Behavior: Concept, Measurement and Empirical research. *Journal of Human Resource and Sustainability Studies*, 03(03), 150–155. <https://doi.org/10.4236/jhrss.2015.33020>

Mishra, M., Ghosh, K., & Sharma, D. (2022). Unethical Pro-organizational Behavior: A Systematic Review and Future Research Agenda. *Journal of Business Ethics*, 179(1), 63–87. <https://doi.org/10.1007/s10551-021-04764-w>

Steele, L. M., Rees, R., & Berry, C. M. (2024). The role of self-interest in unethical pro-organizational behavior: A nomological network meta-analysis. *The Journal of Applied Psychology*, 109(3), 362–385. <https://doi.org/10.1037/apl0001139>

Stern, A. D. (2022). The Regulation of Medical AI: Policy Approaches, Data, and Innovation Incentives. <https://doi.org/10.3386/w30639>

Umphress, E. E., & Bingham, J. B. (2011). When employees do bad things for good reasons: Examining unethical pro-organizational behaviors. *Organization Science*, 22(3), 621–640. <https://doi.org/10.1287/orsc.1100.0559>