

REPORT ON SPECIALIST SCIENTIFIC CONFERENCE "COMPLIANCE MANAGEMENT IN INSTITUTIONS OF THE HEALTHCARE SYSTEM" ON MARCH 9, 2018 IN BIELEFELD

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The insufficient entry of the registered doctors by the criminal offense elements of the German Criminal Code, which serve the protection against corruption, caused a significant reform of the 26th Section of the German Criminal Code in 2016. With the entry into force of Sections 299a and b Criminal Code (corruption and bribery in the healthcare system) the doors of the Healthcare Compliance have been opened. The topic is still relatively new and unexplored, however, several focuses can be identified already, which were discussed at this conference.

Bielefeld is distinguished in the Healthcare Compliance field by the research center Bielefeld Center for Healthcare Compliance (BCHC) under the management of Professor Dr. Michael Lindemann, professor for criminal law, criminal procedural law and criminology at the University of Bielefeld, as well as co-publisher of an important magazine in the German language relating to medical criminal law (medstra). The Bielefeld Center for Healthcare Compliance (<http://www.jura.uni-bielefeld.de/lehrstuehle/lindemann/bchc>) concerns a non-commercial university institution, which researches theoretical and practical questions of Healthcare Compliance in an interdisciplinary context.

An important exchange of opinions took place on March 9, 2018 at the University of Bielefeld with the specialist scientific conference "Compliance Management in Institutions of the Healthcare System", which was organized by the BCHC in cooperation with the working group medical law of the German Lawyers' Association [Deutscher Anwaltsverein]. The Compliance questions were in particular presented from the point of view of criminal law, criminology and labor law. The speakers (besides Professor Lindemann: attorney-at-law Dr. Maximilian Warntjen, Berlin, attorney-at-law Dr. Matthias Dann, Düsseldorf, attorney-at-law Dr. Rudolf Ratzel from Munich and Prof. Dr. Oliver Ricken, University of Bielefeld) involve experts in the field of German law. International references were only established marginally by this selection of the group of speakers. The following knowledge was discussed as a summary:

Various studies¹ have examined the distribution and effectiveness of Compliance Management systems in the healthcare system². After the entry into force of the criminal offense elements relating to the prevention of corruption in the healthcare system in 2016 in the German Criminal Code, the attention paid to Compliance questions in the sanitary working environment has increased substantially. In the opinion of the speakers, however, the effectiveness of the internal company systems for the prevention of Compliance incidents is still insufficient. Under this aspect criminology can make a contribution. The

¹ Prof. Dr. H. Schneider, Dr. jur. K. Grau & Dipl. Soz. K. Kißling, *The shock of Berlin hit deep! – Results of an empirical research project relating to Compliance in the healthcare system and the pharmaceutical industry*, 2, CORPORATE COMPLIANCE ZEITSCHRIFT 48 et seqq. (2013), shows that 2011-2012 only 28.3% of those questioned in the healthcare system and 76% of those questioned in pharmaceutical industries have written Compliance regulations. According to the study "Compliance on the clinic market" (2017) 83.8% of the questioned hospitals have a Compliance Management System, [http://www.ey.com/Publication/vwLUAssets/EY_-_Compliance_im_Klinikmarkt/\\$FILE/ey-compliance-im-klinikmarkt.pdf](http://www.ey.com/Publication/vwLUAssets/EY_-_Compliance_im_Klinikmarkt/$FILE/ey-compliance-im-klinikmarkt.pdf).

² The following presentation refers to the lectures and the presentations of the speakers.

efficiency of a Compliance Management Systems is to be fully linked with the corporate culture and its aims. The Compliance debate is thus to be connected with the discussion about business ethics, for which, in the opinion of the speaker, criminology is also responsible. The ethic components were neglected so far owing to a focus on the legal questions. The Compliance System can be compared to a house, with which the foundation walls consisted of ethical guidelines and values³.

Whether Compliance Guidelines are effective as a means of conduct control within the scope of the prevention of corruption, cannot be examined empirically yet owing to the circumstance that the relevant German criminal laws have only been in force since 2016. The central task of the prevention by Compliance Management is, however, to clarify under which prerequisites fees for the conducting of clinical trials, invitations of the industry to further training or further training trips, or cooperation contracts between clinics and doctors operating in the outpatient sector (procurement of clinic patients by the doctor operating in the outpatient sector against financial advantages) are possible still. There are no doubts that with such complex legal questions the Compliance Management will place an important role. The development of approval or examination procedures is of central importance before the doctor enters into a cooperation with the industry. Further decisive is the quality of the information provided to the standard addresses (employees). Criminal offences are committed, because the subtle limits between permitted cooperation and corruption are not always known. Therefore, it is necessary to teach and train employees accordingly by Compliance programs.

Special attention was further paid to the topic of the "panel doctor" (according to German law this concerns a doctor, who treats patients, who have a statutory health insurance) and his remuneration. The German settlement system is susceptible for manipulations and settlement fraud. The analysis of this phenomenon requires a differentiated analysis, depending on whether it concerns the settlement of an outpatient service in the doctor's practice or an inpatient service in the hospital. On the other hand, Compliance risks and favorable opportunities for an offence to be committed arise in the system of German healthcare owing to the lack of transparency and the complexity of the statutory regulations. As these make a distinction between the insurance status of the patient and the place where the service is provided (practice or hospital). A patient with statutory health insurance does not receive any settlement of the treatment in the German healthcare system (no "bill") so that settlement manipulations, for example the settlement of services that were not provided, are not recognizable for him.

Finally, aspects under labor law are to be taken into consideration in the Compliance organization. Significant in the field of the effectiveness of the Compliance Management System is the topic of "whistleblowing". After all, this concerns the only element in the system that envisages a "bottom up" communication. In Germany, there is no general obligation to report criminal offences. The protection of the person giving an indication is

³ Cf. with regard to these aspects also Daniela Dietzfelbinger, *Integrity Culture as a Forward-Looking Success Factor: A Practical Example*, 3, COMPLIANCE ELLIANCE JOURNAL, 53 et seqq. (2017).

not yet sufficiently provided for either. Furthermore, reporting obligations by whistleblower regulations for company employees should be discussed. These are currently at the most envisaged by regulations in the employment contract (for example for Compliance Officers), however not by law.

The food for thought offered by the conference is numerous and productive. The penetration between science and practice, which made substantial progress, is additionally successful.

A comparison of the discussion about Healthcare Compliance with the international position of research is useful beyond the topic of the conference. Germany should not, however, be representative for Europe either. In Italy, Pandora's Box has not even been opened yet. The gradually beginning discussion is deemed equivalent to breaking a taboo, because the topic has been concealed under a veil of silence so far.