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COMPLIANCE MANAGEMENT AT THE DÜSSELDORF UNIVERSITY HOSPITAL

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In light of the demanding requirements inherent to the operation of a university hospital, a multitude of compliance risks are entailed in the medical care, training, and research entail which such institutions are engaged in. If such risks materialize, the public will notice, which will substantially tarnish not only the public's confidence in the proper functioning and the integrity of the impacted hospital, but ultimately, the whole German health care system. In examining the structural and requisite prevention protocols, three risk groups can be distinguished. The Düsseldorf University Hospital provides a leading example in the area of compliance management.[1]

To begin with, compliance risks originate out of deficiencies in both process and control mechanisms, which—contingent upon the remoteness of the participating personnel—may lead to criminal liability in a negligence tort. Associated with this group of compliance risks are (among others) the following situations: the inadequate observation of hygienic protocols[2]; deficiencies in the sterilization of medical equipment[3]; informed consent[4] and other documentation concerns[5]; medical malpractice; the negligent authorization of access to patient records via records management software (hospital information systems)[6]; and the billing of foreign doctors whose professional license (§10 BÄO) has expired.[7]

The next risk group principally arises as a result of ignorance of the boundaries of criminal and/or civil law, and the corresponding social and professional rules of conduct; this also plays into the fact-finding phase of legal action, regarding the material facts required

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1 *See* Hendrik Schneider, Kevin Grau & Kristin Kißling, *„Der Schock von Berlin saß tief!" Ergebnisse eines empirischen Forschungsvorhabens zu Compliance im Gesundheitswesen und der Pharmaindustrie,* CORPORATE COMPLIANCE ZEITSCHRIFT 48, 48 (2013).

2 Case example: Birgit Hibbeler, *Hygiene-Skandal in Bremen: Auf der Suche nach den Schuldigen,* 108 (48) DEUTSCHES ÄRZTEBLATT A-2586 (2011).

3 Peter T. Schmidt, *Klinik-Skandal: Zwei weitere Manager suspendiert,* MÜNCHNER MERKUR (July 09, 2010), *available at* http://www.merkur-online.de/lokales/muenchen/klink-skandal-zwei-weitere-manager-suspendiert-835703.html (Sept. 15, 2014).

4 Kokularajah Paheenthararajah, Christian Hick & Axel Karenberg, *Medizinprodukteberater im Operationssaal: Patientenaufklärung erforderlich,* 110 (46) DEUTSCHES ÄRZTEBLATT A-2190 (2013).

5 Jutta Rippegather, *Rhön-Klinikum in der Kritik,* FRANKFURTER RUNDSCHAU (Nov. 14, 2009), *available at* http://www.fr-online.de/rhoen-klinikum-marburg/behandlungsfehler-rhoen-klinikum-in-der-kritik,2641638,4431464.html (Sept. 15, 2014).

6 *Compare Michael Schumacher: Diebe bieten Krankenakte zum Kauf an,* SPIEGEL-ONLINE, (June 24, 2014), *available at* http://www.spiegel.de/panorama/leute/michael-schumacher-krankenakte-gestohlen-und-zum-kauf-angeboten-a-976999.html (Sept.5, 2014).

7 Wanja Andreas Welke, *Zum strafrechtlichen Risiko der Tätigkeit angestellter Mediziner ohne Berufsausübungserlaubnis (Approbation) an Krankenhäusern*, Heft 5 GESUNDHEITSRECHT 269, 269 (2011).

to prove an offense or claim.

This case group is a result of the increasing legal regulation of medicine[8] and the development of advancing evolution of commercial law. This development is a concise, albeit not sharply contoured, legal concept.[9] For example, these types of risks crop up when professors and senior physicians work in collaboration with representatives from the pharmaceutical and medical instrument industries. The collaboration between medical staff and the various actors present in the pharmaceutical and medical instrument industries is critical to medical advancement. This is especially true in the context of university hospitals engaged in research projects. However, both these justifications may lead to conflicts of interest.[10] Lucrative contracting possibilities may present professionals in the field with incentives to promote and use certain pharmaceutical products (for example consulting agreements with medical corporations which participate in medical research) or medical devices (for example, sponsorships provided by medical specialists' associations, grants for continuing medical education, or corporate promotions which lend medical facilities medical equipment for specified projects).[11]

In relation to this compliance concern, it must be noted that university physicians, so called "Key Opinion Leaders"[12], are highly sought after in the medical industry. They play a decisive role in determining medical guidelines regarding recommended therapeutic approaches in medical care. Furthermore, they contribute to leading, influential medical publications, and through the lecture circuit they influence current methodologies and procedures in the medical field. It should be noted that raising funds from third-parties is expected from tenured professors active in research through the university; this

8 *Compare* Gernot Steinhilper, *„Kriminogene" Normgebung oder mangelnde Kontrolle? – Kriminalpolitische Überlegungen zur Eindämmung ärztliche Abrechnungsbetruges*, *in* Kriminalpolitik und ihre wissenschaftlichen Grundlagen, Festschrift für Professor Dr. Hans-Dieter Schwind zum 70. Geburtstag 163 (Thomas Feltes et al eds., 2006); in addition Adolf Laufs, *Die jüngere Entwicklung des Arztberufs im Spiegel des Rechts, in* Das Bild des Arztes im 21. Jahrhundert 18 (Christian Katzenmeier & Klaus Bergdolt, 2009).

9 Hendrik Schneider, *Wachstumsbremse Wirtschaftsstrafrecht*, Heft 1, NEUE KRIMINALPOLITIK 30, 32, (2012); additionally Hendrik Schneider, *Kriminalpolitische Grundlagen des Wirtschaftsstrafrechts*, *in* Wirtschaftsstrafrecht 48 (Hauke Brettel & Hendrik Schneider, 1st ed. 2014).

10 International MARC RODWIN, CONFLICTS OF INTERESTS AND THE FUTURE OF MEDICINE: THE UNITED STATES, FRANCE AND JAPAN (2013); for Germany KLAUS LIEB, DAVID KLEMPERER & WOLF-DIETER LUDWIG, INTERESSENKONFLIKTE IN DER MEDIZIN: HINTERGRÜNDE UND LÖSUNGSMÖGLICHKEITEN, (2011); Klaus Lieb et al., *Interessenkonflikte in der Medizin: Mit Transparenz Vertrauen stärken*, 108 (6) DEUTSCHES ÄRZTEBLATT A-256 (2011).

11 *Compare* specifically Hendrik Schneider *in* Korruptionsprävention im Gesundheitswesen (Susanne Boemke & Hendrik Schneider, 1st ed. 2011).

12 This is particularly instructive insofar as all published decisions on the corruption in the field of health care affect all university clinic health providers; BGH; judgment from 2/25/2003, Az: V StR 363/02, NEUE ZEITSCHRIFT FÜR STRAFRECHT-RR 171, 172 (2003); BGH, judgement from 10/23/2002, Az.: I StR 541/01, NEUE JURISTISCHE WOCHENSCHRIFT 763, 764 (2003); OLG Karlsruhe, decision from 3/30/2000, Az: II Ws 181/199, STRAFVERTEIDIGER 288, 290 (2001); OLG Hamburg, decision from 1/14/2000, Az.: II Ws 243/99, MEDIZINRECHT 371, 373 (2000).

compels collaboration between researchers, and corporations in the medical industry. Section 25 of the German federal regulations governing universities (Ger.: *Hochschulrahmengesetz*) and their respective state regulations specifically contemplate a funding scheme which permits tenured professors to execute research projects which are financed using third-party funds as opposed to ordinary budgetary funds.[13] To this end, North Rhine-Westphalia (NRW) higher education policies call for and encourage research to be sponsored by third-party funding, which are to be allocated based on merit (Ger: *leistungsorientierte Mittelverteilung* [*LOM*]). To fund their operating costs (Ger: *Zuführungsbetrag)* NRW gives separate grants to universities engaged in medical research.[14] NRW's Department for Innovation, Science, and Research appropriates a portion of this *Zuführungsbetrag* based on certain merit-criteria, among which are third-party funding and publications.[15] This scheme creates a situation where the type and amount of third-party funding becomes a factor which appeal proceedings will consider.

Within the scope of applicable malpractice law (§§ 331 ff. StGB), the boundaries between permissible and desirable cooperation and punishable corruption are fluid and legally uncertain. This is also the case for the acquisition of third-party funding, which is a crucial source for medical practices. In fact the German Supreme Court (Ger: *Bundesgerichtshof* [*BGH*]) has established case law concerning this issue.[16] The holdings of these precedential cases and their ramifications are, however, not always familiar to doctors in the field. Therefore, it is difficult to rule out that tenured professors or other doctors employed in university hospitals may acquire third-party funding proposals/projects from nonprofit organizations—which are outside the control of the university hospital—or other corresponding corporations. Such funding arrangements may lie outside the parameters outlined by the *BGH* for acceptable industry-funded research schemes. In accordance with the *BGH*'s decisive holding on May 23, 2002, the acquisition of third-party funding is legally unobjectionable only if the faculty member has satisfactorily observed the regulations governing universities.[17]

With nearly 5,000 personnel and 300 trainees on staff at Düsseldorf University Hospital at the end of 2013, it is difficult to exclude that intentional torts may be committed by tortfeasors who realize the unlawful nature of such actions. The risk of genuine, intentional torts presents the third type of conceivable compliance-risks university hospitals

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13 *Compare* for NRW. § 71, paragraph 1 HG NRW.

14 § 31b HG NRW.

15 http://www.wissenschaft.nrw.de/hochschule/hochschulen-in-nrw/hochschulmedizin/leistungsorientierte-mittel-lom-in-der-medizin/.

16 BGH, judgment from 3/23/2002 (LG Heidelberg), Az.: I StR 372/01, BGHSt 47, 295 (300); Brigitte Tag, *Drittmitteleinwerbung – strafbare Dienstpflicht? – Überlegungen zur Novellierung des Straftatbestandes der Vorteilsannahme* JURISTISCHE RUNDSCHAU 50, 52 (2004); Torsten Verrel, *Überkriminalisierung oder Übertreibung?* MEDIZINRECHT 319, 323 (2003).

17 Hans Kudlich, *Strafbare Erfüllung einer Dienstpflicht? Strafrechtliche Risiken bei der Einwerbung von Drittmitteln*, FORSCHUNG & LEHRE 106, 107 (2014).

must contend with. This risk brings harm not only to the university hospital, but also to involved third-parties. Theft and embezzlement of company property, including medication and anesthesia, are the typical case configurations facing a university hospital. With reference to characteristic risks involving third-parties are, for instance, the underlying circumstances surrounding organ transplant investigation files, embezzlement of funds or resources appropriated by the hospital or third-parties, or fraudulent accounting practices to the detriment of either the national healthcare system[18] or the privately-insured patient.

The underlying case configurations of organ transplant scandals evidence the presence of an autocratic management structure that may emerge in a university hospital. Such a management style may produce what could be termed a bottom-up power vacuum. Fear of repression or concern for their own careers may discourage lower associates from reporting the misconduct of leading, high-ranking hospital staff to senior management of the university hospital—the illusion of a class of untouchables[19].[20] This phenomena could be counteracted by whistleblower policies and protections (for example CIRS, or complaint management) that would provide avenues to anonymously report incidents to hospital senior management or compliance-authorities.

These specters facing a university hospital has been diagramed below in Table 1 ("Triad of Compliance Risks").

Compliance Risk	Attributes	Explanations	Example
1. Process and Control deficiencies	Negligence, missing monitoring (for example, because of downsizing), or fateful coherences cause damages on legal rights	Inconsistent observance of internal guidelines, deficits in the monitoring and enforcement of process standards and regulations, problematic outsourcing	A hospital allows an external company to perform the sterilization of medical equipment and tools. It leads to serious irregularities and hygiene defects.

18 Hendrik Schneider & Claudia Reich, *Abrechnungsbetrug durch „Upcoding" Ein Beitrag zu den Fallgruppen der „konkludenten Täuschung" im Straftatbestand des Betruges*, ONLINEZEITSCHRIFT FÜR HÖCHSTRICHTERLICHE RECHTSPRECHUNG ZUM STRAFRECHT 267, 268 (2012).

19 On the criminological background *see* HENDRIK SCHNEIDER & DIETER JOHN, DAS UNTERNEHMEN ALS OPFER VON WIRTSCHAFTSKRIMINALITÄT, EINE VIKTIMOLOGISCHE UNTERSUCHUNG; PUBLIC UND PRIVATE SECTOR IM VERGLEICH (1st ed., 2013).

20 *Compare* the decision of the OLG Braunschweig from 3/20/2013, Az: I Ws 49/13, RDG 2013, 288 (291) (A decision about the further applications of § 310, paragraph 1 Nr. 1 StPO against pretrial detention ordinance in Göttinger proceeding) as evidenced by the reported facts that employees responded to lower hierarchical levels and concerning evidence tampering relating to a Euro-transplant to message-type data to her supervisor and had been appeased with the commentary that they should stay relaxed, that it would eventually help humanly. "This is a medical ordinance which they must follow." A further message to the clinic- or university upper management board remained.

2.	Ignorance of the boundaries of criminal and civil law and their adjoining rules concerning social and professional conduct, which are referential to the material facts required to prove a criminal offense or a civil infraction	Criminality arises because the legal parameters of permissible medical and economic activities were not communicated in a complete or understandable fashion	Increasing codification of the medical field, and the progressive evolution of white collar crime with core legal concepts and definitions, which are, though, not distinctly contoured	University Professor Dr. X is head of the department for heart surgery of a university hospital. He receives medical-technology products, resources and services from companies. The company pays for certain expenses, like the travel costs for trips to professional conferences and for company and Christmas parties, to which Dr. X invited his department. [21]
3.	Compliance risks of intentional torts at the expense of the university hospital or at the expense of third parties	Tortious actions are consciously and knowingly committed, fully aware of the relevant circumstances	Increasing commercialization of medicine as well as a bottom-up control vacuum in an autocratic structured management [22]	An intentional lack allocations in organ procurement [23]

Table 1. Compliance risks in university hospitals

II. COMPLIANCE RISKS DON'T JUST AFFECT "THOSE OTHER GUYS"

In the pursuit of compliance in university hospitals, those responsible must be prepared to acknowledge that the aforementioned risks exist or can exist in any hospital or clinic, not just in other health-care facilities. It is well known that risk awareness and the mission statement established by upper management—the tone and example these set, and the ensuing catalysts and multiplier-effect therefrom—are critical to, and one of the decisive factors to the successful implementation and consequential enforcement of

[21] Case before BGH, judgment from 10/23/2002, Az: StR 541/01, NEUE JURISTISCHE WOCHENSCHRIFT 765, 763 (2003).

[22] *Compare* to Hendrik Schneider, *§ 4 Rdnr. 26*, *in* Wirtschaftsstrafrecht (Hauke Brettel & Hendrik Schneider, 1st ed. 2014).

[23] *Compare* to the so-called organ-donor scandal: Hendrik Schneider & Josephine Busch, *Der Lebensretter als Mörder? Der „Organspendeskandal" an den Grenzen der Strafrechtsdogmatik*, NEUE KRIMINALPOLITIK 362, 363 (2013).

compliance tools.[24] Consequently, this demands an incentive to be presented to promote compliance, and that is typically a yearly function by the enterprise's decision-makers.

In light of this, it's worth highlighting that the impetus to establish a Compliance-Management-System (CMS) in the Düsseldorf University Hospital and this system's sustainability is in the hands of upper management. Therefore, the importance of this support is clear, especially considering the complex conditions involved in the operation of a university hospital. This is a direct result of the cooperation-model which underlies the partnership between the Düsseldorf University Hospital and the Heinrich-Heine University. As a result this analysis requires a consideration of the differing authorities and contextual rights of participation held by both university and faculty leadership. In order to achieve substantial and coordinated results, systematic cooperation is required from all involved parties, and in particular from parties on the managerial level (hospital management, the rectorate, the faculty council, and the dean).

Empirical inquiries into the implementation of compliance mechanisms in varying industries as well as the failure to appreciate the importance of such compliance apparatuses demonstrate that risk consciousness has not spread into the hospital industry as it has in other sectors.[25] Evidently discussions about compliance—which are already taking place in other industries—must gain acceptance in the health care industry, especially in those organizations which operate under the assumption that they have no compliance risks. These organizations face an especially high risk: an organization oblivious to the possibility of risk creation in-house. By developing all hospital employees' risk consciousness, relevant compliance risks can be put into focus, weaknesses in prevalent internal processes can be spotted, and opportunities for intentional torts can be utilized.

After recognizing substantial compliance risks and how they arise at the Düsseldorf University Hospital, key elements addressing those high-priority risks were developed and implemented in the institution's CMS. This process is, though, still ongoing.

A. Analysis of the existing compliance-instruments and identification of key goals in improving the Compliance Management System

At the offset, it should be noted that this process at the Düsseldorf University Hospital has already begun. Different levels of the university hospital have already been engrossed in discussions about compliance and risk-prevention, which encompass the enhancement in the quality of medical care, and diverse provisions by means of guidelines and

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[24] For a political and sociological perspective, *see* COLIN CROUCH & CAMILLA MACLEAN, THE RESPONSIBLE CORPORATION IN A GLOBAL ECONOMY (2011).

[25] Hendrik Schneider, Kevin Grau & Kristin Kißling, *„Der Schock von Berlin saß tief!" Ergebnisse eines empirischen Forschungsvorhabens zu Compliance im Gesundheitswesen und der Pharmaindustrie,* CORPORATE COMPLIANCE ZEITSCHRIFT 48, 48 (2013).

regulations have been advanced.[26] Furthermore, the presented risks are being minimized through various measures, such as in-house data protection, protected health information, managerial control over commercial and medical dimensions, sanitary measures and occupational safety.

Goals were established for further implementation and improvements in the CMS, which were intended to prioritize compliance in the university hospital. These goals were based on an analysis of the existing compliance measures and special workshops. These workshops were attended by members of upper management, the authors of this article, members of human resources, and the administrators in the department of third-party funding in attendance.

Subsequent to this in-house evaluation of the Düsseldorf University Hospital's CMS, corruption prevention became the core concern. This evaluation of the existing instruments revealed that processes were already in motion on several different levels to avoid conflicts of interests and corruption through internal regulation and directives, touching upon the corresponding application forms and procedural standards (for example, "regulation of acquisitions/purchases", "guidelines for dealings and cooperation with third-party providers", "the Heinrich-Heine-University Düsseldorf's anti-corruption guidelines" as well as the applications for information and approval of additional business employment). With the aid of individual cases and proceedings—which were part of the analysis—deficits in different departments, in regulations, applications, and in validation measures were able to be identified. Against this background, it is necessary to harmonize existing regulations, to eliminate redundancies, and to hone, trim and align the substance of regulations to the current legal situation.

Within the scope of this in-house evaluation, it was essential that the involved departments openly criticized and disputed over the up-to-now implemented compliance measures. In regards to the extent, structure, transparency, and tolerability of compliance instruments, those particular departments occasionally have distinct issues ranging from lacking guidelines to non-transparent, over-reaching regulation. Prospective regulations must be carved out into configurations in conformity with the law and simultaneously with an eye to the intended audience. It was also necessary to promote the understanding that compliance requires thinking outside of the box, and to think beyond work environments which are of immediacy to considerations of compliance.

III. GOAL IMPLEMENTATION: ENHANCEMENT OF CORRUPTION-PREVENTION

[26] On this point, *compare* with *Abpfiff für Korruption im Gesundheitswesen*, ÄRZTEZEITUNG (July 23, 2012), http://www.aerztezeitung.de/praxis_wirtschaft/recht/article/818480/abpfiff-korruption-gesundheitswesen.html.

A. Legal Framework

As explained above, corruption prevention concerns above all the cooperation of medical personnel with the medical equipment and pharmaceutical industries, and this touches upon areas of sponsoring (especially business trips), additional business employment, and research involving third-parties. The composition and structure of in-house regulations outlining the requirements and limits of allowable cooperation are compiled in Table 2 below.

Legal Frameworks	Relevant requirements for compliance with AKRL control systems
Higher Education Act of NRW	▪ Freedom to Research and Teaching, § 4 ▪ Competency in the rectorate, president and the university senate, deanship, and faculty department councils ▪ Jurisdiction demarcation between the university hospital and the university in accordance with §§ 31, 31a ▪ Authorization of third-party funded research, § 71 ▪ Regulations regarding the administration of third-party funds, § 71
Regulation of University Additional business employment of NRW [27]	▪ Differentiation between generally approved, notifiable additional business work, and additional business work requiring authorization ▪ Requirements and boundaries of allowable additional business work ▪ Standards for allowing staff to exercise the right to engage in additional business work
Anti-Corruption Law of NRW [28]	▪ Obligations to disclose, inform, consult, inform of an offense in accordance with §§ 12 or if there are indica-

[27] Verordnung über die Nebentätigkeit des wissenschaftlichen und künstlerischen Personals an den Hochschulen des Landes Nordrhein-Westfalen (Hochschulnebentätigkeitsverordnung-HNtV) from 12/11/1981 effective 3/09/2010.

[28] Gesetz zur Verbesserung der Korruptionsbekämpfung und zur Errichtung und Führung eines Vergaberegisters in Nordrhein-Westfalen (KorruptionsbekämpfungsgesetzKorruptionsBG) from 12/16/2004 as amended on 12/19/2013.

	tions that there is a corruption offense present ▪ Commitment to implementation of corruption prevention measures in accordance with § 19 ▪ Implementation of the four-eyes-principle in the execution of certain contracts, § 20 ▪ Rotation principle, § 21
Enactment of the Federal State Department concerning fund allocation corruption	▪ Requirements for management responsibility (Subparagraph 2.1) ▪ Implementation of control mechanisms (Subparagraph 2.2) ▪ Obligation to execute measures which serve to sensitize co-workers (2.4) ▪ Ancillary regulations authorizing additional business (Subparagraph 2.7.2) ▪ Regulations on sponsorship (Subparagraph 4)
State Regulation on Travel Costs for NRW[29]	▪ Limits on travel costs and overnight reimbursements
Rules of Professional Conduct for NRW Doctors[30]	▪ Medical autonomy in accordance with § 30 ▪ Appropriations prohibition in accordance with § 31 ▪ Appropriations in contractual collaborations in accordance with § 33
Criminal and Civil Statutes	▪ §§ 331, etc. [31] ▪ § 266 (duty of asset maintenance of entrusted assets of employers and as appropriate a third-party provider)
UKVO	▪ Delimitation of competencies in accordance with cooperation agreements ▪ Regulations concerning the personnel of university with jobs in the university hospital

[29] Landesreisekostengesetz (Landesreisekostengesetz—LRKG) from 12/16/1998, as ammended on 12/03/2013.

[30] Berufsordnung für die nordrheinischen Ärztinnen und Ärzte from 11/14/1998, as ammended on 11/10/2012.

[31] Concerning attendants at the university hospital, who are affected by the anti-corruptions policy, it primarily deals with officials as defined by §§ 11, 311 pp. StGB.

Codes of conduct and anti-corruption policy of the HHU	▪ Prohibition of acceptance of rewards and gifts ▪ Threat of labor law repercussions and other consequences ▪ Exemplary lists concerning material elements

Table 2. Legal framework addressing anti-corruption guidelines

The above-referenced legal principles illustrate the substantial restrictions placed on the discretionary power to develop the composition of in-house hospital regulations addressing corruption prevention. The practice of additional business work or engaging in third-party funded projects can be hardly be legally restricted sufficiently to where the staff member pursuant to either statute, an employment contract, or an ordinance has an expressed valid claim on the acquisition and execution of a corresponding activity.

B. Objective

Anticorruption policy aim to integrate clearly understandable internal rules for the individual levels of cooperation of physicians and nurses, and the university hospital with the medical device and pharmaceutical industries. They are supplemental to the general policies in place and are not specifically tailored to the specifics of the operation of a university hospital, in this case, the anticorruption policy of the Heinrich-Heine-University.

The focus on the requirements of the anticorruption policy is to ensure that the legal premises and, in particular, the limits of legal liability and culpability are accounted for, without always requiring an individual case-study. The developed schemes should detail the complex criteria of the case law to the admissibility of certain operations (external funding, sponsorship, etc.) to the practical level of the employees in readily understandable language and (without requiring employees to expend effort in researching legal principles) avoid legally actionable acts to be committed out of ignorance of the limits of the law and its subparts. Thus under a socio-legal perspective it involves both a practical reduction in the complexity,[32] which will create a dependable basis of knowledge on which employees can have legal certainty of no wrongdoing. On the other hand the policy processes in the examination and approval of individual collaborations (compliance-by-design) helps standardize and protect the administrative resources of the house ("praise the routine"[33]) and decisions for or against granting authorization and to make these processes transparent. The parallel clarification of legal risks and of strategies for avoiding conflicts of interest and dependency-relationships complements those legal and

[32] Foundationally NIKLAS LUHMANN, VERTRAUEN: EIN MECHANISMUS DER REDUKTION SOZIALER KOMPLEXITÄT 100 (1st ed. 1986).

[33] Niklas Luhmann, *Lob der Routine*, Band 55 VERWALTUNGSARCHIV 1, 23 (1964).

process-oriented perspectives to an ethical and value-based approach, which aims to ensure the compliance commitment[34] of employees.[35]

C. Key Points of the anticorruption policy

1. The scope of application and construction of anticorruption policy

In accordance with the target set out above, the scope of application of anticorruption policies must be extend to third-party funds. These funds are supplemental to the regular budget raised to funding of research projects. They serve to support teaching, training and improvement in the health care system; they complement those funding schemes in the private sector or company. Other types of grants by third-parties are to be considered: donations, gifts, invitations, relevant grants of drug- and medical products, the financing of attending continuing education events and congresses by the industry, etc.[36]

The rules are complemented and widened by implementing regulations, which are already situated in the various existing administrative areas. These rules would be to create additional instruments and regulations for compliance. The content of the implemented regulations are based on the organizational structure of the administration. It is therefore based upon the department. Implementing regulations should be created only if additional regulations appear as absolutely necessary—in order words, compliant behavior has to be practically applicable. The anticorruption policy as a guiding document should include all the essential principle of information (for example, definitions), so that provisions are not redundant in the implementing regulations. This document's hierarchy is divided between its labor and information processes, so that on the one hand the administrative assistant and the addressee on the other hand are ensured that can key information can be easily accessible without any important information requiring a different employee to educate on the policy. In this way, policy would not be muddled by different administrative areas' interpretation of, for example, the four basic principles of compliance.

Therefore, there would ideally would be a program to educate (particularly new) employees on these policies, which would educate employees how to conduct themselves if

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34 Christoph E. Hauschka & Gina Greeve, *Compliance in der Korruptionsprävention – was müssen, was sollen, was können die Unternehmen tun?,* BETRIEBS-BERATER 165, 166 (2007); Martin Schulz & Hartmut Renz, *CB-Standard: Zum Berufsbild des Compliance Officers – Entwicklung branchenübergreifender Mindestanforderungen*, BETRIEBS-BERATER 2512, 2513 (2012).

35 For a perspective on the mechanisms and so-called neutralization-strategies, *compare* Hendrik Schneider, *Kognitive Dissonanz als Präventionsstrategie. Überlegungen zu den Möglichkeiten der Neutralisierung von Neutralisierungstechniken*, *in* Kriminologie—Jugendkriminalrecht—Strafvollzug, Gedächtnisschrift für Michael Walter 195 (Frank Neubacher & Michael Kubik eds., 2014).

36 In particular, *compare* to the regulation materials, Hendrik Schneider *in* Korruptionsprävention im Gesundheitswesen 60 (Susanne Boemke & Hendrik Schneider, 1st ed. 2011).

taking part in a third-party projects, in which equipment is loaned. This education will ensure that employees know the rules for the acceptance and use of by third-party funds or equipment/medications/etc. It further ensures that such practices are not undertaken without the execution of a contract or without securing financing for follow-up costs. A contract-exemplar, which addresses the concerns of the university hospital, will address these concerns and are outlined in the implemented regulations. Considering the context of the implemented regulations, in reality there are two essential core elements: (1) detailed information in thematic areas (compliance in general); and (2) communications about to compliance observed, process-procedures, jurisdiction, and coordination.

Where necessary and possible one should reference the already implemented regulations and also forms contract-exemplars or to the contact person. In the current revised implemented regulations provisions concerning business trips and additional business employment were revised and streamlined. Pamphlets on application forms will provide additional information and serve as an action guide, answering employees' questions and facilitate processes. The implemented policies concerning external funds include, among other things, elaborates on the definition of third-parties, gives further instruction and guidelines on the management and use of third-materials and information about it. This further advises the administration on questions to be included, for example, a note on incorporating a coordination center for clinical studies (KKS).

Implemented policies on procurements (purchasing order of purchasing) represent the most comprehensive control, as these relate to every conceivable instance the university hospital may address, include the principles, workflows and regulations that govern. For purchasing acquisitions, the guidelines, e.g. economy and thrift, the separation-principle and the principle of central procurement are mandatory. In terms of product groups and other categories of goods, the corporate procurement officer or contact person should be informed of such acquisitions. In the process organization, the description to the applicable regulations should be outlined (for example, in award procedures, the procurement of investment goods, proper supplies and services), or determining maintenance services (information management area, medical technology and other technology). Essential rules for medical products (acceptance, purchasing, and maintenance) can already be found in the anticorruption policy itself and in the implemented regulations on procurements so that guidelines for medical devices are contained in in-house agreements.

The individual administrative areas responsible for the regular updating and adjustment of their regulations are basically independent, and are to support legality in its participation. By assuming the changes in the implemented regulations to incorporate more interested actors, it follows that this is also within the framework of working groups. It has been shown that the currently envisaged process of implementation of regulation of third-party involvement and donations required not only substantive and legal adjustment, but also an analysis of process procedure and the redefinition of responsibilities among the actors in medical personnel, the external-division of the coordinating center for clinical studies, and a legal administrative body. The framework which guides changes or amendments in the implemented regulations is always the anticorruption policy.

As a result of the anticorruption policy's high reach because of their implemented regulations a document hierarchy is created, which is illustrated in Table. 3.

Anticorruption Policy			
Implemented regulation	Implemented regulation	Implemented regulation	Implemented regulation
Business trips/Additional business	Third-party funding/donations	Acquisitions	Medical products

Table 3. Structure of the anticorruption policy

According to a clarifying preamble, further clarification is needed of the appellative function and the establishment of the personal and material scope which clarifies the policy to be designated as classic basic principles of anti-corruption. These are highlighted in all industry codes.

2. Basic principles of anticorruption; their ascertainment in the AKRL and their implemented regulations

Three basic principles of an anticorruption policy can be delineated: (1) the transparency principle, requiring the disclosure of all grants obtained by the commercial director of the university hospital; (2) the documentation principle, which requires documentation of all dealings and agreements, in particular by unilateral grants (for example, sponsorships); and (3) the authorization principle,[37] which requires all bilateral agreements to be contractually authorized. The authorization with full knowledge of the relevant contractual provisions involves authorization on part of the top members of management, which falls within the meaning of § 331 Abs. 3 StGB. However the scope and meaning as found in the dogmatic §§ 331 ff. StGB has not yet clarified the matter conclusively. The relevant decisions of the *BGH* have shown that the presence of authorization is evidence

[37] The question of who is responsible for the granting of authorization within the meaning of § 331, paragraph 3 of the Criminal Code is disputed and not yet clarified last authentic by a Supreme Court decision. The law speaks of "the competent authority". Thus, the assumption is derived in criminal literature. In all cases in which no authorities structure are present due to the organizational structure of the house, the respective heads of the legal department is responsible (Siegfried Jutzi, *Genehmigung der Vorteilsannahme bei nicht in einem öffentlich-rechtlichen Amtsverhältnis stehenden Amtsträgern,* NEUE ZEITSCHRIFT FÜR STRAFRECHT 105, 106 (1991). The opposite conception (Albus, the cooperation between industry and physicians at medical university school directions. Under the suspicion of beneficial adoption and corruption according to §§ 331, 332 of the Criminal Code, 1st edition, pp 104) according to which jurisdiction in this important practical cases (about transfers to an account opened and monitored by the hospital externally-account) is to go for example at university hospitals in the respective federal standing, is a hardly viable and dogmatic unconvincing; in particular, *compare* Hendrik Schneider, *Die Dienstherrengenehmigung des § 331 Abs. 3 StGB. Bedeutung und Reichweite am Beispiel der Kooperation zwischen Ärzten und der Arzneimittel- bzw. Medizinprodukteindustrie*, *in* Festschrift für Hans-Heiner Kühne zum 70. Geburtstag 477 (Esser et al. eds., 2013).

against the presence of an illicit agreement.[38] Apart from that, the transparency and authorization principle also stem from relevant public-regulations and collective agreement provisions.

In addition—without dispensing with the medical expertise which professors and doctors provide—the separation principle must be considered. In addition to the relevant provisions in the anticorruption policy this principle is supported by organizations in the procurement processes and a separate procurement regulatory bill. The procurement regulatory requires truthfulness on part of the employee. Incorruptibility, loyalty to one's own company, and fairness to suppliers guide the values in compliance culture.

The procurement of equipment and durable goods requires proper services and maintenance services on behalf of the board of management; these are the sole responsibility of the central procurement offices. In essence, it is the four-eyes-principle. Orders and performance requirements executed by unauthorized employees are considered not legally enforceable. Medical, qualitative, and economic aspects are harmonized through a continued constructive exchange of experiences of the central shopping as well as those employees involved in purchasing. In accordance with the complementary actions of the risk-management office in procurement decisions it is further provided that at least three offers must be solicited, in some cases five. The end results of this decision-making processes must be documented in writing on specified forms. The existence of conflicts of interest is determined on an ad hoc basis, for example, by request of the Human Resources Department (e.g. with respect to additional business employment, consultation agreements with certain providers).

The equivalence principle, which is developed the allowance and upper limits of pay, is embodied in other provisions of the anticorruption policy. This ensures an appropriate balance between the services of doctors and refunds/inducements on the part of industry. Note that it is the concept of appropriateness legal status may be a so-called enhancement concept, which opens up a certain economic playroom by the investigating authorities. Against this background, there is not an appropriate remuneration, but a corridor of reasonable lower limits, which are marked out by the already adequate and the upper limit of equitable remuneration.[39]

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[38] Paradigmatically, BGH, judgment from 2/25/2003, Az. V StR 363/02, NEUE ZEITSCHRIFT FÜR STRAFRECHT -RR 173, 171 (2003); "With the penal regulations of § 331 of the Criminal Code - intensified by the anti-corruption law – it is also the cause of an appearance of possible 'venality', which is encountered by officials. The sensibility of the legal community, when considering the culpability of the counter measure of benefits by officials, is also present in cases of this kind, and have now been sharpened considerably. Thus, in such cases with future officials, the adoption of any advantages that can be brought in connection with their official exercise will be demanded with strict hedging of transparency in respect to openness and solicitations on permits in regards to the legality of the university"; in the academic literature, *compare* Daniel Geiger*, Antikorruption im Gesundheitswesen,* CORPORATE COMPLIANCE ZEITSCHRIFT 5, 1 (2011); *see* also the comments to the FS drug industry to service men's approval (May 2010). *Available online at* www.fsa-pharma.de

[39] *See* Hendrik Schneider & Thorsten Ebermann, *Das Strafrecht im Dienste gesundheitsökonomischer Steuerungsinteressen*, ONLINEZEITSCHRIFT FÜR HÖCHSTRICHTERLICHE RECHTSPRECHUNG ZUM STRAFRECHT

3. Regulations on the individual levels of cooperation with the industry

In the above sections, it was shown that the anticorruption policy regulates the details of the cooperation of the medical professional personnel of the Düsseldorf University Hospital with the pharmaceutical and medical devices industry. Regulations have clarified the research with third-party funding the administrative sovereignty is to be vested in the financial department. Third-party contracts are to be translated into English or another foreign language when necessary. It is the written-form requirement. It also deals with the permissible purposes of the use of third-party funds, the corresponding personnel measures and the possible uses in case of surplus external funds that are allowed to remain in accordance with the underlying contract at the university hospital. In the implemented regulations of third-party dealings, it is prohibited the adoption of any kind of remuneration contained in third-party funds. Corresponding research projects are exclusively to be unwound through the university hospital. For each third-party-plan a separate accounting book are set up. It is also ensured that a project manager can, at any time, conduct an online account-query.

Principle schemes also exist to set regulations addressing the acceptance of donations and for dealing appropriately with grants of the medical devices industry, the acceptance of gifts and invitations (including the setting of an unobjectionable value limits). Through the relevant regulations, those additional public and legal regulations (including collective bargaining arrangements) are enhanced and refined.

Another focus is on arrangements for the participation of so-called external (that is unaligned from UKD) and internal (that is, aligned by the workers of UKD) congresses and continuing education events—that is, as far as these are funded by the industry, or at least supported by their sponsorship. In this respect, a distinction must be made between active and passive participation. The anticorruption policy contains upper limits for legally acceptable, adequate sponsorship and standards for transparent contract design (including such areas as travel expenses/entertainment expenses/overnight stays /remuneration), which aim for a good balance of performance and reward. This would include, for example, renting exhibition booths.

IV. SUMMARY OF THE ESSENTIAL STEPS FOR THE IMPLEMENTATION OF THE COMPLIANCE MANAGEMENT SYSTEM IN UKD

The essential steps for the implementation of the CMS can be summarized in Illustration 1 below.

219, 221 (2013); Daniel Geiger, *Das Angemessenheitspostulat bei der Vergütung ärztlicher Kooperationspartner durch die Industrie*, ARZNEIMITTEL UND RECHT 99, 101 (2013).

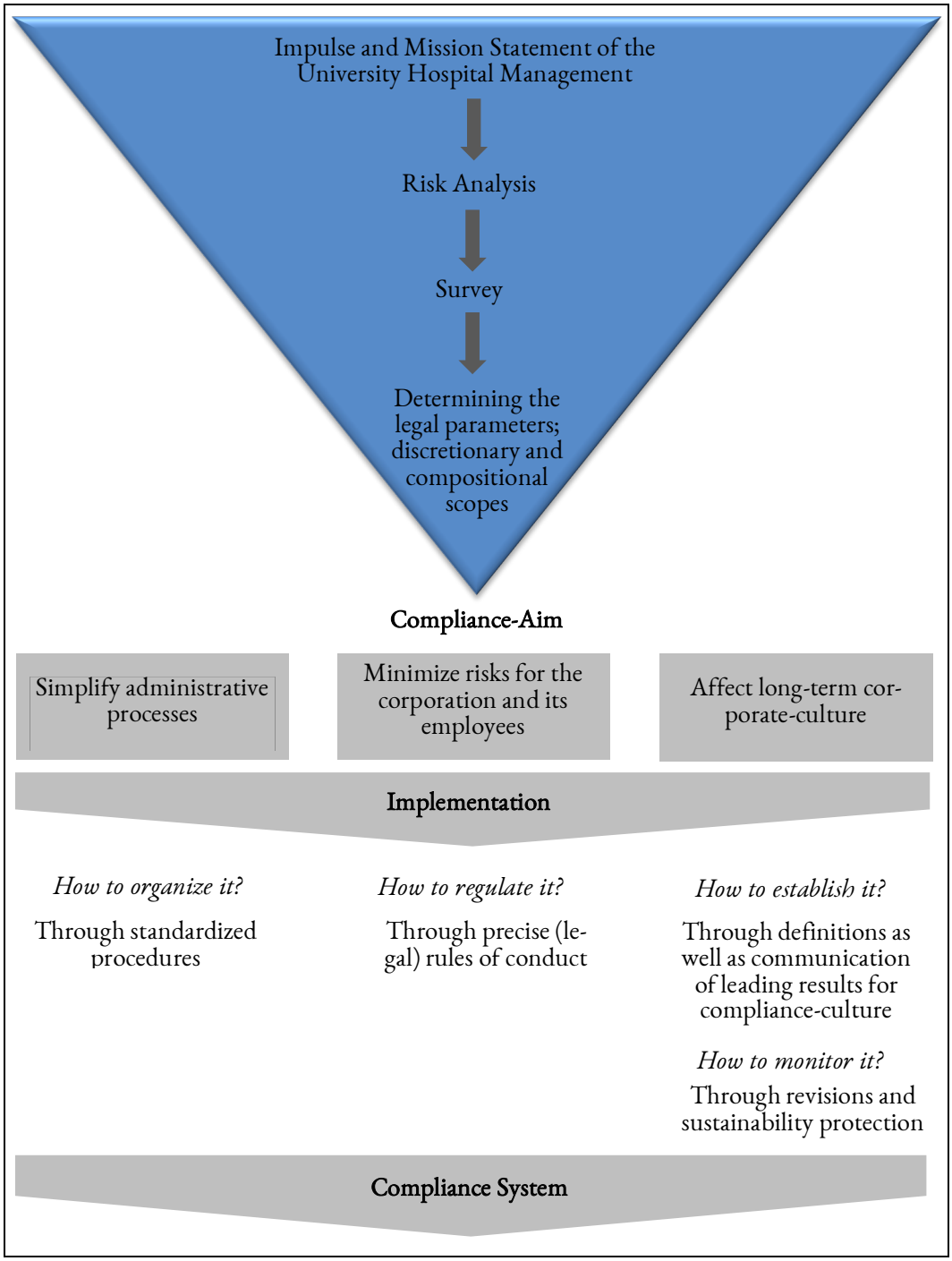

Illustration 1. Steps in implementing the CMS

V. COMPLIANCE ORGANIZATIONS

The Düsseldorf University Hospital has deliberately refrained from creating an independent agency to exclusively engage in compliance functions. At the university hospi-

tal, compliance is in the form of three-lines-of-defense model (see illustration 2). This means that after the operational management of compliance in the medical, nursing and administrative areas, the staff functions stand as the second line of defense. In particular are the controlling, the administrative body right and quality control (medical-organizational). The third line is the function of internal audit, which measures risk management and evaluates their results.

Empirically, compliance violations are known by various representatives of the three lines. An exchange between second and third line defenses is implemented to evaluate incidents and to consider specifics and draw conclusions therefrom. Reporting lines exist for incorporating experiences, and to initiate response from the public relations officers.

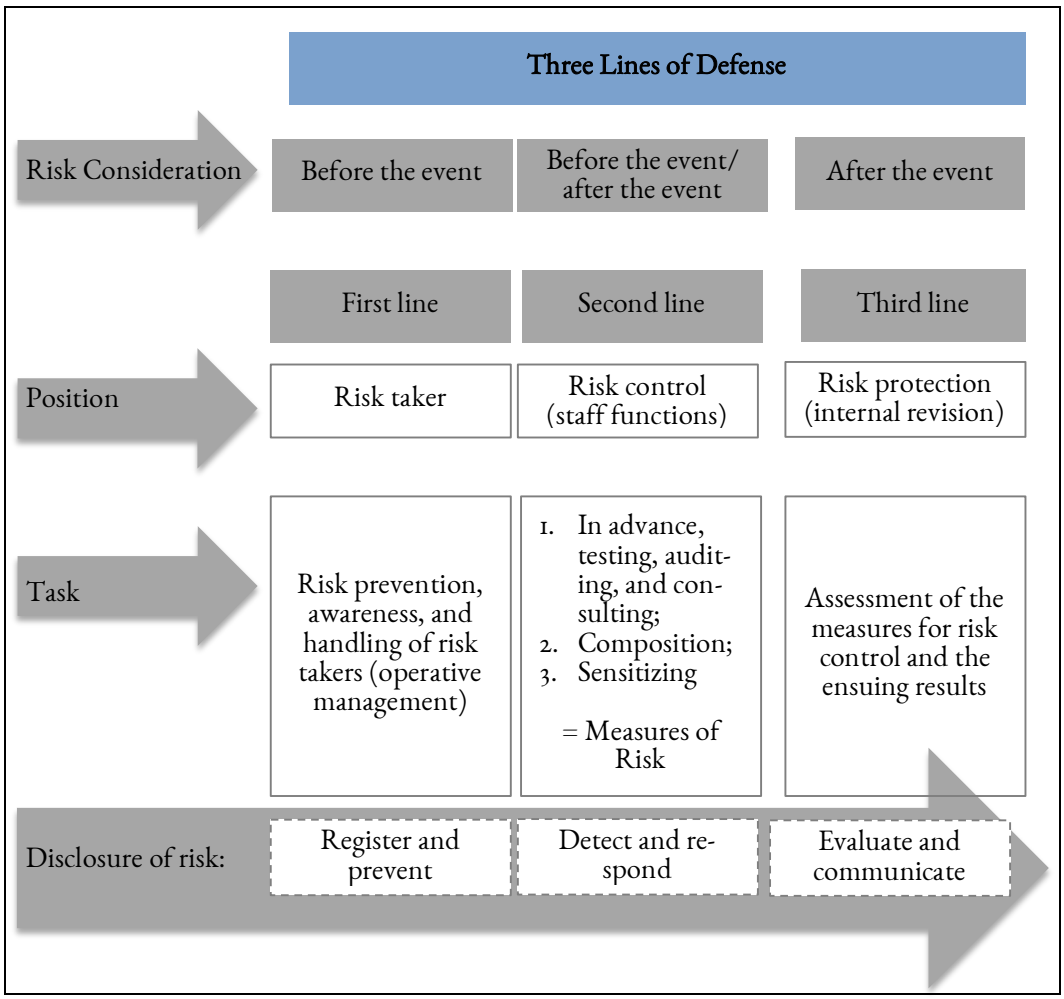

Illustration 2. The Three-lines-of-Defense at the Düsseldorf University Hospital

(Graphic by Thomas Breitfeld, Head of Internal Audit, Mechthild Lambers and Prof. Dr. Hendrik Schneider)

VI. LOOKING FORWARD

In the future, the Düsseldorf University Hospital will essentially faces the following challenges and questions:

It could be asked whether a centralization of compliance would result in higher levels of productivity as a byproduct of the second line of defense. Currently, a model is in place which already involves actors in compliance regulation through a office of compliance. A separate compliance organization could be created to address jurisdictional issues and questions concerning (policy-) skills.

The creation of a compliance board has not yet been conclusively approved. A compliance board shouldn't only regulate particular cases on an ad hoc basis based on referrals from affected areas, but to serve as a middleman between the individual areas of the university hospital (shopping, finance, personnel, etc.) to allow a rule-based exchange about compliance issues. This exchange should aim at identifying the fundamental issues in compliance in the organization and then developing solutions. Moreover, it would be designed so to have at least one board member who would have an obligation to report to the executive board.

Overall, compliance should not lead into compliance overkill. Like the adage of the medieval pharmacist: it is the dosage that makes the poison.