Compliance in the Healthcare Industry

CEJ
COMPLIANCE ELLIANCE JOURNAL

Content Curators:
Michele DeStefano (University of Miami School of Law)
Dr. Hendrik Schneider (University of Leipzig Faculty of Law)

ISSN 2365-3353
Volume 2 • Number 2
Summer 2016

Compliance Elliance Journal (CEJ)
Volume 2, Number 2, 2016
ISSN: 2365-3353
This version appears in print and online. CEJ is published twice per year, in the summer and winter.

Title: Compliance in the Healthcare Industry

Content Curators:
Michele DeStefano, University of Miami School of Law and LawWithoutWalls
Dr. Hendrik Schneider, University of Leipzig Faculty of Law

Technical Support:
Dr. Kristin Kißling
Hans-Henning Gonska
Antonia Orterer

Website: www.cej-online.com

Email: info@cej-online.com

Address:
Klostergasse 12
04109 Leipzig, Germany

Telephone: +49 0341 / 97 35 220

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

COMPLIANCE IN THE HEALTHCARE INDUSTRY

TABLE OF CONTENTS

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

EDITORIAL

COMPLIANCE IN THE HEALTHCARE INDUSTRY

We are pleased to present the latest issue of the Compliance Elliance Journal ("CEJ").

In this edition, we take a closer look at compliance in the healthcare industry, and focus on questions arising from the fast-growing healthcare compliance system. Our first set of articles explicitly deals with that issue.

This edition begins with a piece called "Conflicts of Interest in Medicine and their Management – Current Challenges and Initiatives in Germany," written by Dr. Cora Koch, Dr. Gisela Schott, Dr. David Klemperer, Dr. Thomas Lempert, Dr. Wolf-Dieter Ludwig and Dr. Klaus Lieb. The authors address the issue of conflicts of interest from a medical-scientific point of view. They uncover inherent risks of undue influences arising from conflicts of interest, which have consequences for healthcare. They outline the existing domestic developments relating to the management of conflicts of interest. Their main conclusion is that transparency is absolutely essential in order to prevent conflicts of interest. However, the authors admit that more research still remains to be done and that transparency might not be enough.

In our second article, Mechthild Lambers and Dr. Hendrik Schneider explore the topic of university hospitals. The article focuses on special compliance risks in university hospitals and the implementation of compliance measures in order to prevent corruption. The authors take a close look at the importance and role of conflicts of interest in this context.

Thereafter, Bettina Irmscher depicts the "New Compliance Management System of the University Hospital Frankfurt, Germany." The author illustrates the six tasks that necessarily have to be met in this Compliance Management System.

This edition then turns to an article about the issues that arise when companies are asked to voluntarily comply with investigations. Dr. Thomas Kopp and Dr. Valentin Pfisterer deal with the concernment of German companies or German-based subsidiaries by investigations conducted by regulatory or law enforcement authorities. In their piece "Between a Rock and a Hard Place – Legal Pitfalls of Voluntary Cooperation of German Companies with German and Foreign Regulatory and Law Enforcement Authorities," they expose the problems of informal requests and related voluntary cooperation.

This article and the following report of the 5th Munich Compliance Talk are included in this edition as teasers for our upcoming edition that focuses on legal privilege and its variances around the world. This event and similar ones mark the recognition of the importance around legal privilege and underline the market's relevancy in this area.

This is followed by the proceedings of the 5th Munich Compliance Talk, which took place in this past April, written by Antonia Orterer and Theresa Albert. The authors provide their impressions of the expert conference, where the focus was set on the legal framework of legal privilege as well as on legal privilege from a company viewpoint.

Finally Sara M. Klock describes her journey in LawWithoutWalls in developing a solution to compliance transgressions along the supply chain – an issue facing many international corporations today. The law student at the University of Miami worked with experts, entrepreneurs, lawyers, and students from around the globe to find an adequate solution to this special compliance issues. She details her scholastic and personal learnings in the "Student's Corner."

With our best regards,

Michele DeStefano & Dr. Hendrik Schneider
Founders and Content Curators of CEJ

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

CONFLICTS OF INTEREST IN MEDICINE AND THEIR MANAGEMENT – CURRENT CHALLENGES AND INITIATIVES IN GERMANY

Cora Koch, Gisela Schott, David Klemperer, Thomas Lempert, Wolf-Dieter Ludwig & Klaus Lieb

AUTHORS

Klaus Lieb, MD, is director and chair of the Department of Psychiatry and Psychotherapy at the University Medical Center Mainz, Germany. He completed his medical training at the universities of Ulm, Tübingen and UC Los Angeles. He has been doing research on conflicts of interest since 2007 and is one of the editors of the German book "Conflicts of Interest in Medicine. Overview and solutions" published in 2011. He is a regular member of the Drug Commission of the German Medical Association (DCGMA) and has been the chairman of its expert committee for transparency and independence since 2014. In addition, he is a regular member of the German Medical Association's "Scientific board of psychotherapy" . He is co-founder and member of the German branch of the „no free lunch" organization MEZIS e.V., where he was a board member from 2007-2011. He has not accepted personal honoraria from industry since 2008.

Cora Koch, MD, is a resident physician at the Department of Psychiatry and Psychotherapy at the University Medical Center Mainz, Germany. She completed her medical studies in Münster, Germany, in 2014. The topic of her doctoral thesis was "Conflicts of interest in medical students". She is a member of the German branch of the "no free lunch" organization MEZIS e.V., where she was a board member from 2010-2012.

Gisela Schott, MD, is a consultant at the Drug Commission of the German Medical Association (DCGMA). She completed her medical training at the universities of Münster and Berlin. She has published numerous articles concerning the topic of conflicts of interest, pharmacovigilance and rational medication use. She is a member of the German Network for Evidence-based Medicine (DNEbM) and the German branch of the „no free lunch" organization MEZIS e.V..

David Klemperer, MD, is professor of Social Medicine and Public Health at the Faculty of Social and Health Sciences at the Ostbayerische Technische Hochschule Regensburg (Technical University of Applied Sciences). He completed his medical training at the universities of Bonn, Cologne, and Düsseldorf. He is one of the editors of the book "Conflicts of Interest in Medicine. Overview and solutions". He is an associate member of the Drug Commission of the German Medical Association (DCGMA) and a member of its

expert committee for transparency and independence. In addition, he is a member of the German branch of the „no free lunch" organization MEZIS e.V. and the standing commission on guidelines of the Association of Scientific Medical Societies (AWMF). He is a member of the German Network for Evidence-based Medicine (DNEbM), where he was chairman of the board from 2009 to 2011.

Thomas Lempert, MD, is director of the Department of Neurology at Schlosspark-Klinik as well as professor of neurology at the University of Berlin. He graduated from the University of Berlin and pursued his clinical and scientific training in Berlin, Munich and London. He is a member of the Drug Commission of the German Medical Association (DCGMA) and its expert committee for transparency and independence. He is co-founder of the initiatives NeurologyFirst and Leitlinienwatch.de, which promote independent medical conventions and clinical guidelines. In addition, he is a member of the German branch of the „no free lunch" organization MEZIS e.V..

Wolf-Dieter Ludwig, MD, is director and chair of the department of hematology, oncology, tumor immunology, and palliative care at the HELIOS Klinikum in Berlin-Buch as well as professor for internal medicine at the Charité, University of Berlin. He completed his medical studies in Louvain (Belgium), Innsbruck (Austria), Frankfurt a. Main and Berlin (Germany). He is chairman of the Drug Commission of the German Medical Association (DCGMA), co-editor of the independent drug bulletin "DER ARZNEIMITTELBRIEF", and as a representative of the European doctors' organisation a member of the Management Board of the European Medicines Agency. He is a member of the German branch of the „no free lunch" organization MEZIS e.V..

ABSTRACT

Conflicts of interest (COI) in healthcare have increasingly gained attention in the lay press as well as among healthcare professionals. COIs increase the risk of undue influence on professional decision-making and may have far-reaching consequences in healthcare. Therefore, it is essential to develop strategies to deal with such risk situations in order to prevent negative outcomes for patients and the health care system. This article describes recent research on COIs in Germany as well as initiatives aiming at more transparency and better management of COIs in Germany.

TABLE OF CONTENTS

I. INTRODUCTION

A conflict of interest (COI) has been defined as a set of circumstances that creates a risk that a professional judgement or action regarding a primary interest will be unduly influenced by a secondary interest.[1] In healthcare, the primary interest of a doctor or a medical researcher is the well-being of the patient – either directly when treating a patient or indirectly via valid research that benefits patients. Secondary interests can be of very different natures, from financial interests to interactions with industry and intellectual interests such as the allegiance to a certain therapy.

It is important to note that a COI represents a risk factor for biased decision-making. COIs do not necessarily lead to an influenced decision and they are not necessarily caused by wrongdoing. On the contrary, they are ubiquitous and often unavoidable. As such, they are not always an issue of compliance, neither in the strict sense of the word nor in a broader ethical sense. However, they can become an issue of compliance when they are not made transparent as required, or when they are not managed appropriately to reduce their risk of bias.

In healthcare, COIs are a controversial topic, especially those arising from interactions between industry and physicians. These interactions constitute COIs because the industry's primary interest is profit and not the well-being of the patient. Industry may therefore influence professional medical decisions to the possible harm of patients. However, physician-industry interactions may also have beneficial effects when collaborations on research lead to the development of better therapeutic strategies. This leads to controversy between those warning against negative consequences of industry interactions and those fearing obstacles for research if interactions are regulated too strictly.

Interactions between industry and physicians are common,[2] and there is a large body of evidence showing that these COIs may lead to decisions that are potentially harmful to patients. There is evidence that they may lead to higher prescriptions in general and specifically of patented drugs to the benefit of industry as well as to prescriptions not in

---

1 Dennis F. Thompson, *Understanding financial conflicts of interest*, THE NEW ENGLAND JOURNAL OF MEDICINE, 329 (1993) and Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009).

2 Eric G. Campbell, *Doctors and drug companies--scrutinizing influential relationships*, Dennis F. Thompson, *Understanding financial conflicts of interest*, THE NEW ENGLAND JOURNAL OF MEDICINE, 357 (2007)., Eric G. Campbell et al., *Institutional academic industry relationships*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 298 (2007)., Eric G. Campbell et al., *Physician professionalism and changes in physician-industry relationships from 2004 to 2009*, ARCHIVES OF INTERNAL MEDICINE, 170 (2010)., and Klaus Lieb & Simone Brandtönies, *A survey of german physicians in private practice about contacts with pharmaceutical sales representatives*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 107 (2010).

line with clinical guidelines.[3] In addition, associations with biased trial designs,[4] biased publication of trial results[5] and biased assessments of drug safety and efficacy[6] have been found.[7]

Financial COIs arising from interactions with industry have been the main focus of COI research and debate. However, it is important to note that COIs may also arise from non-financial interests, such as allegiance to a certain type of therapy, membership in professional societies, or individual research focus. There has been much less research into how these COIs might influence different aspects of medical doctors' decision-making.[8]

Considering the importance of unbiased decision-making in healthcare, it is essential to develop strategies to prevent or at least reduce bias resulting from COIs. A growing body of literature addresses the adequate management of COIs in different areas of health care. One publication that was especially influential is the Institute of Medicines (IOM) report of 2009, *"Conflict of Interest in Medical Research, Education, and Practice"* by Lo and Field.[9] It gives an overview of COIs in healthcare and suggests strategies for their management in different contexts. It describes the ultimate goals of COI policies as *"maintaining the integrity of professional judgment and sustaining public confidence in that judgment"*.

Most COI research has been performed in the US, Australia and the UK. In Germany,

---

3 Klaus Lieb & Armin Scheurich, *Contact between Doctors and the Pharmaceutical Industry, Their Perceptions, and the Effects on Prescribing Habits*, PLOS ONE , 9 (2014). and Geoffrey K. Spurling et al., *Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: A systematic review*, PLOS MEDICINE, 7 (2010).

4 Andreas Lundh et al., *Industry sponsorship and research outcome*, THE COCHRANE DATABASE OF SYSTEMATIC REVIEWS, 12 (2012) , Maria E. Flacco et al., *Head-to-head randomized trials are mostly industry sponsored and almost always favor the industry sponsor*, JOURNAL OF CLINICAL EPIDEMIOLOGY, 68 (2015).

5 Justin E. Bekelman et al., *Scope and impact of financial conflicts of interest in biomedical research: a systematic review*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 289 (2003) and Gisela Schott et al., *The financing of drug trials by pharmaceutical companies and its consequences. Part 1: A qualitative, systematic review of the literature on possible influences on the findings, protocols, and quality of drug trials*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL , 107 (2010).

6 Amy T. Wang et al., *Association between industry affiliation and position on cardiovascular risk with rosiglitazone: Cross sectional systematic review*, BRITISH MEDICAL JOURNAL, 340 (2010) and Adam G. Dunn et al., *Financial conflicts of interest and conclusions about neuraminidase inhibitors for influenza: an analysis of systematic reviews*, ANNALS OF INTERNAL MEDICINE, 161 (2014).

7 Lisa Cosgrove et al., *Under the Influence: The Interplay among Industry, Publishing, and Drug Regulation*, ACCOUNTABILITY IN RESEARCH, 23 (2016) gives a good overview of the topic using a recent case study.

8 Alexander M. Clark et al., *Addressing conflict of interest in non-pharmacological research*, THE INTERNATIONAL JOURNAL OF CLINICAL PRACTICE, 69 (2015) , Klaus Lieb et al., *Conflicts of interest and spin in reviews of psychological therapies: a systematic review*, BRITISH MEDICAL JOURNAL OPEN, 6 (2016).

9 Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009).

COI research has only begun to gather momentum in the past few years. Initiatives such as the *"no free lunch"*[10] organization MEZIS, Transparency International and NeurologyFirst have additionally stimulated interest in the topic. This article will therefore focus on recent developments in Germany regarding COIs and their management in healthcare.

We will start by giving an overview of research on the frequency of and attitudes toward COIs among physicians and medical students especially with regard to the pharmaceutical industry in Germany. Then, we will describe different initiatives that have made efforts to improve the management of COIs in healthcare in Germany. Such efforts have focused firstly on how to make COIs transparent, and secondly on how to develop adequate strategies to reduce their resulting bias.

II. CONFLICTS OF INTEREST IN MEDICINE – SURVEY DATA FROM GERMANY

As mentioned above, most existing data on COIs in healthcare are from the US, Australia and the UK. However, considering the differences in health care policy in different countries, research results from one country may not be representative of another. In recent years, there has been a growing number of German contributions to COI-research. In the following section, they will be discussed in the context of evidence from the above mentioned countries.

A. Survey on Medical Professionals' Interactions with Industry in Germany

In Germany, the first survey of physicians' interactions with pharmaceutical sales representatives (PSRs) was done in 2006, funded by a trust associated with the professional society of registered doctors in Germany.[11] While the response rate was low (11%), it had similar results to later independent surveys. German doctors were visited by PSRs on average seven times per week and most physicians (63%) considered these interactions to be valuable. The first independent study by our group in 2008 questioned 300 randomly selected doctors from a sample of cardiologists, neurologists/psychiatrists and primary care physicians (response rate 69.3%, n=208).[12] Almost 80% of the surveyed doctors received at least one weekly visit from PSRs, while almost 20% received daily visits. Almost all doctors had received gifts and/or pharmaceutical samples from industry within the last year (96% and 92%, respectively). These percentages are higher than in the US, where in 2010, about 80% of surveyed doctors reported relationships with drug compa-

[10] „No free lunch" is an organization of healthcare providers that tries to encourage evidence-based prescribing independent of industry influence., *see* www.nofreelunch.org

[11] KLAUS GEBUHR, DER PHARMAREFERENT IN DER BEWERTUNG DER VERTRAGSÄRZTESCHAFT (2008).

[12] Klaus Lieb & Simone Brandtönies, *A survey of german physicians in private practice about contacts with pharmaceutical sales representatives*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 107 (2010).

nies and just over 60% of doctors reported receiving drug samples[13]. In this 2010 study, a trend of decreasing interactions in the US was reported compared with an earlier study from 2007.[14] A similar trend has not been found in Germany, where a survey from 2011 found similar rates to the previous one.[15]

In Germany, most doctors in the 2008 survey stated that the PSRs were trying to influence their prescribing patterns most of the time. However, few doctors considered themselves to be influenced by PSRs, while they were more likely to believe this of their colleagues.[16] This phenomenon of a so-called *"bias blind spot"* has been described in many other studies, where medical doctors consistently underestimate their own risk of being influenced by COIs.[17]

Another German study focused on the impact of interactions between doctors and industry. An online survey by our group in 2011 asked 1,386 medical doctors (response rate 11.5%; n = 160) with a prescription volume of > €100,000 (psychiatrists, neurologists, general practitioners or internal medicine specialists) or >€20,000 (cardiologists) per quarter about their interactions with industry in the previous year and correlated those interactions with their overall prescription data during the same time period.[18] We found an association between the acceptance of office stationery, the attendance of sponsored continuing medical education (CME) events and the perception of being adequately and accurately informed by drug representatives with changes in overall prescription data of the doctors. The acceptance of office stationery was associated with prescriptions of higher daily doses per patient in general and more prescriptions of generics. Attendance at sponsored CME events was associated with the prescription of a higher proportion of on-patent branded drugs and a higher expenditure for off-patent branded drugs per patient. While this survey was not able to prove causality, it adds to the body of evidence suggesting that interactions with industry influences the prescrib-

13 Eric G. Campbell et al., *Physician professionalism and changes in physician-industry relationships from 2004 to 2009,* ARCHIVES OF INTERNAL MEDICINE, 170 (2010).

14 Eric G. Campbell, *Doctors and drug companies--scrutinizing influential relationships,* THE NEW ENGLAND JOURNAL OF MEDICINE, 357 (2007).

15 Klaus Lieb & Armin Scheurich, *Contact between Doctors and the Pharmaceutical Industry, Their Perceptions, and the Effects on Prescribing Habits*, PLOS ONE, (2014).

16 Klaus Lieb & Simone Brandtönies, *A survey of german physicians in private practice about contacts with pharmaceutical sales representatives* , DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 107 (2010).

17 Joyce Ehrlinger et al., *Peering into the bias blind spot: people's assessments of bias in themselves and others*, PERSONALITY & SOCIAL PSYCHOLOGY BULLETIN, 31 (2005), Ashley Wazana, *Physicians and the pharmaceutical industry: Is a gift ever just a gift?*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 283 (2000) and Daniella A. Zipkin & Michael A. Steinman, *Interactions between pharmaceutical representatives and doctors in training. A thematic review*, JOURNAL OF GENERAL INTERNAL MEDICINE, 20 (2005).

18 Klaus Lieb & Armin Scheurich, *Contact between Doctors and the Pharmaceutical Industry, Their Perceptions, and the Effects on Prescribing Habit*s, PLOS ONE, (2014).

ing behavior of physicians.[19]

To the best of our knowledge, there have been only two studies on the interactions between medical students and industry in Germany. The first one conducted by our group in 2011 was a survey of 1,151 medical students at eight randomly selected German universities (response rate 90%).[20] All but 12% of the students had received at least one gift from a pharmaceutical company or participated in an event sponsored by a pharmaceutical company. Most common gifts were small, non-informational gifts such as mugs or tourniquets (65%). Another simultaneous study that was done at only one German university showed similar results, with 80% of students having received some kind of gift from the pharmaceutical industry and 44% of students having had direct contact with a PSR.[21]

Both surveys also assessed students' attitudes toward these interactions. Both studies found that students found more expensive gifts less appropriate.[22] In our study, almost half of the students considered it appropriate to accept gifts because the students believed that they have only minimal influence on them or because they considered themselves to be in a bad financial situation, respectively. We also found that students were more likely to believe that their fellow students were influenced by gifts than that they themselves were influenced by gifts, showing a blind spot in medical students comparable to that in doctors. 40% of students considered sponsored educational events to be biased and at the same time helpful and informative.[23] We also surveyed medical schools' deans and student affairs' deans regarding policies and lectures on COIs.[24] Only one of 36 medical schools in Germany had a policy governing the interactions between medical students and industry and only six schools (20%) offered lectures on the topic. Consequently, we found that most students (77.8%) would like to learn more about interactions with PSRs.

---

19 Geoffrey K. Spurling et al., *Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: A systematic review*, PLOS MEDICINE, 7 (2010), James S. Yeh et al., *Association of Industry Payments to Physicians With the Prescribing of Brand-name Statins in Massachusetts*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION INTERNAL MEDICINE, 176 (2016).

20 Klaus Lieb & Cora Koch, *Medical students' attitudes to and contact with the pharmaceutical industry: a survey at eight German university hospitals*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 110 (2013).

21 Kristine Jahnke et al., *German medical students' exposure and attitudes toward pharmaceutical promotion: a cross-sectional survey*, GMS ZEITSCHRIFT FÜR MEDIZINISCHE AUSBILDUNG, 31 (2014).

22 Id. at. and Klaus Lieb & Cora Koch, *Medical students' attitudes to and contact with the pharmaceutical industry: a survey at eight German university hospitals*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 110 (2013).

23 Klaus Lieb & Cora Koch, *Medical students' attitudes to and contact with the pharmaceutical industry: a survey at eight German university hospitals*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 110 (2013).

24 Klaus Lieb & Cora Koch, *Conflicts of interest in medical school: missing policies and high need for student information at most German universities*, GMS ZEITSCHRIFT FÜR MEDIZINISCHE AUSBILDUNG, 31 (2014).

B. Survey of Patients' Views on Medical Professionals' Interactions with Industry in Germany

There has been generally little research on the awareness and attitudes of patients with regard to COIs of their treating physicians. In Germany, a survey conducted by our group in 2012/2013 shed some light on this topic.[25] As expected, most of the 765 surveyed patients (response rate 80%; n = 612) said that it was important to them that decisions by their doctors were made only in their best interest. However, patients were generally not well informed about possible COIs their doctors could have and underestimated the frequency with which doctors interacted with PSRs. In addition, only very few patients expected that their doctor could be unduly influenced by COIs. Still, most patients would welcome transparency regarding COIs of their doctors and expected their trust in their doctors to increase if they were to disclose secondary interests.

III. GERMAN INITIATIVES FOR IMPROVED TRANSPARENCY OF CONFLICTS OF INTEREST FOR MEDICAL DOCTORS

The first and essential step in the management of COIs is to make them transparent, so that in turn, strategies can be developed to reduce the risk of bias resulting from them. Nevertheless, research has shown that COIs continue to be underreported in many contexts.[26] In the US, the Physician Payments Sunshine Act (PPSA), as part of the Affordable Care Act, mandates the publication of payments from the pharmaceutical and medical device industry to physicians since 2012. The PPSA is one of the most prominent and largest transparency initiatives with regard to COIs in healthcare globally. Since its initiation, it has published 15.71 million payments with a total value of 9.92 billion Dollars.[27] A similar law in Germany does not appear on the horizon. However, there are several German initiatives that have worked to increase transparency regarding COIs for medical doctors and medical advisors. We will describe steps that have been taken by the Drug Commission of the German Medical Association (DCGMA) as well as the Association of Research-Based Pharmaceutical Companies (VfA) in cooperation with the association Voluntary Self-regulation for the Pharmaceutical Industry (FSA). In addition, we will discuss how transparency with regard to non-financial COIs could be improved.

---

25 Elena M. Riedl et al., *Patient attitudes and expectations towards conflicts of interest of attending physicians*, ZEITSCHRIFT FÜR EVIDENZ, FORTBILDUNG UND QUALITÄT IM GESUNDHEITSWESEN, 110-111 Z (2016).

26 Michelle Roseman et al., *Reporting of conflicts of interest in meta-analyses of trials of pharmacological treatments*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 305 (2011), Michelle Roseman et al., *Reporting of conflicts of interest from drug trials in Cochrane reviews: cross sectional study*, BRITISH MEDICAL JOURNAL, 345 (2012), Shanil Ebrahim et al., *Meta-analyses with industry involvement are massively published and report no caveats for antidepressants*, JOURNAL OF CLINICAL EPIDEMIOLOGY, 70 (2016).

27 Department of Health and Human Services and Centers for Medicare and Medicaid Services, *Annual Report to Congress on the Open Payments Program* (2016), *available at* https://www.cms.gov/OpenPayments/Downloads/Open-Payments-Report-to-Congress.pdf.

While transparency is a prerequisite for the better management of COIs, it is important to note that bias is not eliminated if hidden COIs are made transparent.[28] Furthermore, it has been shown that the declaration of COIs may have negative consequences, e.g. by leading to a strategic exaggeration of bias by the person declaring the COI or by increasing the burden on patients to follow their doctors' recommendations so as not to appear to mistrust them.[29] Nevertheless, if doctors declare their COIs, this openness about COIs may motivate them to reduce their COIs in the future.[30] In sum, transparency can only be a first step of COI management and has to be followed by measures that are useful in reducing the resulting bias.

A. The Drug Commission of the German Medical Association (DCGMA)

The Drug Commission of the German Medical Association is a scientific expert committee of the German Medical Association (GMA) for drug-related matters. Its main tasks are to advise the GMA on questions of pharmaceutical policy, to assess benefits of pharmaceuticals, to document and assess adverse drug reactions and to keep the medical public up to date on rational drug therapy and drug safety.[31] These important and influential tasks necessitate a high level of independence from secondary interests among the currently 37 full and 130 associate members. Within the DCGMA, the expert committee for transparency and independence in medicine aims to strengthen the independence of DCGMA members as well as the broader community of medical doctors.[32] It was initiated in 2014 and develops strategies to declare, prevent and manage conflicts of interest. Before this, the DCGMA had already begun to address COIs in a less formal working group established in 2003.

It has been shown that COIs tend to be underreported if questioning is not specific enough or leaves the judgment of whether a secondary interest is relevant or not to the person declaring the secondary interests.[33] To increase transparency of members' COIs, the DCGMA has developed a questionnaire to register its members' secondary interests

---

28 Sheldon Krimsky, *Combating the funding effect in science: What's beyond transparency?*, STANFORD LAW POLICY REVIEW, XXI (2010).

29 George Loewenstein et al., *The limits of transparency: Pitfalls and potential of disclosing conflicts of interest*, THE AMERICAN ECONOMIC REVIEW, 101 (2011).

30 ARCHON FUNG et al., FULL DISCLOSURE: THE PERILS AND PROMISE OF TRANSPARENCY (Cambridge University Press. 2007).

31 Arzneimittelkommission der deutschen Ärzteschaft, *Drug Commission of the German Medical Association*, *available at* http://www.akdae.de/en/index.html.

32 Arzneimittelkommission der deutschen Ärzteschaft, *Expert Committee for Transparency and Independence in Medicine*, *available at* http://www.akdae.de/Kommission/Organisation/Mitglieder/Fachausschuesse/Transparenz/eng/Transparency/index.html.

33 Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009).

based on the above-mentioned IOM-report. It asks for COIs arising from different types of interactions with *"institutions"*, defined as pharmaceutical or medical device companies, health insurance providers or other interest groups. Interactions that are asked for include employment, consultancy work, personal remuneration for lectures, CME events or authorship of scientific publications, third party funding for research, shares or patents, and active membership in professional associations, specialist societies, or other interest groups.[34]

Since 2014, the COIs of the last three years of the current full and associate members are publicly accessible on the website of the DCGMA. The amount of payments received in 2014 was additionally published for full members in 2015.[35] The publication of the amount of payments received by associate members is planned in 2016 for the year 2015. These measures ensure a high degree of transparency not only among members but also for the public. Informing the public aims to increase public trust in the DCGMA. An unpublished analysis of the development of COIs over the last several years has shown that relationships between DCGMA members and the pharmaceutical industry have decreased considerably, underlining the successful work of the DCGMA in their efforts to decrease the number of members with COIs and confirming that transparency may decrease interactions with industry.

As mentioned above, however, mere transparency does not prevent bias. The DCGMA has therefore developed ways to manage COIs that are described in more detail below.

B. The Association of Research-Based Pharmaceutical Companies (VfA)

The Association of Research-Based Pharmaceutical Companies (VfA) is a lobby group for German pharmaceutical manufacturers. It represents 45 member companies and over 100 of their subsidiaries, representing about 70% of the German pharmaceutical market.[36] Its members have declared to abide by certain codes specified by the association Voluntary Self-regulation for the Pharmaceutical Industry (FSA) concerning for example the interaction between the member companies with health care professionals or patient organizations. In 2013, a new *"transparency codex"* was published with the goal of bringing more transparency into interactions between pharmaceutical manufacturers and other cooperating partners within the health care system. This was a reaction to the announcement by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2012 to publish payments to doctors and other healthcare pro-

34 The questionnaire is *available at* http://www.akdae.de/Kommission/Organisation/Statuten/Interessenkonflikte/Interessenkonflikte.doc (in German)

35 Arzneimittelkommission der deutschen Ärzteschaft, *Ordentliche Mitglieder*, *available at* http://www.akdae.de/Kommission/Organisation/Mitglieder/OM/index.html.

36 Frank Gailberger, *Verband und Mitglieder* (2016), *available at* http://www.vfa.de/de/verband-mitglieder.

fessionals.[37]

In June of 2016, the first disclosure report declared payments of € 575,000,000 to German doctors and hospitals.[38] Most, though not all, member companies have also published their individual payments to doctors, where doctors consented to publication.[39] According to the VfA, only about one third of doctors consented to the publication of their data, but where consent was not given, aggregated anonymous data were published.[40] In principle, the transparency codex is similar to the PPSA: Pharmaceutical companies publish the payments they make to physicians or other health care professionals.[41] The commitment is laudable, if it is well implemented. However, there are some important differences that make this codex less likely to succeed than the PPSA in arriving at full transparency of medical doctors` interactions with the pharmaceutical industry.

The first and most obvious difference is that the German code is voluntary, whereas the PPSA is a law and therefore mandates publication of payments. It is therefore to be expected that companies will not establish full transparency.[42] A study on the quality of non-interventional studies from 2012 found that member companies of the VfA only rarely complied with their own requirements for non-interventional studies.[43] The VfA therefore does not have a trustable track record regarding compliance with its own rules. Additionally, the sanctions for non-compliance remain vague in the transparency codex of the FSA, further questioning the true commitment to transparency. Lastly, due to strict data protection laws in Germany, publication depends on the permission of individual doctors that their data can be published. As mentioned above, about two thirds of doctors have refused to allow the publication of their data and it seems plausible to

37 *Ärzte erhielten 2015 rund 575 Millionen Euro von Pharmafirmen,* DEUTSCHES ÄRZTEBLATT 2016 *available at* http://www.aerzteblatt.de/nachrichten/68213/#.

38 Verband Forschender Arzneimittelhersteller e.V., *Pressemitteilung 015/2016: Transparenzkodex zeigt Forschungsstärke* (2016), *available at* http://www.vfa.de/de/presse/pressemitteilungen/pm-015-2016-transparenzkodex-zeigt-forschungsstaerke.html.

39 Holger Diener, *Veröffentlichungen* (2016), *available at* http://www.pharma-transparenz.de/fachkreisangehoerige/veroeffentlichungen/.

40 *Ärzte erhielten 2015 rund 575 Millionen Euro von Pharmafirmen*, DEUTSCHES ÄRZTEBLATT 2016.

41 FSA e.V., *Code of Transparency of the Association of Voluntary Self-Control of the Pharmaceutical Industry (Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie - FSA) for interaction with Healthcare Professionals and Healthcare Organisations* (2013), *available at* http://www.fsa-pharma.de/fileadmin/Downloads/Pdf_s/Kodizes__Empfehlungen/Transparency_Code.pdf.

42 Margaret McCartney, *Margaret McCartney: Optional disclosure of payments is pointless*, BRITISH MEDICAL JOURNAL, 354 (2016).

43 Beatrice K. J. G. von Jeinsen & Thomas Sudhop, *A 1-year cross-sectional analysis of non-interventional post-marketing study protocols submitted to the German Federal Institute for Drugs and Medical Devices (BfArM)*, THE EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY 1453, 69 (2013).

assume that these include those that have received high payments or have many COIs.[44] Consequently, a continued lack of full transparency regarding COI of individual doctors is likely. Even in the US, about 40% of the data remain unpublished because of unresolved disputes between doctors and industry.[45]

Another disadvantage of the VfA/FSA transparency initiative is a practical one. While in the US, all data of payments to doctors are published on a single website (https://openpaymentsdata.cms.gov/), the FSA has compiled a list of links to individual company websites.[46] This makes it time consuming to search for payments to specific doctors or to analyze the data for certain specialties (all payments made to cardiologists, for example), both important in bringing more transparency to the situation.

Even if all member companies of the VfA/FSA comply with the transparency codex, there will still be a lack of transparency for those pharmaceutical companies which are not members of the VfA as well as all medical device manufacturers. While this is not a criticism of the VfA/FSA, as they have no control over non-members, it does illustrate the need for a legal basis for transparency if one aims to arrive at full transparency.

On the other hand, considering that transparency is only a first step and can have unintended negative consequences by itself,[47] it is also important to consider the costs of such a transparency legislation. The implementation of full transparency through a legal mandate in Germany would be very expensive; the costs of the PPSA have been estimated at $269 million during the first year of implementation and at $180 million each following year.[48]

In conclusion, while there are many critical points regarding the German FSA transparency codex, it is a positive first step towards more transparency, especially considering that at the moment, there is no better alternative in Germany.

C. Transparency of Non-financial Conflicts of Interest

While the transparency of financial COIs has markedly improved in pharmaceutical and medical device research within the last few years, non-financial COIs are declared less often. Their effect on research methodology or outcomes has also been researched less

44 Nigel Hawkes, *Doctors getting biggest payments from drug companies don't declare them on new website*, BRITISH MEDICAL JOURNAL, 354 (2016).

45 Sachi Santhakumar & Eli Y. Adashi, *The physician payment sunshine act: Testing the value of transparency*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 313 (2015).

46 Holger Diener, *Veröffentlichungen* (2016).

47 George Loewenstein et al., *The Limits of Transparency: Pitfalls and Potential of Disclosing Conflicts of Interest*, THE AMERICAN ECONOMIC REVIEW, 423 (2011).

48 Elizabeth Richardson et al., *Health Policy Brief: The Physician Payments Sunshine Act*, HEALTH AFFAIRS (2014).

extensively.[49] One area of research and practice where these types of COIs are relevant and have also been investigated in some detail is psychotherapy. In this context, allegiance to a certain type of psychotherapy constitutes a non-financial COI that might influence the framing of research questions, the interpretation of results, the decision to publish certain results and not others, or the type of psychotherapy recommended to a patient. Allegiance describes the belief that a certain treatment is superior.[50] It may be due to training in this particular type of treatment or active involvement in the development of an etiological model of this treatment, among other factors.[51] Allegiance was shown to be associated with the outcome of psychotherapy studies with a moderate effect size in a large meta-meta-analysis by Munder and colleagues in 2013.[52]

A recent study by our group investigated the transparency of non-financial COIs in reviews on the efficacy of psychological therapies and addressed the question whether these COIs influenced authors` interpretations of study results.[53] Among the 95 reviews studied, only in 4 reviews (4.2%) were non-financial COIs declared, while on further analysis, non-financial COIs were found for authors of 34 (35.8%) of the reviews. The two main reasons for the under-reporting seemed to be that many journals do not require disclosure of non-financial COI at all (33/50 journals) and that those journals that did require such a disclosure rarely asked for a specific type of non-financial COI or gave examples. Additionally, because non-financial COIs have attracted less attention than financial ones, researchers might not realize the effect of non-financial COIs and therefore not consider it necessary to declare them. We further found that a biased interpretation of results (spin) was found in 28% of the studied reviews and that reviews with a conclusion in favor of psychological therapies (vs. pharmacological interventions) were at a high risk for spin in their conclusions (OR=8.31; 1.41 to 49.05). This might be interpreted as a hint that authors of psychological reviews (who are mostly psychotherapists) overestimate the effects of *"their own"* therapies. However, this has to be taken with caution because we only found a trend for an association of spin in review conclusions with researcher allegiance or the inclusion of own primary studies by the review authors

---

49 Alexander M. Clark et al., *Addressing conflict of interest in non-pharmacological research*, THE INTERNATIONAL JOURNAL OF CLINICAL PRACTICE, 69 (2015).

50 YAN LEYKIN & ROBERT J. DERUBEIS, ALLEGIANCE IN PSYCHOTHERAPY OUTCOME RESEARCH: SEPARATING ASSOCIATION FROM BIAS (2009) and Michael J Lambert, *Are differential treatment effects inflated by researcher therapy allegiance? Could Clever Hans count?*, CLINICAL PSYCHOLOGY: SCIENCE AND PRACTICE , 6 (1999).

51 Elizabeth. A. Gaffan et al., *Researcher allegiance and meta-analysis: the case of cognitive therapy for depression*, THE JOURNAL OF CONSULTING AND CLINICAL PSYCHOLOGY, 63 (1995) , Thomas Munder et al., *Testing the allegiance bias hypothesis: a meta-analysis*, PSYCHOTHERAPY RESEARCH , 21 (2011) , and Scott Miller et al., *Direct comparisons of treatment modalities for youth disorders: a meta-analysis*, 18 *see id*. at (2008).

52 Thomas Munder et al., *Researcher allegiance in psychotherapy outcome research: an overview of reviews*, CLINICAL PSYCHOLOGY REVIEW, 33 (2013).

53 Klaus Lieb et al., *Conflicts of interest and spin in reviews of psychological therapies: a systematic review*, BRITISH MEDICAL JOURNAL OPEN, (2016).

into the review.

Considering that non-financial COIs may influence research conclusions similarly to financial COIs, it seems important to develop ways of improving their declaration. So far, there is no scientific consensus as to how non-financial interests should be declared or how best to ask for them. However, the scientific advisory board of psychotherapy (WBP) of the German medical association and the German Federal Chamber of Psychotherapists has recently recognized the need for such declarations. The WBP is a scientific board made up of medical doctors and psychologists that advises government agencies on the scientific approval of specific psychotherapies as well as the federal approval of training institutions for psychotherapy.[54] In 2015, it composed suggestions for how to declare the COIs of its members starting in 2016. These suggestions have not yet been published, but table 1 gives a list of our suggestions on how non-financial COIs should best be declared.

Employment

Allegiance

- Psychotherapeutic method (e.g. analytical psychotherapy, psychodynamic psychotherapy or behavior therapy) in which the declaring person is trained
- Psychotherapeutic method which the declaring person uses in his/her own current psychotherapeutic practice
- Psychotherapeutic methods which are established in the institute which the declaring person heads (i.e. as a director or attending physician in a hospital)

Activity/shares in an education/training institute for psychotherapy

Cooperation/personal relationships with the pharmaceutical industry or medical device manufacturers (non-financial)

Research

- Subject of research (psychotherapeutic techniques/methods; research on other non-pharmacological methods for treatment of mental disorders; and pharmacological research).
- Public and non-public funding of research activities (e.g. German research Foundation (DFG), Federal Ministry for Education and Research (BMBF), other foundations as well as pharmaceutical industry or medical device manufacturers)

Other activities

- Activities in professional societies, professional associations, institutions of self-government, professional bodies, other thematically relevant associations, patient support groups or others.

Table 1. Proposal for the declaration of non-financial COIs – here for psychotherapists and researchers on psychotherapy

54 Wissenschaftlicher Beirat Psychotherapie, *Wissenschaftlicher Beirat Psychotherapie*, *available at* http://www.wbpsychotherapie.de/.

IV. MANAGEMENT OF CONFLICTS OF INTEREST IN GERMANY

In principle, avoiding COIs completely would be the best way to ensure that they do not unduly influence professional decision-making. Although this is impossible considering their sheer frequency and the beneficial effects of some COIs, it is important to motivate all medical doctors and researchers to avoid situations that create a COI wherever possible. The fact that it is not possible to avoid COIs completely should not distract from this intention.

However, as some COIs are unavoidable, it is important to manage them in order to mitigate their negative influence on professional decision-making to the highest possible degree. As mentioned above, transparency is an essential step on the way to managing COIs, but is not in itself effective in preventing their influence.[55] In Germany, steps have been taken in several different areas to manage COIs. Following, we will describe initiatives to reduce publication bias, bias in early benefit assessment of new therapeutic strategies, bias in the development of guidelines and bias in continuing medical education (CME).

A. Management of Publication Bias through the German Clinical Trials Register (DRKS)

One of the most influential biases that result from COIs is publication bias. Because pharmaceutical manufacturers have an interest mainly in publishing positive trial results, many trials – around 50% – are never published. It has been shown that those trials with a positive outcome are more likely to be published.[56] This leads to a skewed evidence base for the succeeding assessment of benefits and risks of therapeutic strategies which overestimates the benefits of these strategies and underestimates the risks. One way of trying to reduce this bias is to mandate registration of clinical trials. While this does not ensure that they will be published, it still has several advantages that help to mitigate publication bias. Firstly, it makes it possible to at least analyze which trials have not been published and to contact the authors for results of those trials, i.e. when authoring a systematic review. Secondly, it is usually possible to publish the study results on registries if no journal publication has appeared. Thirdly, it is possible to track

---

55 Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009), Holger. J. Schünemann et al., *Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines*, ANNALS OF INTERNAL MEDICINE, 163 (2015), and Klaus Lieb, *Transparency alone is not sufficient for the management of conflicts of interest - pro*, PSYCHIATRISCHE PRAXIS 12, 42 (2015).

56 Annelieke M. Roest et al., *Reporting Bias in Clinical Trials Investigating the Efficacy of Second-Generation Antidepressants in the Treatment of Anxiety Disorders: A Report of 2 Meta-analyses*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION PSYCHIATRY, 72 (2015), Maria E. Flacco et al., *Head-to-head randomized trials are mostly industry sponsored and almost always favor the industry sponsor*, JOURNAL OF CLINICAL EPIDEMIOLOGY, (2015) and Erick H. Turner et al., *Selective publication of antidepressant trials and its influence on apparent efficacy*, THE NEW ENGLAND JOURNAL OF MEDICINE, 358 (2008).

whether the (primary) outcomes of a trial that are published correspond with the predefined outcomes mentioned in the registration. Adding, revising, or failing to publish certain outcomes of trials can skew the results available to the public and is quite a common practice.[57]

In several countries, such as the US, Switzerland and India, it is therefore legally required to register all clinical trials. In Germany, this only applies to those clinical trials that are subject to the Medicines Act (AMG) or the Medical Device Act (MPG).[58] However, since 2007 the possibility exists to register any clinical trial on the German Clinical Trials Register (DRKS), the WHO primary registry for Germany. It is a cooperation of the Department for Medical Biometrics and Medical Informatics of the University of Freiburg and was funded initially by the Federal Ministry of Education and Research (BMBF).[59] Funding by the BMBF had to be discontinued by July 2016 due to the regulations of the BMBF on project funding. At the time of writing, negotiations were underway with the Federal Ministry of Health to find sustainable funding options for the DRKS.[60]

For the management of publication bias, it is essential that the DRKS remains functioning. It is the only registry that gives an overview of clinical trials in Germany. It is therefore also a good resource for patients, practitioners and researchers in Germany who want to search the evidence regarding a certain condition or drug or who want to find trials that might offer patients access to novel therapies. The fact that all trials can be registered means that even trials that are not subject to the AMG/MPG can be searched. And because the DRKS offers the possibility to submit data even if there was no publication on a certain trial means that one can gain access to a broader evidence base than by simply searching usual medical publication databases.

B. Management of Conflicts of Interest in the Evaluation of Drugs and Medical Devices by the DCGMA

In Germany, the DCGMA is one of the few organizations that are authorized to comment on the early benefit assessment of newly approved pharmaceuticals.[61] This has

57 Ben Goldacre et al., *The COMPare Trials Project* (2016).

58 Gesetzgeber, *Gesetz über den Verkehr mit Arzneimitteln - Arzneimittelgesetz* (1976, letzte Änderung 2014). and Gesetzgeber, *Gesetz über Medizinprodukte (Medizinproduktegesetz - MPG)*, (1994, letzte Änderung 2015).

59 Susanne Jena, *DRKS- Deutsches Register Klinischer Studien (German Clinical Trials Register)*, *available at* https://drks-neu.uniklinik-freiburg.de/drks_web/setLocale_EN.do.

60 Hinnerk Feldwisch-Drentrup, *Gesundheitspolitiker wollen Studien-Register retten*, DEUTSCHE APOTHEKER ZEITUNG, 2016.

61 Bundesministerium für Gesundheit, *Bekanntmachung eines Beschlusses des Gemeinsamen Bundesausschusses über die Bestimmung von Stellungnahmeberechtigten nach §92 Absatz 3a des Fünften Buches Sozialgesetzbuch (SGB V)*, 58 BUNDESANZEIGER (2009).

direct repercussions for the ensuing price negotiations with the drug manufacturer and the definition of a price that will be refunded by statutory health insurance. As was described in detail above, the DCGMA has initiated a high level of transparency regarding COIs. Taking this as a first step, the DCGMA has moved further to formulate rules for the management of COIs that are adapted from the suggestions of the 2009 IOM report.[62]

The main principles of the DCGMA rules for managing COIs are to reduce the proportion of members with COIs in regard to the pharmaceutical or therapeutic strategy being assessed and to reduce the amount of influence on decisions by conflicted members. With regard to the first point, the DCGMA aims to create a committee of members free of COIs when performing a benefit/risk analysis for a newly approved drug. Should this be impossible, at least the chairman of the committee has to be free of COIs for the last three years and the proportion of members with COIs should not exceed one third. The DCGMA does acknowledge that it might sometimes be necessary to include members with close industry contacts because of their expertise; in research, cooperation with industry is common and while leading to COIs, it may also have benefits. Excluding experts with COIs completely might therefore lead to a loss of scientific expertise. Members with very close personal relationships, such as members of speaking bureaus or shareholders in pharmaceutical companies, however, are excluded from the assessments in any case. To reduce the amount of influence of members with COIs, they are not allowed to be part of the decision-making process and are not allowed to formulate the text of the final statement of the DCGMA regarding a new drug or medical device.[63]

To decide whether a COI is relevant to the assessment of a drug, the DCGMA looks for relationships with the company producing the original drug, as well as companies producing generic versions and all competitor companies. If a whole class of substances is being assessed, relationships with the corresponding companies are considered to be relevant. COIs of DCGMA members are evaluated by the board of directors of the DCGMA. As mentioned above, physicians tend to underestimate their own bias, so it is essential that a third party judges the relevance of a COI for the respective task.[64]

In sum, DCGMA rules try to ensure a balance between ensuring access to all relevant expertise, while guarding a distance between possibly biased members and decision-making so that decisions remain as free as possible from undue influence.

---

62 Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009) and Arzneimittelkommission der deutschen Ärzteschaft, *Regeln zum Umgang mit Interessenkonflikten bei Mitgliedern der Arzneimittelkommission der deutschen Ärzteschaft* (2014) *available at* http://www.akdae.de/Kommission/Organisation/Statuten/Interessenkonflikte/Regeln.pdf.

63 Arzneimittelkommission der deutschen Ärzteschaft, *Regeln zum Umgang mit Interessenkonflikten bei Mitgliedern der Arzneimittelkommission der deutschen Ärzteschaft* (2014).

64 *Id.* at.

C. Management of Conflicts of Interest in the Development of Guidelines

Guidelines are some of the most influential documents in health care, as they inform doctors' decisions regarding diagnostic and treatment strategies. Non-adherence may have legal consequences as guidelines are often used as the basis for arguments in malpractice suits. It therefore seems obvious that it is important to keep guidelines free from bias caused by secondary interests.

There are some international data to suggest that guidelines can be influenced when authors have COIs.[65] In Germany, studies have been published that assessed transparency of COIs of guideline panel members in German guidelines[66] and possible bias in current guidelines through panel members with conflicting interests.[67] Guideline development in Germany is coordinated by the Association of Scientific Medical Societies (AWMF), and rules for the declaration of COIs were released in 2010.[68] A study by Langer and colleagues in 2012 found that among guidelines published between 2009 and 2011, the frequency of declarations of COIs increased markedly from 8% to about 94% after the rules had taken effect.[69] However, only 50% of guidelines described assessing the relevance of COIs; and in most cases, the authors of the guidelines rated the relevance of their own COIs. Only one of the studied guidelines described how the risk of bias through COIs was minimized. Another study by our own group assessed guidelines that resulted from a less formal process of expert consensus (so called S1 guidelines) that were released after 2010.[70] In more than 90% of the guidelines, COI declarations were given; COIs were most commonly memberships in a specialist society or professional association and 50% of experts had declared financial COIs. However, only 11% of the guidelines described assessing the declared COIs and only in one case did a COI lead to consequences for the conflicted member.

---

65 *See* Lorraine Johnson & Raphael B. Stricker, *Attorney General forces Infectious Diseases Society of America to redo Lyme guidelines due to flawed development process*, JOURNAL OF MEDICAL ETHICS, 35 (2009) and Paivi Hietanen, *Does the expert panel at the St Gallen meeting provide an unbiased opinion about the management of women with early breast cancer?*, ANNALS OF ONCOLOGY, 20 (2009) for recent examples.

66 Thomas Langer et al., *Conflicts of interest among authors of medical guidelines: an analysis of guidelines produced by German specialist societies*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 109 (2012) and Gisela Schott et al., *Does the pharmaceutical industry influence guidelines? Two examples from Germany*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 110 (2013).

67 Gisela Schott et al., *Deklaration und Umgang mit Interessenkonflikten in deutschen Leitlinien*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 112 (2013).

68 Arbeitsgemeinschaft Wissenschaftlicher Medizinischer Fachgesellschaften (AMWF), *Empfehlungen zum Umgang mit Interessenkonflikten bei Fachgesellschaften* (2010), *available at* http://www.awmf.org/medizin-versorgung/stellungnahmen/umgang-mit-interessenkonflikten.html.

69 Thomas Langer et al., *Interessenkonflikte bei Autoren medizinischer Leitlinien,* DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 109 (2012).

70 Gisela Schott et al., *Declaration and Handling of Conflicts of Interest in Guidelines: A Study of S1 Guidelines From German Specialist Societies From 2010-2013*, 112 *see id.* at (2015).

Another study of our group demonstrated that the German clinical practice guideline for psoriasis vulgaris gives a stronger recommendation for the use of efalizumab and considers the evidence base to be better than guidelines developed by more independent institutions.[71] This correlated with the fact that many of the German authors contributing to the guideline had financial COIs with regard to efalizumab. While this study did not prove causality of influence of COI on the guideline, it does suggest that authors with COI give different recommendations than those without, to the possible detriment of patients.

The initiative *"Leitlinienwatch"*[72] has started to rate the transparency and management of COIs in guidelines published by the AWMF. The initiative assesses guidelines with regard to transparency, proportion of members of the guideline group with COIs, independence of the lead authors, chairmen and coordinators, abstention from voting by members with COI and external review of the guideline by the scientific public or patient representatives. In addition, they give *"bonus points"* when further measures to reduce bias through COIs have been documented, such as a search for authors without COIs, a system of assessment of COIs, etc. Of the 116 guidelines that have so far been assessed, only 11 guidelines received a rating of *"good"* (the best rating), while 53 guidelines received a rating of *"reform necessary"*.[73] However, this sample is not representative of the 755 guidelines that are in effect, the method has not been validated or scientifically published and does not cover all efforts by the AWMF to reduce bias.

In conclusion, while there has been progress on the transparency of COIs in guideline development in Germany, there is still a lot of work to be done regarding their management.

The 2010 rules of the AWMF regarding the management of COIs in guideline development were a good step toward better management but remain rather unspecific.[74] They recommend that members of a guideline development group with a relevant COI should not participate in the decision making process. However, it is relatively vague who should assess the relevance of a COI and what the criteria for such relevance are. The rules also suggest that authors of guidelines should only have COIs with a small potential for bias, though how this judgment is made also remains unclear. The current rules are therefore under revision and the AWMF is planning to model new rules on the

---

71 Gisela Schott et al., *Deklaration und Umgang mit Interessenkonflikten in deutschen Leitlinien*, DEUTSCHES ÄRZTEBLATT INTERNATIONAL, 112 (2013).

72 *Leitlinienwatch. Das Transparenzportal für medizinische Behandlungsleitlinien*, *available at* www.leitlinienwatch.de.

73 *Id.* at., accessed July 14th 2016.

74 The rules formulated concerning transparency are more specific and there is little to criticize in this regard. Arbeitsgemeinschaft Wissenschaftlicher Medizinischer Fachgesellschaften (AMWF), E*mpfehlungen zum Umgang mit Interessenkonflikten bei Fachgesellschaften* (2010).

recommendations of the Guidelines International Network (GIN) that have recently been published[75]. At the time of writing, the new rules were not yet published. Therefore, following we will give some recommendations to refine the AWMF rules based on the GIN-recommendations,[76] the recommendations of the IOM[77] as well as the DCGMA rules.[78]

Firstly, medical specialist societies should make every effort to find experts for the development of guidelines that are free of COIs, similar to the commitment made by the DCGMA and as recommended by GIN. This will lead to an emphasis on independence from the very beginning of the process. Similarly, it is essential to define the proportion of members of a guideline development group that must be free of COIs to ensure a balance between conflicted members and those without conflicts, as recommended by the IOM and the DCGMA. Secondly, special effort should be made to find guideline coordinators who are free of COIs. Some might criticize that it is not possible to find such a coordinator; however, this is mostly based on the argument that those with considerable research expertise often have COIs. We believe that those experts with primarily clinical experience have just as much to add to the development of guidelines, while being conflicted less often. Members with research experience and COIs are welcome to add their expertise in the role of external advisers, but should not be in a leadership position. Thirdly, it is important to ensure that no guideline panel member assesses his or her own COIs, as most people tend to underestimate their own bias.[79] It would make sense to establish a panel within the AWMF that assesses the COIs of guideline-coordinators. In turn, coordinators free of COIs could then decide to appoint members within the guideline development group or outside of it as *"COI-managers"*, who would be in charge of assessing COIs and implementing rules for the management of COIs, as was suggested by the GIN. Fourthly, we would welcome the establishment of a system of *"grading"* COIs as to their severity, meaning the likelihood that they will lead to undue influence on decision making. This could then have different consequences, i.e. members with very severe COIs could be completely excluded from the panel while members with COIs that are unlikely to lead to a relevant bias might only be excluded from leadership positions within the guideline development group while being allowed to participate in discussions.

---

75 Holger J. Schünemann et al., *Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines*, ANNALS OF INTERNAL MEDICINE, (2015).

76 *Id*. at.

77 Bernard Lo & Marilyn J. Field, *Free Executive Summary*, *in* Conflict of Interest in Medical Research, Education, and Practice (Bernard Lo & Marilyn J. Field eds., 2009).

78 Arzneimittelkommission der deutschen Ärzteschaft, *Regeln zum Umgang mit Interessenkonflikten bei Mitgliedern der Arzneimittelkommission der deutschen Ärzteschaft* (2014).

79 Joyce Ehrlinger et al., *Peering Into the Bias Blind Spot: People's Assessments of Bias in Themselves and Others*, PERSONALITY & SOCIAL PSYCHOLOGY BULLETIN, 680 (2005).

D. Management of Conflicts of Interest in Continuing Medical Education

Globally, around 33% of all accredited events in continuing medical education (CME) are funded by pharmaceutical companies.[80] For Germany, there are no exact figures, but many CME-events are funded at least in part by pharmaceutical or medical device manufacturers, and often the speakers involved have financial COIs even if the event is not sponsored by a company. In both cases, the risk is increased that speakers will present biased information.[81]

In Germany, CME has to be accredited by the state medical associations. There is a guideline on accreditation that mentions that the content of the event has to be independent from *"economic interests"* as a prerequisite for accreditation.[82] COIs of the organizer, the scientific supervisor and the speakers have to be declared to the medical associations and the event's participants. However, these rules are relatively vague on how the influence of CME content by economic interests is to be avoided. For doctors it is therefore currently difficult to recognize which events are truly independent.

The DCGMA is one organization that regularly organizes CME events and in 2015 initiated rules to ensure their independence.[83] These rules are stricter than internationally proposed suggestions regarding the independence of CME.[84] One of the main requirements for a CME event to be considered independent by the DCGMA is that it is sponsored neither directly nor indirectly by a pharmaceutical or medical device manufacturer. Indirect sponsoring describes when a pharmaceutical manufacturer transfers funds to an organization or a hospital, which in turn organizes the CME event, instead of organizing the event directly. The second important requirement is that speakers have not received personal remuneration from a pharmaceutical or medical device manufacturer for at least two years. It is important to note that an exception is made for speakers who have research relationships with industry and have therefore received funding from industry. In this case, it is important that the funds were/are only used for research, that

80 Julie Simper, *Cologne Consensus Conference, Management of conflict of interest, 12 and 13 September 2014, Cologne, Germany*, JOURNAL OF EUROPEAN CME, 4 (2015).

81 Nils Schneider et al., *Interessenkonflikte in der ärztlichen Aus-, Weiter- und Fortbildung und Vorschläge zu deren Minimierung*, *in* Interessenkonflikte in der Medizin. Hintergründe und Lösungsmöglichkeiten. (Klaus Lieb et al. eds., 2011).

82 Bundesärztekammer, *(Muster-)Fortbildungsordnung 2013* (2013), *available at* http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/_Muster-_Fortbildungsordnung_29052013.pdf.

83 Klaus Lieb, *Regeln für unabhängige ärztliche AkdÄ-Fortbildungsveranstaltungen* (2015), *available at* http://www.akdae.de/Fortbildung/Regeln.pdf.

84 Julie Simper, *Cologne Consensus Conference, Management of conflict of interest, 12 and 13 September 2014, Cologne, Germany*, JOURNAL OF EUROPEAN CME, 4 (2015) describes examples by the American Accreditation Council for CME (ACCME) and Royal College of Physicians and Surgeons in Canada.

they were/are managed by third party funding accounts and that no money has gone to the speaker personally. While this type of cooperation also creates COIs, speakers that have research experience also bring valuable expertise to a CME event. In this case, the DCGMA judges that it is worth taking the risk of bias to profit from the expertise of these speakers. Additionally, the DCGMA has defined rules to ensure that the content of an event be as balanced as possible. These rules are modeled after suggestions by Lo and Ott.[85] Speakers should:

- Discuss all alternative therapeutic strategies (including generic medication and life style changes, among others)
- Describe systematic reviews, meta-analyses and recommendations by independent institutions as evidence base
- Describe advantages and disadvantages of the discussed therapeutic strategies
- Mention limitations of the evidence base
- Not use presentations or suggestions for talks designed by a pharmaceutical/medical device manufacturer.

Lastly, the DCGMA requires speakers to declare their COIs during the event, with adequate time for the participants to discuss these COIs and their relevance. In addition, the scientific supervisor of the event is required to let the participants evaluate the event, including an evaluation of its potential bias.

While it is unclear whether such strict rules can be implemented within all CME events, it is important that the DCGMA has taken this step to ensure the independence of their events. We hope that this will influence other CME organizers to reconsider their rules with regard to the management of COIs.

V. CONCLUSION

To summarize, there are several promising developments in Germany regarding the management of COIs. Especially the transparency of COIs has improved markedly within the last few years, at least in some organizations such as the DCGMA and the AWMF. Research has begun to shed some light on the frequency of doctor-industry interactions in Germany. Other parties have begun to follow the lead set by the DCGMA requiring a high level of transparency from their members and the AWMF's approach of improving transparency of COIs in guideline-development. Even many pharmaceutical manufacturers have advocated a higher level of transparency, which is a welcome development despite several flaws of their proposal.

The management of COIs has also made progress, but there still remains a lot to be

[85] Bernard Lo & Chelsea Ott, *What is the enemy in CME, conflicts of interest or bias?*, THE JOURNAL OF AMERICAN MEDICAL ASSOCIATION, 310 (2013).

done. However, the DCGMA has taken on an important role in this domain as well, serving as an example in their early benefit assessment as well as in the organization of CME. It remains to be seen whether the ideas of the DCGMA on independent CME will have a positive impact on the broader CME-community; this would be an essential step forward and help doctors to base their decisions on evidence-based information. Further developments from the AWMF and the WBP concerning management of COIs and transparency of non-financial COIs will hopefully be finalized soon, adding to the momentum towards more evidence-based decision-making in medicine in Germany. While the future of the German Clinical Trials Register is uncertain at the moment, one can hope that when sustainable funding is secured, it can continue to diminish publication bias in Germany.

There are still many areas of healthcare in Germany where COIs remain unaddressed, however. Transparency in regard to medical device manufacturers remains extremely low; there has been no self-regulation regarding transparency in this area. Similarly, there has been little effort to address COIs in early medical education, even though our survey showed that medical students already interact with the pharmaceutical industry. Non-financial COIs have also barely been addressed outside of psychotherapy and much work remains to be done on improving their transparency, for example by developing better survey instruments. Even less explored has been the question of management of non-financial COIs. While in some cases, strategies similar to the ones used for financial COIs can be used to reduce bias, in other cases, new strategies will have to be developed.
All in all, Germany is catching up with the international COI-discussion. The current developments raise hopes that medical professionals will continue to strengthen their independence from secondary interests to the benefit of the patients that depend on their expertise.

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

COMPLIANCE MANAGEMENT AT THE DÜSSELDORF UNIVERSITY HOSPITAL

Mechthild Lambers & Hendrik Schneider

AUTHOR

Mechthild Lambers is the Chief Legal Officer of Düsseldorf University Hospital. Since 2001 she has been working in the health care field as an inhouse lawyer and general counsel being in charge of various legal aspects concerning running a hospital. One focus of her work is the implementation of inhouse compliance measures and to provide counsel on compliance matters concerning the University Hospital.

Hendrik Schneider is presently the head of the department of Criminal Law, Criminal Procedure, Criminology, Juvenile Law, and Sentencing at the University of Leipzig Faculty of Law. His current practice includes serving as legal counsel on corporate- and medical- criminal cases and advising on criminal matters surrounding issues of economic transactions and forensic investigations. Additionally, he acts as a compliance consultant with particular emphasis on the healthcare industry, including risk analysis, development and implementation of internal guidelines, change management, employee training, and sustainable protection.

TABLE OF CONTENTS

I. COMPLIANCE RISKS OF A UNIVERSITY HOSPITAL

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

---

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

---

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

---

[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

---

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]

---

[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).

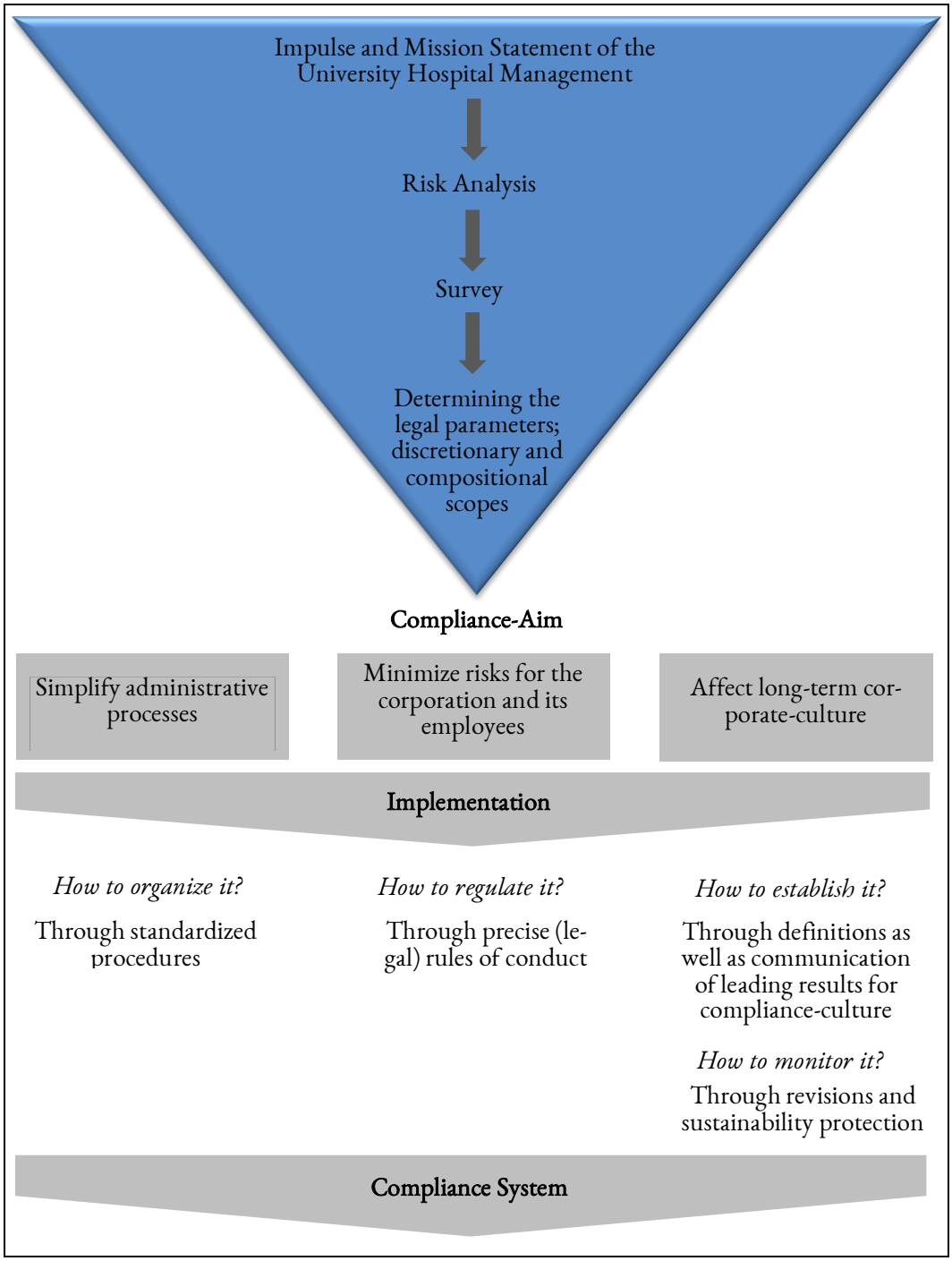

Illustration 1. Steps in implementing the CMS

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.

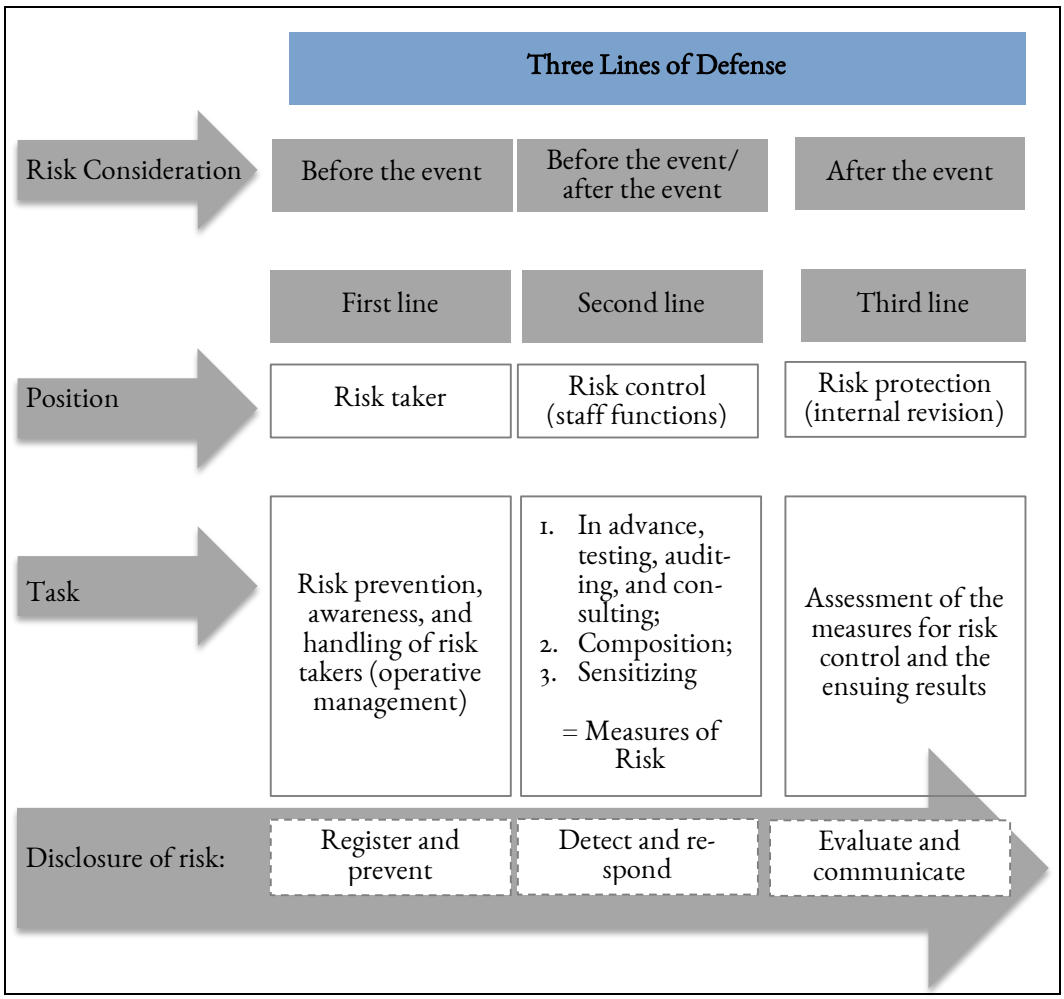

Illustration 2. The Three-lines-of-Defense at the Düsseldorf University Hospital

(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.

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

NEW COMPLIANCE MANAGEMENT SYSTEM OF THE UNIVERSITY HOSPITAL FRANKFURT, GERMANY

Bettina Irmscher

AUTHOR

Since 2013 Bettina Irmscher is a board member of the University Hospital Frankfurt, Germany. She studies economics at the Goethe – University in Frankfurt and started her career with Treuarbeit AG in 1983. In 1989 she headed the Internal Auditors (Revision) of Degussa AG in Frankfurt and joined 1994 the Martin Luther University in Halle where she served in 1996 as Head of Business Administration (Verwaltungsdirektorin). In 2003 she became a Managing Director of Business Administration (Kaufmännische Direktorin) within the University Hospital Rostock. In 2010 she was honoured as "Hospital Manager of the Year" of the "Institut für Medizin-Ökonomie und Medizinische Versorgungsforschung der Rheinischen Fachhochschule", Cologne and "Clustermanagment Gesundheitswirtschaft" Northrhine –Westfalia. She writes and speaks to Compliance issues within the Health Care Sector.

TABLE OF CONTENTS

I. COMPLIANCE

The meaning of Corporate Governance is all values and principles guiding or regulating good and responsible business management.

Clearly defined roles and responsibilities for managing compliance, risks and checks is the prerequisite for the latter.

For that reason, a compliance management system was set up at the University Hospital Frankfurt in 2015.

The management system "*Recht im Betrieb*" assists the Management Board, senior executives and officers in charge of various delegated statutory tasks facing the executives and officers in charge (*Betriebsbeauftragte*) to identify, monitor and verifiably delegate or fulfill their statutory obligations, as well as monitor, update and document them.[1]

The purpose of a compliance management system consists in fulfilling the legal obligations. As at every other company, the members of the Hospital Management also need to conduct themselves in a legally compliant manner and ensure that all the employees likewise conduct themselves in a legally compliant manner.[2]

For the University Hospital Frankfurt 5,570 legal obligations have been ascertained. The Management Board is not in a position to fulfill over 5,500 obligations of the hospital personally. It needs to be ensured by means of organizational steps that the company and its employees operate in accordance with the legal framework. This obligation to ensure legal compliance at the company by means of organizational steps is the responsibility of the Commercial and Medical Directors. They are liable for any loss caused through their organizational fault.

There are six tasks that need to be fulfilled in order to avoid organizational fault. How a company, and thus also the University Hospital, is to be organized can be seen from the new ISO 19600 standard.[3] It has been applicable since 15/12/2014 as a set of new, interna-

---

1 ISO 19600 „Compliance-Management-System-Guidelines" published 12/15/2014; Manfred Rack, *CB-Test: Die rechtlichen Voraussetzungen für ein Compliance-Management-System*, COMPLIANCE BERATER, 279 (2014).

2 ANNEMARIE MATUSCHE-BECKMANN, DAS ORGANISATIONSVERSCHULDEN, 143 (2001); GERALD SPINDLER, UNTERNEHMENSORGANISATIONSPFLICHTEN, 760 (2002); TIM NEELMEIER, ORGANISATIONSVERSCHULDEN PATIENTENFERNER ENTSCHEIDER UND EINRICHTUNGSBEZOGENE AUFKLÄRUNG, 64 (2014); Jürgen Klauber et al., *Schwerpunkt Patientensicherheit*, *in* Krankenhaus-Report 2014 3 (Jürgen Klauber et al. eds., 2014).

3 ISO 19600 "Compliance-Management-System-Guidelines" published 12/15/2014.

tional self-regulatory provisions for compliance management. Whoever complies with these rules on corporate governance will avoid being accused of organizational fault.

a. All the obligations of a company are to be ascertained. Ignorance is no protection against punishment. For the University Hospital Frankfurt a total of 5,579 pertinent obligations have been ascertained, based on 1,100 relevant regulations, which have in turn been sifted out by the database from an aggregate corpus of more than 15,000 regulations. As further, specific types of regulations and sources of legal obligations, the recommendations of the Robert Koch Institute, S3 guidelines, Guidelines of the Federal German Medical Association (*Bundesärztekammer*), Guidelines of the Joint Federal Committee (GBA) and Court judgments taken from medical legislation and hospital legislation have been analyzed, searching for legal obligations. The compliance of legal obligations serves the purpose of averting risk still prior to it being able to cause any damage.

b. The **second** organizational obligation consists of delegating these obligations to the 6,000 employees of the University Hospital Frankfurt. No obligation may remain without anyone being responsible for it. The legal obligations are to be delegated to the departments of the hospital in which the risk to be averted is caused. All officers having a staff function, including the Quality and Compliance Officers, need to co-operate in complying with any legal obligations, in particular the Management Board and senior executives have to provide advice, inform the employees of the hospital about their obligations, and monitor their compliance. They are subject to officers' liability, and may be held responsible based on aiding and abetting. All things considered, after delegating all obligations ascertained the "*Recht im Betrieb*" management system offers one-click information on which hospital employees are required to fulfill which obligations in which department and in what period of time.

c. All the legal obligations need to be updated. On average around 400 legal obligations are amended every month, out of which, on average, only 40% are relevant at a given company. The 400 amended, new or repealed legal obligations are automatically sifted out by the database of the "*Recht im Betrieb*" management system. Sixty per cent of the usual effort is saved through the digitalized filter.

d. All the legal obligations need to be fulfilled. In order to avoid directors' and officers' liability and liability of authorized representatives, as well as officers' liability, all the employees of the hospital need to be interested in fulfilling their obligations - the Management Board, the executives who are line managers and the Quality and Compliance Officers having a staff function.

e. The fulfillment of all obligations is to be monitored. The Management Board is obliged to carry out superintendence. This task cannot be delegated. It will remain exclusively the management's responsibility. In the Compliance manage-

ment system, the superintendence can be attended to using a single user interface. The respective current process status can be retrieved. The digitalized Compliance management system allows for checking compliance at a glance. The officers responsible for the obligations that are overdue and have not been fulfilled can be notified about it from the user interface by e-mail, and have it brought to their attention.

f. As a **sixth point**, all the organizational procedures are automatically documented in the system. The reversal of the burden of proof applies. Should patients suffer loss or damage, the hospital - and not the patient affected - needs to provide evidence that the obligations were known and fulfilled. Should losses occur at the hospital, it must not be the result of poor organization. The University Hospital Frankfurt has, for the first time, deployed a digitalized Compliance management system that has been tried and tested at several hundred industrial companies over the past 20 years. The organizational obligations are the same. Only the applicable legal obligations are different, that avert typical risks at a clinic.

II. CONCLUSION

Through the digitalization of the Compliance Management System "*Recht im Betrieb*", the effort required for compliance management has been considerably reduced. Patient safety is increased. The D&O liability, as well as the representatives' liability of the other executives, and the officers' liability is reduced. The potential for conflict between patient safety due to medical services provided to the highest standard and simultaneous compliance with the efficiency rule in accordance with the Social Security Code (SGB) and the regulations of the Joint Federal Committee (GBA) becomes transparent, and enables targeted solutions. Especially conflicts between the doctors carrying out the treatment and the Hospital Management, which is remote from the patient, are avoided through compliance with all the organizational obligations. Medical malpractice due to organizational defects can be avoided. Through efficient compliance management, the Management Board, senior executives and all the doctors carrying out the treatment, and ultimately the patients treated, whose protection from damage due to organizational malpractice is the issue, benefit.

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

BETWEEN A ROCK AND A HARD PLACE – LEGAL PITFALLS OF VOLUNTARY COOPERATION OF GERMAN COMPANIES WITH GERMAN AND FOREIGN REGULATORY AND LAW ENFORCEMENT AUTHORITIES

Thomas Kopp & Valentin Pfisterer

AUTHOR

Thomas Kopp is a partner at Cleary Gottlieb Steen & Hamilton LLP, based in the firm's Frankfurt office. Thomas Kopp's practice focuses on financial institutions, corporate and sovereign clients and covers a broad range of practice areas, including corporate governance, regulatory compliance & enforcement, capital markets, mergers & acquisitions and dispute resolution, in a post-transactional context or otherwise.

Valentin Pfisterer is an associate at Cleary Gottlieb Steen & Hamilton LLP, based in the firm's Frankfurt office. Valentin regularly publishes, inter alia, on financial institutions regulatory topics and aspects of privacy and data protection in both German and European law.

ABSTRACT

German companies or German-based subsidiaries of international businesses may become subject of, or otherwise involved in, investigations by German or foreign regulatory or law enforcement authorities. In the context of such investigations, it is not unusual for the concerned company to face informal requests from German or foreign regulatory and law enforcement authorities for voluntary cooperation. Oftentimes, such requests focus on the transfer of electronic data for investigatory purposes, and such data typically relate, in whole or in part, to individuals (e.g. employees, suppliers and customers).

In these and other cases, compliance of German companies or German-based subsidiaries with informal requests from regulatory and law enforcement authorities may itself entail a compliance risk or even constitute a breach by the corporate entity of the German data protection laws resulting in criminal prosecution, administrative sanctions, or damage claims and other actions by third party individuals. This article outlines the scope of application of the German Federal Data Protection Act, introduces the applicable statutory provisions, and discusses the relevant considerations in the context of an informal request by a regulatory or law enforcement authority for voluntary cooperation in the context of global investigations, in particular where a German-based entity faces requests from authorities abroad.

TABLE OF CONTENTS

Many German companies maintain business operations or perform business activities abroad and, equally, many international businesses maintain subsidiaries in Germany. In doing so, the German companies are required to comply with the laws applicable to them in the countries where they maintain operations or perform business activities, and the German-based subsidiaries of international businesses are required to comply with German law. Against this background, in suspected cases of non-compliance with applicable laws, it is not unusual for corporate entities based in Germany to become subject of, or otherwise involved in, investigations by German or foreign regulatory or law enforcement authorities. The *Siemens* case, the *Daimler* case, the LIBOR case or, most recently, the investigations in the automotive sector are prominent examples of global investigations involving German companies or German-based subsidiaries of international businesses. In the context of such investigations, it is not unusual for the concerned company to face informal requests from German or foreign regulatory and law enforcement authorities for voluntary cooperation. Oftentimes, such requests focus on the transfer of electronic data for investigatory purposes, and such data typically relate, in whole or in part, to individuals (e.g. employees, suppliers and customers).[1] In the context of an investigation by the U.S. Department of Justice ("DOJ") or the Securities and Exchange Commission ("SEC"), for example, pursuant to a memorandum issued by the Deputy Attorney General of the DOJ on September 9, 2015 on the individual accountability for corporate wrongdoing ("Yates Memorandum"), "*to be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.*"[2] Given the variety of potential adverse consequences of non-cooperation including fines, sanctions, loss of cooperation credit, and negative media coverage[3], companies will typically be inclined to comply with any such informal request for voluntary cooperation including the required data transfers.

While this position is understandable, German companies and subsidiaries of international businesses located in Germany should thoroughly reflect on the legal implications of the actions required to comply with such a request.[4] The reason for this is that, under German law, informal requests by German or foreign regulatory and law enforcement authorities do not per se form a legal basis for the required actions. Rather, the German-based corporate entity has to asses, taking into account the legal rules and regulations

---

1 Tim Wybitul, *How to Conduct E-mail Reviews in Germany*, COMPLIANCE ELLIANCE JOURNAL, 59, 62 (2016).

2 DOJ, Office of the Deputy Attorney General, *Yates* Memorandum, September 9, 2015 (www.justice.gov/dag/file/769036/download), p. 3.

3 For an account of a case of operational and reputational damage as a consequence of the lack of cooperation, *see* Folker Bittmann, *Internal Investigations under German Law*, COMPLIANCE ELLIANCE JOURNAL, 74, 84 (2015).

4 On the conflicting priorities in such situations, *see* Sascha Süße & Carolin Püschel, *Collecting Evidence in Internal Investigations in the Light of Parallel Criminal Proceedings*, COMPLIANCE ELLIANCE JOURNAL, 26, 52 *et seq.* (2016).

applicable to it, whether or not it is actually permitted to meet an informal request of a German or foreign regulatory and law enforcement authority. In certain cases, compliance of the corporate entity with such an informal request may itself entail a compliance risk or even constitute a breach by the corporate entity of the laws applicable to it resulting in criminal prosecution, administrative sanctions, or damage claims and other actions by third party individuals.[5] In this context and in relation to requested transfers of personal data, the data protection laws applicable in Germany, particularly the German Federal Data Protection Act (*Bundesdatenschutzgesetz* – "FDPA"), are especially important to be taken into consideration.[6]

This article outlines the scope of application of the FDPA (I.), introduces the applicable statutory provisions, and discusses the relevant considerations in connection with an informal request by a regulatory or law enforcement authority for voluntary cooperation in the context of global investigations (II. and III.), in particular where a German based entity faces requests from authorities abroad (III.). While this article focuses on the current legal framework in Germany governed by the FDPA and the European Data Protection Directive of 1995 ("DPD"), it also takes into account the General Data Protection Regulation ("GDPR")[7] as published in the Official Journal of the European Union on May 4, 2016 by way of reference where appropriate. As from May 2018, the legal framework for the protection of personal data in the European Union will be primarily governed by the provisions of the GDPR.

I. THE SCOPE OF APPLICATION OF THE GERMAN FEDERAL DATA PROTECTION ACT

At present, the FDPA constitutes the central legal framework in the area of data pro-

---

5 *See* Sascha Süße & Carolin Püschel, *Collecting Evidence in Internal Investigations in the Light of Parallel Criminal Proceedings*, COMPLIANCE ELLIANCE JOURNAL, 26, 36 (2016): *"The collecting of evidence itself must certainly be compliant with all applicable laws, i.e. must not violate any criminal, data protection or labor laws."*

6 *See* Christian Pelz, *Ambiguities in International Internal Investigations*, COMPLIANCE ELLIANCE JOURNAL, 14, 16 (2016): "*Privacy and data protection issues are of major concern in any kind of compliance review, compliance audit and in particular in international internal investigations.*"

Under certain circumstances, stricter legal standards may apply in addition to, or in lieu of, the FDPA, such as the German Telemedia Act and the German Telecommunications Act, or in the case of the personal data of the customers of credit institutions, the principles of banking secrecy. These standards will not be addressed in this article. As to the standards applicable under German law to email reviews, *see* Tim Wybitul, *How to Conduct E-mail Reviews in Germany*, COMPLIANCE ELLIANCE JOURNAL, 59 *et seq.* (2016); Tim Wybitul & Wolf-Tassilo Böhm, *E-Mail-Kontrollen für Compliance-Zwecke und bei internen Ermittlungen*, CORPORATE COMPLIANCE-ZEITSCHRIFT, 133, 133 (2015).

7 *See* Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), O.J. 2016, L 119/1 (hereinafter "GDPR").

tection in Germany. The FDPA implements the DPD which aims to harmonize the data protection regimes in all EU Member States.[8] The purpose of the DPD is *"to protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data"*.[9] Correspondingly, it is the purpose of the FDPA *"to protect the individual against his/her right to privacy being impaired through the handling of his/her personal data"*.[10]

A. The Concept of "Personal Data"

The concept of "*personal data*", under German and European law, is broad[11] and encompasses any information relating to an identified or identifiable natural person, the so-called data subject.[12] Pursuant to the Article 29 Working Party, a committee of representatives of the national data protection authorities of the EU Member States, *"a person can be considered as "identified" when, within a group of persons, he or she is "distinguished" from all other members of the group."*[13] In contrast, an *"identifiable"* person is *"a person who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity"*.[14] Personal data within this meaning can be included, for instance, in notebook entries, personal files, minutes, documentation relating to goods, services and financial transactions, information about customers, suppliers and business partners. Such data is often significant for regulatory or criminal investigations as it can provide evidence for the behavior of one or more individuals, corporate bodies such as boards or committees or even the business practice throughout a company or an entire corporate group.

---

8 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, O. J. 1995, L 281/31 ("Data Protection Directive" or "DPD"). For information on the DPD, *see* Paul M. Schwartz &Daniel J. Solove, *Reconciling Personal Information in the United States and European Union,* CALIFORNIA LAW JOURNAL, 877, 882-884 (2014); Paul M. Schwartz, *The EU-U.S. Privacy Collision: A Turn to Institutions and Procedures,* HARVARD LAW REVIEW, 1966, 1971-1979 (2013); Paul M. Schwartz, *Information Privacy in the Cloud,* UNIVERSITY OF PENNSYLVANIA LAW REVIEW, 1624, 1639-1642 (2013); Virginia Boyd, *Financial Privacy in the United States and the European Union: A Path to Transatlantic Supervisory Harmonization*, BERKELEY JOURNAL OF INTERNATIONAL LAW, 939, 958-967 (2006).

9 Article 1(1) DPD.

10 Section 1(1) FDPA.

11 *See* Article 29 Working Party, Opinion 4/2007 on the concept of personal data, WP 136, June 20, 2007, p. 4 (*"The Directive contains a broad notion of personal data"*). As to the common features and differences of the concepts used in the U.S. and Europe, *see* Paul M. Schwartz & Daniel J. Solove, *Reconciling Personal Information in the United States and European Union,* CALIFORNIA LAW JOURNAL, 877, 881 *et seq.* (2014); Paul M. Schwartz, *The EU-U.S. Privacy Collision: A Turn to Institutions and Procedures,* HARVARD LAW REVIEW, 1966, 1968-1992 (2013); more profoundly, James Q. Whitman, *The Two Western Cultures of Privacy: Dignity versus Liberty*, YALE LAW JOURNAL, 1151, 1153 *et seq.* (2004).

12 Section 3(1) FDPA, Article 2a) DPD.

13 Article 29 Working Party, Opinion 4/2007 on the concept of personal data, WP 136, June 20, 2007, p. 12.

14 Article 2a) DPD. For a more detailed analysis, *see* Article 29 Working Party, Opinion 4/2007 on the concept of personal data, WP 136, June 20, 2007, p. 12 *et seq*.

B. "Collection, Processing and Use" of Personal Data

The FDPA governs the "*collection, processing and use of personal data*" in Germany.[15] "*Collection*", per its definition, is the obtaining of data regarding the data subject.[16] *"Processing"*, on the other hand, includes various activities within the scope of activity of a company subject to an information request by an authority. Thus, "*processing"* captures, *inter alia*, the transfer of such personal data.[17] "*Transfer*", in turn, means the disclosure to a third party of personal data stored or obtained by means of data processing through transmission of the data to the third party or, in the terms of the DPD, the *"disclosure by transmission, dissemination or otherwise making available"* of personal data.[18]

In view of the above, the provision by companies of information relating to individuals such as employees, suppliers and customers to public authorities may be relevant under the FDPA in two respects: First, the provision by the company may qualify as transfer and, thus, processing of personal data within the meaning of the FDPA. Second, the receipt of the information by the public authority may qualify as collection of personal data within the meaning of the FDPA.

II. DATA TRANSFERS TO GERMAN REGULATORY OR LAW ENFORCEMENT AUTHORITIES

In regard to the collection of personal data by a public authority from a private sector entity, the FDPA establishes a clear distinction: In such cases, the public authority shall either inform the private sector entity of the legal provision requiring the disclosure, *i.e.* the transfer, of the relevant personal data or, alternatively, of the fact that such disclosure is voluntary.[19] In the former case, and assuming the requirements of the relevant provision are met, the private sector entity is legally obliged to transfer the relevant personal data to the public authority. In the latter case, *i.e.* in the absence of a *statutory obligation* to transfer the relevant personal data, the private sector entity, before transferring the relevant personal data, has to ensure that it is actually allowed to do so.[20]

---

15 Section 1(2) FDPA, Article 3(1) DPD. Also *see* Article 4(2) GDPR.

16 Section 3(3) FDPA. Examples in legal literature for the "collection" of personal data include the request of personal records or the active receiving of media or documentation including personal information, *see* Ulrich Dammann, *in* BDSG, Section 3 m.n. 109, (Spiros Simitis, 8th ed. 2014); *see* also Benedikt Buchner, *in* BDSG, Section 3 m.n. 26 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

17 Section 3(4) Sent. 1 FDPA. *See* Article 29 Working Party, Working Document on surveillance of electronic communications for intelligence and national security purposes, December 5, 2014, p. 37-38.

18 Section 3(4) Sent. 2 No. 3a) FDPA and Article 2b) DPD. Also *see* Article 4(2) GDPR.

19 Section 13(1a) FDPA.

20 Bettina Sokol & Philip Scholz, *in* BDSG, Section 13 m.n. 30 (Spiros Simitis, 8th ed. 2014); Peter Wedde, *in* BDSG, Section 13 m.n. 21 (Wolfgang Däubler, Thomas Klebe, Peter Wedde & Thilo Weichert, 5th ed. 2016);

Pursuant to the general rule set forth in Section 4(1) FDPA, the transfer of personal data by a private entity to a third party, including a requesting regulatory or law enforcement authority, requires either the *consent* of the data subject or a *statutory authorization*.

A. Consent

As regards the consent of the data subject, such consent shall be effective only when based on the *"data subject's free decision"* (Section 4a(1) FDPA).[21] Further, *"data subjects shall be informed of the purpose of collection, processing or use and, in so far as the circumstances of the individual case dictate or upon request, of the consequences of withholding consent. Consent shall be given in writing unless special circumstances warrant any other form"*.[22] Additionally, due to its voluntary nature, consent can be withdrawn at any time, removing the legal basis for the processing.[23] In an investigation context, for a company facing an information request by a public authority, it is oftentimes not a viable option to obtain the consent of the relevant data subjects. In some cases, where the relevant information relates to a vast number of individuals, this would require an excessive administrative effort; in other cases, the request for consent would make the relevant individual aware of the investigation and, thus, potentially defeat its objective and purpose. Also, with regard to employees' personal data (*see* II.B. below), there is a controversy as to whether and to what extent an employee's consent *vis-à-vis* the employer can be regarded as a free decision within the meaning of Section 4a(1) FDPA due to the imbalance of power inherent in the employment relationship, and, consequently, calls the processing of the data by the employer into question.[24] Finally, the concerned individuals may decide not to grant their consent or, after having initially granted the consent, to withdraw it at a later stage.

B. Statutory Authorizations – Legitimate Purpose, Necessity and Balancing of Interests

Jutta Stender-Vorwachs, *in* BeckOK BDSG, Section 13 m.n. 16 (Heinrich Amadeus Wolff & Stefan Brink *et al* 15th ed. 2015).

21 The concept of consent remains a legal basis for processing also under the GDPR (*see* Article 6(1) a) GDPR). The requirements for a consent to be valid under the GDPR are stipulated in Article 7 GDPR.

22 Section 4a(1) FDPA.

23 After the withdrawal of the consent by the data subject, the consent no longer constitutes a legal basis for the use of the relevant personal data. Correspondingly, the relevant personal data may no longer be used, unless a statutory authorization is available. Spiros Simitis, *in* BDSG, Section 4a m.n. 94, 96, 103 (Spiros Simitis, 8th ed. 2014); Kai-Uwe Plath, *in* BDSG, Section 4a m.n. 70 *et seq.* (Kai-Uwe Plath, 1st ed. 2013); Jürgen Taeger, *in* BDSG, Section 4a m.n. 81 *et seq.* (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

24 The Article 29 Working Party has voiced its skepticism in this context, *see* Opinion 8/2001 on the processing of personal data in the employment context, 5062/01/EN/Final, WP 48, September 13, 2001, p. 23; Working document on a common interpretation of Article 26(1) of Directive 95/46/EC of 24 October 1995, 2093/05/EN, WP 114, p. 11. The German Federal Labor Court (*Bundesarbeitsgericht*), though, has stated that even in an employment context there is no reason in principle why an employee's consent should not be considered a free decision, judgment of December 11, 2014 (8 AZR 1010/13).

As regards the statutory authorization to process personal data, the FDPA contains a number of provisions which explicitly allow for the processing, including transfer and collection, of personal data, subject to the requirements and limitations described therein. The common feature of these provisions is that each one of them sets forth a *specific purpose* for which, and only for which, the data controller is authorized to process the relevant personal data. While most of the statutory purposes are not relevant in an investigation context, the statutory authorizations relating to data processing *for criminal prosecution purposes*, *for averting threats to state or public security*, and *for the protection of the legitimate interests of the company or a third party* may generally be applicable.

1. Criminal Prosecution Purposes

The FDPA allows for processing of personal data for criminal prosecution purposes.[25] In this context, however, slightly different legal regimes are applicable to personal data relating to employees and personal data relating to other individuals.

Employee data. While, pursuant to Section 32(1) FDPA, personal data of an employee may be collected, processed or used to detect criminal offences, employees benefit from a higher level of data protection than other individuals. In the case of employees, documented factual indications are required that the data subject has committed a criminal offence in connection with his employment.[26] As a consequence, first, the suspicion of a *criminal offense* is required as opposed to an offense of an administrative nature.[27] Second, mere assumptions or speculations as to a potential criminal offense potentially committed by a given employee are not sufficient, as strong as they may be; actual *factual indications* are required.[28] Third, indications of a criminal offense potentially committed by a given employee unrelated to his *employment* are not in scope.[29] Fourth, the relevant indications, including the damage occurred, the potential suspects, and the indications which are at the heart of the suspicion, are to be *duly documented* in written

---

[25] Section 32(1) and 28(2) No. 2b) FDPA.

[26] Section 32(1) Sent. 2 FDPA.

[27] Achim Seifert, *in* BDSG, Section 32 m.n. 102 (Spiros Simitis, 8th ed. 2014); René Erfurth, *Der „neue" Arbeitnehmerdatenschutz im BDSG*, NEUE JURISTISCHE ONLINE-ZEITSCHRIFT, 2914, 2921 (2009); Tim Wybitul, *Das neue Bundesdatenschutzgesetz: Verschärfte Regeln für Compliance und interne Ermittlungen*, BETRIEBS-BERATER 1582, 1584 (2009).

[28] Oliver Zöll, *in* BDSG, Section 32 m.n. 50 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Achim Seifert, *in* BDSG, Section 32 m.n. 103 (Spiros Simitis, 8th ed. 2014); Uwe H. Schneider, *Investigative Maßnahmen und Informationsweitergabe im konzernfreien Unternehmen und im Konzern*, NEUE ZEITSCHRIFT FÜR GESELLSCHAFTSRECHT, 1201, 1206 (2010); Christiane Bierekoven, *Korruptionsbekämpfung vs. Datenschutz nach der BDSG-Novelle*, COMPUTER UND RECHT, 203, 206 (2010); René Erfurth, *Der „neue" Arbeitnehmerdatenschutz im BDSG*, NEUE JURISTISCHE ONLINE-ZEITSCHRIFT, 2914, 2920 (2009); Tim Wybitul, *Das neue Bundesdatenschutzgesetz: Verschärfte Regeln für Compliance und interne Ermittlungen*, BETRIEBS-BERATER, 1582, 1584 (2009).

[29] Oliver Zöll, *in* BDSG, Section 32 m.n. 51 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Achim Seifert, *in* BDSG, Section 32 m.n. 102 (Spiros Simitis, 8th ed. 2014).

form or electronically.[30] Finally, the *rights of participation of works councils* must be observed.[31] This relates to certain participation and consultation rights granted to works councils by applicable labor laws.[32]

Data relating to other individuals. To the extent applicable in an employment context[33], as well as more generally in a commercial context, the data transfer to regulatory or law enforcement authorities must otherwise meet the requirements stipulated in Section 28 FDPA.[34] This provision sets forth *various specific statutory authorizations* which allow for the processing and transfer of personal data under certain conditions including to *prosecute criminal offences*.[35] As is the case in the employment context, only the prosecution of criminal offenses, as opposed to administrative offenses, is in scope.[36] Other than that, the requirements under Section 28 FDPA are less stringent than in an employment context, and, for example, the documentation of the suspicion or the involvement of a works council, if any, are not mandatory (*see* above).

2. Averting Threats to State or Public Security

The FDPA further also allows for the processing of personal data in order *to avert threats to state or public security*.[37] The powers granted under this provision are relatively broad. This notwithstanding, it does not generally allow for the processing of personal data for public interest purposes; in using the term "*threats to state or public security",* the legislator has deliberately opted for a narrower term as opposed to a general public interest exemption.[38] Also, the provision requires a concrete risk of such a threat, a mere

---

30 Oliver Zöll, *in* BDSG, Section 32 m.n. 52 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

31 Section 32(3) FDPA.

32 *See*, for example, Section 75(2), 80, and 87(1) No. 6 of the Works Council Constitution Act (*Betriebsverfassungsgesetz*); for additional detail, *see* Tim Wybitul, *How to Conduct E-mail Reviews in Germany*, COMPLIANCE ELLIANCE JOURNAl, 59, 72 (2016).

33 There is some dispute in legal literature as to whether or to what extent Section 28 FDPA is applicable alongside Section 32 FDPA in an employment context, *see* Oliver Zöll, *in* BDSG, Section 32 m.n. 7 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Achim Seifert, *in* BDSG, Section 32 m.n. 17 (Spiros Simitis, 8th ed. 2014); Uwe H. Schneider, *Investigative Maßnahmen und Informationsweitergabe im konzernfreien Unternehmen und im Konzern*, NEUE ZEITSCHRIFT FÜR GESELLSCHAFTSRECHT, 1201, 1205 (2010); Christiane Bierekoven, *Korruptionsbekämpfung vs. Datenschutz nach der BDSG-Novelle*, COMPUTER UND RECHT, 203, 206 (2010); René Erfurth, *Der „neue" Arbeitnehmerdatenschutz im BDSG*, NEUE JURISTISCHE ONLINE-ZEITSCHRIFT, 2914, 2922 (2009).

34 *See* Jürgen Taeger, *in* BDSG, Section 28 m.n. 31 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); similar Spiros Simitis, *in* BDSG, Section 28 m.n. 22 (Spiros Simitis, 8th ed. 2014).

35 Section 28(2) No. 2 b) FDPA.

36 Spiros Simitis, *in* BDSG, Section 28 m.n. 190 (Spiros Simitis, 8th ed. 2014); Kai-Uwe Plath, *in* BDSG, Section 28 m.n. 97 (Kai-Uwe Plath, 1st ed. 2013); Jürgen Taeger, *in* BDSG, Section 28 m.n. 146 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

37 Section 28(2) No. 2b) FDPA.

38 Spiros Simitis, *in* BDSG, Section 28 m.n. 190 (Spiros Simitis, 8th ed. 2014).

abstract risk is not sufficient.[39] Finally, specific statutory authorizations set forth in the laws applicable to the relevant regulatory or enforcement authorities take precedence over this particular exemption to the effect that such authorities have to rely on such specific authorizations, if any, to request the relevant data from private companies and may not rely on Section 28(2) No. 2b) FDPA where such statutory authorization does not exist or its requirements are not met.[40]

3. Protection of the Legitimate Interests of the Company or a Third Party

Finally, the FDPA allows for the processing of personal data to *protect the legitimate interests of the company or a third party*.[41] Both authorizations are to be interpreted narrowly.[42]

Legitimate interests of the company. Legitimate interests of the company within this meaning may be both monetary as well as non-monetary interests.[43] The keen interest of a requesting third party, including regulatory or law enforcement authorities, does not qualify as a legitimate interest of the company.[44] A cooperative relationship of the company with the relevant regulatory or law enforcement authority in general and the compliance with an informal request of such an authority, including to avoid potential adverse consequences of non-cooperation, should typically count among the legitimate interests of a company, the warranted narrow interpretation notwithstanding.

Legitimate interests of a third party. There is no reason in principle why regulatory or law enforcement authorities should be excluded from the term "third party". Therefore, the company facing an informal information request has to assess whether or not such information request is based on reasonable needs for information on the part of the requesting authority and whether or not such informational needs qualify as legitimate interests within this meaning.

4. Additional Requirements: Necessity and Balancing of Interests

Necessity. In each of the cases described above, the processing of the personal data must be "*necessary*" to pursue the legitimate purpose, *i.e.* to investigate the alleged criminal offence, to avert the threats to state or public security, or to protect the legitimate inter-

---

39 Kai-Uwe Plath, *in* BDSG, Section 28 m.n. 97 (Kai-Uwe Plath, 1st ed. 2013); Jürgen Taeger, *in* BDSG, Section 28 m.n.144 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

40 Jürgen Taeger, *in* BDSG, Section 28 m.n.146 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 28 m.n. 192 (Spiros Simitis, 8th ed. 2014).

41 Section 28(2) No. 1 and No. 2a) FDPA.

42 Spiros Simitis, *in* BDSG, Section 28 m.n. 98 and 174 (Spiros Simitis, 8th ed. 2014).

43 Spiros Simitis, *in* BDSG, Section 28 m.n. 104 (Spiros Simitis, 8th ed. 2014); Jürgen Taeger, *in* BDSG, Section 28 m.n.55 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

44 Spiros Simitis, *in* BDSG, Section 28 m.n. 107 (Spiros Simitis, 8th ed. 2014).

ests of the company or a third party.[45] The term *"necessary"* is generally interpreted narrowly and strictly.[46] As a consequence, it has to be examined carefully whether the envisaged data transfer could be replaced by a less intrusive action or the corresponding goal otherwise pursued by less intrusive means.[47]

Balancing of interests. Further, in each of the cases described above, the data subject's *"legitimate interest"* in keeping his personal data undisclosed are to be adequately taken into account.[48] More precisely, in the case of data processing for the purpose of criminal prosecution, averting threats to state or public security and the protection of legitimate interests of a third party, there must not be any *"reason to believe that the data subject has such legitimate interest*" at all.[49] In other words, a data transfer may not be based on the corresponding statutory authorizations if there is at least one single reason for the concerned individual providing for a legitimate interest of such individual to maintain his personal data undisclosed. Slightly less strict, in the case of data processing for the purpose of the protection of legitimate interests of the company, the data subject must not have an "*overriding legitimate interest"* in maintaining the confidentiality of his data.[50] This requires a comprehensive proportionality assessment to evaluate the suitability of the data processing for the purpose pursued, its necessity relative to potentially less intrusive means (*see* above), as well as its adequacy, especially in regards to the type and extent of data processing.[51] In the course of this assessment, a comprehensive balancing of interests is required whereby the interests in favor of the data transfer (the self-interests of the company) are to be weighed against the interest of the data subject in keeping his data confidential. As a result of such assessment, the interests of the data

---

45 Section 28(2) No. 1 and No. 2a) and b) FDPA. *See* Article 6(1) d), e) and f) GDPR.

46 Achim Seifert, *in* BDSG, Section 32 m.n. 11 (Spiros Simitis, 8th ed. 2014); Katrin Stamer & Michael Kuhnke, *in* BDSG, Section 32 m.n. 16 (Kai-Uwe Plath, 1st ed. 2013); Oliver Zöll, *in* BDSG, Section 32 m.n. 16 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 28 m.n. 182 *et seq.* (Spiros Simitis, 8th ed. 2014); Jürgen Taeger, *in* BDSG, Section 28 m.n. 135 *et seq.* (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

47 Achim Seifert, *in* BDSG, Section 32 m.n. 105 (Spiros Simitis, 8th ed. 2014); Tim Wybitul, *Das neue Bundesdatenschutzgesetz: Verschärfte Regeln für Compliance und interne Ermittlungen*, BETRIEBS-BERATER, 1582, 1583 (2009).

48 Section 32(1) Sent. 2 and Section 28(2) No. 1 and No. 2 FDPA.

49 Section 28(2) No. 1 and 2 FDPA. A similar requirement is explicitly mentioned only in Article 6(1) f) GDPR (data processing necessary for the purposes of the legitimate interests pursued by a controller or a third party). However, Article 6(3) GDPR states that the legal basis of the data processing referred to in Article 6(1) c) and e) GDPR (processing necessary for compliance with a legal obligation to which the controller is subject or necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller) must be rooted in European Union law or the law of the Member State to which the controller is subject. The law of the Member State must meet a public interest objective or must be necessary to protect the rights and freedoms of others, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued. In the context of the corresponding assessment, the legitimate interests of the data subject should obviously be taken into consideration.

50 Section 28(1) Sent. 1 No. 2 FDPA.

51 Oliver Zöll, *in* BDSG, Section 32 m.n. 53 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Achim Seifert, *in* BDSG, Section 32 m.n. 106 (Spiros Simitis, 8th ed. 2014); Jan Pohle, *Unterlagen-, Daten- und E-Mailauswertung unter Berücksichtigung datenschutzrechtlicher Aspekte, in*: Deutsch-Amerikanische Korruptionsverfahren 309, 316 (Jürgen Wessing & Matthias Dann eds., 2013).

subject take precedence particularly in situations where the type and extent of the data processing are disproportionate to the purpose pursued.[52] Also, in the context of regulatory or criminal investigations, it is of particular relevance whether the concerned individual is a suspect, a potential witness or a person not involved in the investigated misconduct. While the FDPA also generally protects the personal data of criminal suspects[53], in connection with the proportionality assessment, the interest of not getting involved in, or subject of, a regulatory or criminal investigation may weigh stronger in the case of potential witnesses or persons unrelated to the investigated misconduct than in the case of suspects.

III. DATA TRANSFERS TO FOREIGN REGULATORY OR LAW ENFORCEMENT AUTHORITIES

The FDPA applies where the controller is either located or collects or processes personal data in Germany.[54] A German-based corporate entity subject to an informal information request by a foreign regulatory or law enforcement authority has to assess, in addition to the legality of the preparatory data collection, the permissibility of the envisaged data transfer in light of Sections 4b and 4c FDPA.[55] These provisions establish specific requirements for the transfer of personal data across borders which apply in addition to the requirements applicable in a domestic context (*see* II. above).[56] They further differentiate between data transfers to recipients located in EU or EEA Member States (*see* A. below) and data transfers to recipients located in what is known as Third Countries (*see* B. below).

A. Regulatory or Law Enforcement Authorities located in EU or EEA Member States

Data transfers to recipients located in EU or EEA Member States are primarily governed by Section 4b(1) FDPA which reads: *"The transfer of personal data to bodies 1. in other Member States of the European Union, 2. in other states parties to the Agreement on the European Economic Area or 3. institutions and bodies of the European Communities shall be subject to (...) Sections 28 to 30a in accordance with the laws and agreements ap-*

---

52 Spiros Simitis, *in* BDSG, Section 28 m.n. 180 (Spiros Simitis, 8th ed. 2014); Kai-Uwe Plath, *in* BDSG, Section 28 m.n. 53 and 95 *et seq.* (Kai-Uwe Plath, 1st ed. 2013); Jürgen Taeger, *in* BDSG, Section 28 m.n. 61 *et seq.* (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

53 *See* Spiros Simitis, *in* BDSG, Section 28 m.n. 190 et. seq and 195 (Spiros Simitis, 8th ed. 2014); Kai-Uwe Plath, *in* BDSG, Section 28 m.n. 97 (Kai-Uwe Plath, 1st ed. 2013); Jürgen Taeger, *in* BDSG, Section 28 m.n. 141 and 145 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013). Also *see* Article 10 GDPR.

54 Section 1(5) FDPA.

55 Detlev Gabel, *in* BDSG, Section 4b m.n. 9 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013) Spiros Simitis, *in* BDSG, Section 4b m.n. 38-39 (Spiros Simitis, 8th ed. 2014); Philipp Räther & Nicolai Seitz, *Übermittlung personenbezogener Daten in Drittstaaten Angemessenheitsklausel, Safe Harbor und die Einwilligung,* MULTIMEDIA UND RECHT, 425, 426 (2002).

56 Section 28 *et seq.* FDPA.

plicable to such transfer, in so far as transfer is effected in connection with activities which fall in part or in their entirety within the scope of the law of the European Communities." Hence, the transfer of personal data to recipients in EU or EEA Member States is generally subject to the requirements applicable in a domestic context as discussed above, although in accordance with the laws and agreements applicable to such transfer, inasmuch as the transfer is effected in connection with activities which fall either entirely or in part within the scope of the law of the European Communities.[57]

1. Prerequisite Requirements: Precedence Rule and Limited Scope of Applicability

This requirement raises at least two potential pitfalls to companies willing to comply with an informal request from an EU or EEA authority.

Precedence rule. First, the provision states that the cross-border transfer of personal data has to occur "*in accordance with the laws and agreements applicable to such transfer"*.[58] This requirement implies that the envisaged data transfer, including its limits and conditions, is subject to special laws or bilateral or multilateral agreements, if any such law or agreement applies in the specific case.[59] Such laws or agreements may take precedence over the general data protection provisions contained in the FDPA and set forth the legal requirements applicable to the envisaged transfer.[60] As a consequence, special attention should be paid to whether or not a specific legal regime for cross-border data transfer exists in a given case and, if so, whether the specific requirements set forth in such regime are met.

Limited scope of applicability. Second, the provision generally only authorizes cross-border data transfers to the extent *"activities which fall in part or in their entirety within the scope of the law of the European Communities"* are affected. This refers to what was formerly known as the first pillar of the European Union pursuant to the Maastricht Treaty and, broadly speaking, comprised the area of economic and trade cooperation.[61] The first pillar should be distinguished from what was formerly known as the second pillar (Common Foreign and Security Policy) and the third pillar (Police and Judicial Cooperation in Criminal Matters).[62] The wording of Section 4b FDPA should be seen

---

57 Detlev Gabel, *in* BDSG, Section 4b m.n. 10-13 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 4b m.n. 25-37 (Spiros Simitis, 8th ed. 2014).

58 Section 4b(1) FDPA.

59 Spiros Simitis, *in* BDSG, Section 4b m.n. 37 and 40 (Spiros Simitis, 8th ed. 2014).

60 LUTZ BERGMANN, ROLAND MÖHRLE & ARMIN HERB, BDSG, Section 4b m.n. 24 (loose-leaf booklet ed. 2014); Spiros Simitis, *in* BDSG, Section 4b m.n. 40 (Spiros Simitis, 8th ed. 2014); Detlev Gabel, *in* BDSG, Section 4b m.n. 12 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

61 Detlev Gabel, *in* BDSG, Section 4b m.n. 11 and 14 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 4b m.n. 33 (Spiros Simitis, 8th ed. 2014).

62 Detlev Gabel, *in* BDSG, Section 4b m.n. 11 and 14 (Jürgen Taeger & Detlev Gabel 2nd ed. 2013).

in light of Art. 3(2) DPD. Pursuant to this provision, the DPD shall not apply to the processing of personal data *"in the course of an activity which falls outside the scope of Community law (...) and in any case to processing operations concerning public security, defense, State security (...) and the activities of the State in areas of criminal law"*.[63] Rather, the protection of personal data in connection with data transfers between EU Member States in the area of police and judicial cooperation in criminal matters is, since recently, governed by a particular directive.[64] As to the qualification of a given activity as falling inside or outside the scope of Community law, neither the wording nor case law of German courts give clear guidance as to which activity should be taken into account in this context – the business activities of the company (which should usually fall within the scope of the first pillar) or the investigative activities of the regulatory or law enforcement authorities to which the company is supposed to contribute by transferring the data (which may fall into the scope of the third pillar). In the so-called *PNR* decision of 2006, however, the European Court of Justice ("ECJ") implicitly decided in favor of the latter.[65] In the corresponding case, the ECJ had been asked by the European Parliament to annul the so-called PNR Agreement concluded between the EU and the U.S. in 2004.[66] The 2004 PNR Agreement allowed for the competent U.S. authority to access the PNR data stored in the reservation/departure control systems of air carriers located within the territory of EU Member States for the purpose of *"preventing and combating terrorism and related crimes and other serious crimes that are transnational in nature, including organised crime"*. In the decision handed down by the ECJ, the ECJ held that the 2004 PNR Agreement was invalid due to the lack of a suitable legal basis in Community law. The ECJ explained that *"the transfer of PNR data to CBP constitutes processing operations concerning public security and the activities of the State in areas of criminal law"*[67] and, therefore, could not be based on the DPD or otherwise on Com-

---

63 The scope of application of the GDPR is similarly restricted to the processing of personal data *"in the course of an activity which falls within the scope of Union law"* (which is, admittedly, more extensive than the law of the (former) European Communities) (*see* Article 2(2) a) GDPR). However, the GDPR also excludes from its scope of application data processing *"by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties"* (Article 2(2) d) GDPR) which mirrors what is set forth in Article 3(2) DPD.

64 Directive of the European Parliament and of the Council of 04/27/2016 on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data, and repeating Council Framework Decision 2008/977/JHA, O.J. 2016, L 119/89.

65 *See* ECJ, judgment May 30, 2006 (*PNR*) – C-317/04 – m.n. 56. The acronym PNR stands for Passenger Name Record data (specific files on every passenger and journey created by air carriers) and relates to the transatlantic transfer of information contained in these files for law enforcement purposes. For additional detail, *see* Valentin M. Pfisterer, *PNR in 2011: Recalling Ten Years of Transatlantic Cooperation in PNR Information Management,* THE UNIVERSITY OF MIAMI NATIONAL SECURITY & ARMED CONFLICT LAW REVIEW, 114, 120 *et seq.* (2012).

66 Agreement between the European Community and the United States of America on the processing and transfer of Passenger Name Record data by air carriers to the United States Department of Homeland Security, O.J. 2004, L 183/84.

67 ECJ, judgment May 30, 2006 (*PNR*) – C-317/04 – m.n. 56.

munity law.[68] Against this background, there are good arguments that at least the transfer of personal data by companies for investigative purposes of law enforcement authorities should be outside the scope of the law of the European Communities and, thus, cannot be justified under Section 4b(1) FDPA.[69] Consequently, such data transfer would be subject to the stricter requirements under Section 4b(2) FDPA. Pursuant to this provision, data transfers to recipients located in the EU or the EEA *"when effected outside of activities which fall in part or in their entirety within the scope of the law of the European Communities"* are also subject to Section 4b(1) FDPA. In addition, however, the provision states that such *"transfer shall not be effected in so far as the data subject has a legitimate interest in excluding transfer, in particular if an adequate level of data protection is not guaranteed".*[70] As this standard equally applies to data transfers to recipients located in so-called Third Countries, it shall be discussed below (*see* B. below).

2. Statutory Authorizations as Applicable in a Domestic Context

In addition to the requirements outlined above and by reference to Sections 28 *et seq.* FDPA,[71] data transfers to recipients located in EU or EEA Member States must also meet the criteria applicable in a domestic context. Hence, the purpose for which the data is transferred must correspond to one or more of the purposes explicitly specified in these provisions (including criminal prosecution, averting threats to state or public security, and the protection of the legitimate interests of the company or a third party) and the additional requirements (necessity and balancing of interests) have to be met (*see* II.B. above).

B. Regulatory or Law Enforcement Authorities located in Third Countries

Section 4b(2) FDPA provides the legal framework for cross-border data transfers to both recipients located in EU or EEA Member States, such transfer falling *"outside of activities which fall in part or in their entirety within the scope of the law of the European Communities"* (*see* III.A.1.) above), and to recipients located in non-EU and non-EEA countries (so-called Third Countries), *prima facie* irrespective of the nature of the data to be transferred. In doing so, it establishes even stricter requirements for such data transfers compared to the requirements applicable in a EU- or EEA-internal context

---

[68] ECJ, judgment May 30, 2006 (*PNR*) – C-317/04 – m.n. 57 and 60; *see also* Valentin M. Pfisterer, *PNR in 2011: Recalling Ten Years of Transatlantic Cooperation in PNR Information Management,* THE UNIVERSITY OF MIAMI NATIONAL SECURITY & ARMED CONFLICT LAW REVIEW, 114, 123 (2012).

[69] This notwithstanding, representatives of the German data protection authorities have indicated that they would look at the business activity of the company only which, as mentioned above, should usually fall within the scope of the law of the (former) European Communities and, therefore, within the scope of the DPD and Section 4b FDPA.

[70] Section 4b(2) FDPA.

[71] Section 4b(1) FDPA.

(such transfer falling within the area of the first pillar of the EU).[72] Pursuant to this provision, data transfers to recipients located in Third Countries are generally also subject to the requirements applicable in a EU- or EEA-internal context. In addition, however, Section 4b(2) FDPA states that such *"transfer shall not be effected in so far as the data subject has a legitimate interest in excluding transfer, in particular if an adequate level of data protection is not guaranteed"*.

1. Prerequisite Requirements: Precedence Rule and Limited Scope of Applicability

By reference to Section 4b(1) FDPA, data transfers to Third Countries are subject to the precedence rule and the limited scope of applicability as is the case for EU- or EEA-internal data transfers. Similar to what was discussed above, this requirement raises two potential pitfalls to companies willing to comply with an informal request from a Third Country authority (*see* A.1.) above).

Precedence rule. The transfer of personal data to recipients located in Third Countries has to be effected "*in accordance with the laws and agreements applicable to such transfer"* such laws and agreements, if applicable, taking precedence over data transfers based on the FDPA.[73] If, in a given case, such a treaty is applicable, the FDPA no longer serves as a suitable legal base for a transfer of personal data.

Limited scope of applicability. Further, by reference to the requirements applicable in a EU- or EEA-internal context, cross-border data transfers to recipients located in Third Countries are only admissible with regard to "*activities which fall in part or in their entirety within the scope of the law of the European Communities"*.[74] As a consequence, any data transfer to occur in the area of foreign and security policy or police and judicial cooperation in criminal matters, as opposed to the area of economic and trade cooperation, is out of scope and may not be based on Section 4b(2) FDPA.[75] Data transfers in these areas typically occur based on treaties on legal and administrative assistance ("MLATs").[76] Examples are the U.S.-Germany MLAT from 2003[77] or the so-called

---

[72] Detlev Gabel, *in* BDSG, Section 4b m.n. 14-17 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 4b m.n. 38-40 (Spiros Simitis, 8th ed. 2014). The requirements and conditions for transfers of personal data to Third Countries are extensively regulated in Article 44 *et seq* GDPR.

[73] Section 4b(1) FDPA. *See* LUTZ BERGMANN, ROLAND MÖHRLE &ARMIN HERB, BDSG, Section 4b m.n. 24 (loose-leaf booklet ed. 2014); Spiros Simitis, *in* BDSG, Section 4b m.n. 40 (Spiros Simitis, 8th ed. 2014); Detlev Gabel, *in* BDSG, Section 4b m.n. 12 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

[74] Section 4b(2) read in connection with Section 4b(1) FDPA.

[75] Detlev Gabel, *in* BDSG, Section 4b m.n. 11 and 14 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 4b m.n. 33 (Spiros Simitis, 8th ed. 2014).

[76] LUTZ BERGMANN, ROLAND MÖHRLE & ARMIN HERB, BDSG, Section 4b m.n. 24; Detlev Gabel, *in* BDSG, Section 4b m.n. 12 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013).

[77] *See* Treaties and other international Acts Series 09-1018, Mutual Legal Assistance Treaty between the United States of America and Germany, October 14, 2003 (www.state.gov/documents/organization/188782.pdf).

U.S.-EU Umbrella Agreement from 2015[78] which both, notably enough, allow for the exchange of personal data between law enforcement authorities as opposed to between private sector companies based in one country and a public authority of another country.[79] As to the qualification of a given activity as falling within or outside the scope of Community law, it is unclear which activity should be taken into account in this context – the business activities of the company or the investigative activities of the regulatory or law enforcement authorities to which the company is supposed to contribute by transferring the data. There are, however, good arguments that at least the transfer of personal data by companies for investigative purposes of law enforcement authorities located in Third Countries should be perceived as falling outside the scope of the law of the European Communities and, thus, cannot be justified under Section 4b(2) FDPA (*see* A.1.) above). This is consistent with a statement made by EU Commissioner of Justice, *Vera Jourova: "The Commission's view is that personal data held by private companies in the EU should not, in principle, be directly accessed by or transferred to foreign enforcement authorities outside of formal channels of cooperation, such as for example the Mutual Legal Assistance treaties (MLATs)."*[80]

2. Adequate Level of Data Protection

In addition, cross-border transfers to recipients located in Third Countries are generally inadmissible to the extent that the "*data subject has a legitimate interest"* in keeping his data confidential which is deemed to be the case if the Third Country does not afford an "*adequate level of data protection"*.[81] Such adequacy is assessed in light of all attendant circumstances. Particular consideration is given to the nature of the data, the purpose, the duration of the proposed data processing operation, the country of origin, the recipient country and the legal norms, professional rules and security measures which apply to the recipient.[82] By virtue of the DPD, the European Commission is authorized to find that a certain Third Country ensures an adequate level of protection within the meaning

---

78 Agreement between the United States of America and the European Union on the Protection of Personal Information relating to the Prevention, Investigation, Detection, and Prosecution of Criminal Offenses. Also *see* the corresponding Fact Sheet, MEMO/15/5612 (europa.eu/rapid/press-release_MEMO-15-5612_de.htm).

79 The requirements set forth in the FDPA may correspond to those established in Article 47 GDPR. Any judgment of a court or tribunal and any decision of an administrative authority of a Third Country requiring a controller or processor to transfer or disclose personal data may only be recognized or enforceable in any manner if based on an international agreement, such as a mutual legal assistance treaty in force between the requesting Third Country and the Union or a Member State, without prejudice to other grounds for transfer pursuant to Article 44 *et seq.* GDPR.

80 Parliamentary Questions, Answer given by Ms. Jourova on behalf of the European Commission, March 4, 2015 (www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2014-010602&language=EN).

81 Section 4b(2) Sent. 2 FDPA. As to the adequacy criterion, *see* Paul M. Schwartz, *The EU-U.S. Privacy Collision: A Turn to Institutions and Procedures,* HARVARD LAW REVIEW, 1966, 1979-1992 (2013); Nikhil S. Palekar, *Privacy Protection: When is "Adequate" actually Adequate?*, DUKE JOURNAL OF COMPARATIVE & INTERNATIONAL LAW, 549 *et seq.* (2007/08).

82 Section 4b(3) FDPA. For transfers based on an adequacy decision by the Commission (and the criteria which taken into account), *see* Article 45 GDPR.

of the DPD.[83] Based thereon, the European Commission has taken a number of adequacy decisions[84] including with respect to the U.S., although not generally but rather limited to certain contexts such as the transfer of PNR data (in connection with the current PNR Agreement)[85] or of account data (in connection with the SWIFT Agreement).[86] Only recently, however, in its *Safe Harbor* decision, the ECJ struck down an adequacy decision by the European Commission in relation to the U.S. highlighting the uncontrolled mass surveillance of personal data by U.S. government agencies.[87] In its decision, the ECJ further emphazised that national data protection authorities may independently examine whether or not the level of data protection afforded in the recipient's home jurisdiction is adequate—even where the European Commission has adopted an adequacy decision in respect of the relevant country.[88] Also, in addition to the level of data protection, other aspects may qualify as a legitimate interest and consequently exclude a cross-border data transfer. It may therefore be relevant whether or not the requesting Third Country authority, under the rules and regulations applicable to it, is legally entitled to collect the relevant data, whether or not the information request is otherwise lawful or unlawful, or, again, whether or not the requesting Third Country authority has formal means at its disposal to request and obtain the relevant data.[89] In addition, it might also be relevant whether the concerned individual is a suspect, a potential witness or a person not involved in the wrongdoing being investigated (*see* II.B.4.) above).[90]

In cases where no adequate level of protection is provided for, or where the data subject has another legitimate interest in keeping his data undisclosed, Section 4b(2) FDPA cannot serve as a legal basis for a data transfer to a regulatory or law enforcement authority, subject to a number of explicitly specified exemptions discussed below (*see* 4. be-

---

83 Article 25(6) DPD.

84 *See* ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm.

85 *See* Article 19 of the Agreement between the United States of America and the European Union on the use and transfer of passenger name records to the United States Department of Homeland Security, O.J. 2012, L215/5. For additional detail on the 2012 PNR Agreement, *see* Valentin M. Pfisterer, *PNR in 2011: Recalling Ten Years of Transatlantic Cooperation in PNR Information Management,* THE UNIVERSITY OF MIAMI NATIONAL SECURITY & ARMED CONFLICT LAW REVIEW, 114, 131 (2012).

86 *See* Article 6 of the (Second) Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for purposes of the Terrorist Finance Tracking Program, O.J. 2010, L8/11. For additional detail on the (Second) SWIFT Agreement, *see* Valentin M. Pfisterer, *The Second SWIFT Agreement Between the European Union and the United States of America – An Overview*, GERMAN LAW JOURNAL, 1173, 1182-1187 (2010).

87 ECJ, Judgment of October 6, 2015 (*Schrems*) – C-362/14 – m.n. 105; as to this decision and its consequences for transatlantic data transfers, *see* Christian Galetzka & Kevin Rodler, *Goodbye Safe Harbor USA? – Datentransfer in die USA nach der Safe Harbor-Entscheidung des EuGH,* COMPLIANCE BERATER, 470 *et seq.* (2015).

88 ECJ, Judgment of October 6, 2015 (*Schrems*) – C-362/14 – m.n. 66.

89 Representatives of the German data protection authorities have indicated that they consider the existence of a mutual legal assistance treaty, and therefore an "official" channel for the requesting authority to request and obtain the relevant data, as a relevant factor in this context.

90 In particular in the case of an uninvolved person, her interest in not getting involved in the "mills" of the judicial system of a Third Country might qualify as a relevant criterion.

low).

3. Statutory Authorizations as Applicable in a Domestic Context

In addition to meeting the prerequisite requirements and the recipient affording an adequate level of data protection (and the data subject not having another legitimate interest in keeping his data undisclosed) as outlined above, by reference to Section 4b(1) FDPA (and, ultimately, to Sections 28 *et seq.* FDPA),[91] data transfers to recipients located in Third Countries must fulfill the criteria applicable in a domestic context. Hence, the purpose for which the data is transferred must correspond to one or more of the purposes explicitly specified in these provisions (including criminal prosecution, averting threats to state or public security, and the protection of the legitimate interests of the company or a third party) and the additional requirements (necessity and balancing of interests) have to be met (*see* II.B. above).

4. Specific Statutory Exemptions for Data Transfers to Third Countries not Affording an Adequate Level of Data Protection

The FDPA stipulates a number of specific exemptions from the general prohibition of the cross-border transfer of personal data to a Third Country in cases where such Third Country does not afford an adequate level of data protection (Section 4c(1) FDPA).[92] These exemptions are fairly limited in scope.[93]

Limited scope of applicability. The exemptions for data transfers to Third Countries not affording an adequate level of data protection are only available *"in connection with activities which fall in part or in their entirety within the scope of the law of the European Communities"*.[94] As discussed above, it is unclear which activity should be taken into account in this context. There are, however, good arguments that at least the transfer of personal data by companies for investigative purposes of law enforcement authorities located in Third Countries should be perceived as falling outside the scope of the law of the European Communities and, thus, cannot be justified under Section 4c(1) FDPA (see II.B. above).

As to the specific exemptions, in addition to the data subject's consent,[95] the data transfer is, *inter alia*, permissible if the transfer is necessary on "*important public interest*

---

[91] Section 4b(1) FDPA.

[92] For the requirements and limits of a data transfer in the absence of an adequacy decision, *see* Article 49 GDPR.

[93] Article 29 Working Party, Working Document on a mutual understanding of Article 26 (1) of the Directive 95/46/E, 24. Oktober 1995, WP 114, 25. November 2005, p. 9; *see* also Spiros Simitis, *in* BDSG, Section 4c m.n. 20 (Spiros Simitis, 8th ed. 2014).

[94] Section 4c(1) FDPA.

[95] For the requirements of an effective consent, *see* II.A. above.

grounds" or for the "*establishment, exercise or defense of legal claims in court"*.[96]

Important public interest grounds. The term "*important public interest grounds"* is not defined or otherwise rendered more precisely in the FDPA or the DPD. Based on the wording, the term is, on the one hand, broader than the term *"for averting threats to state or public security"* used in Section 28 FDPA as it does not necessarily require a threat of the mentioned sort. On the other hand, the term is narrower as not all public interest grounds are sufficient but only *"important"* ones. Investigations of merely administrative offences, as opposed to criminal offences, for example, may not be of sufficient importance to establish the necessary public interest. Further, pursuant to the Article 29 Working Party, a unilateral decision by the requesting authority does not *per se* qualify as relevant important public interest, and it is not to the requesting authority to decide independently whether or not its interest qualifies as an important public interest within this meaning.[97] The reasoning of the Article 29 Working Party is as follows: *"On this point the drafters of the Directive clearly did envisage that only important public interests identified as such by the national legislation applicable to data controllers established in the EU are valid in this connection. Any other interpretation would make it easy for a foreign authority to circumvent the requirement for adequate protection in the recipient country laid down in Directive 95/46. On the other hand, Recital 58 of Directive 95/46*[98] *refers, with regard to this provision, to cases in which international exchanges of data might be necessary "between tax or customs administrations in different countries" or "between services competent for social security matters". This specification, which appears to relate only to investigations of particular cases, explains the fact that this exception can only be used if the transfer is of interest to the authorities of an EU Member State themselves, and not only to one or more public authorities in the third country."*[99] Finally, and also in view of Recital 58 of the DPD, there is some dispute as to whether the important public interest-exemption is at all available to private companies and other private sector entities, given that the examples mentioned in the Recital – and the line of argument brought forward by the Article 29 Working Party – only refer to data transfers between public authorities as opposed to between private sector companies and public authorities.[100]

---

96 Section 4c(1) No. 4 FDPA (German-language version).

97 Article 29 Working Party, Working document on a common interpretation of Article 26 (1) of Directive 95/46/EC of 24 October 1995, WP 114, 25 November 2005, p. 14; Opinion 6/2002 on transmission of Passenger Manifest Information and other data from Airlines to the United States, WP 66, 24 October 2002, p. 6. In this context, the GDPR clarifies that the important reasons of public interest must be recognized in Union law or in the law of the Member State to which the controller is subject (Article 49(4) GDPR).

98 Recital No. 58 of the DPD mentions "cases of international transfers of data between tax or customs administrations or between services competent for social security matters" as potential cases for the important public interest-exemption to apply.

99 Article 29 Working Party, Working document on a common interpretation of Article 26 (1) of Directive 95/46/EC of 24 October 1995, WP 114, 25 November 2005, p. 15.

100 *See* on the one hand: Detlev Gabel, *in* BDSG, Section 4c m.n. 10 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); on the other hand: Wolfgang Däubler, *in* BDSG, Section 4c m.n. 8 (Wolfgang Däubler, Thomas Klebe, Peter Wedde & Thilo Weichert, 4th ed. 2014).

Establishment, exercise or defense of legal claims in court. The FDPA also allows for data transfers to Third Countries not affording an adequate level of data protection for purposes of the *"establishment, exercise or defense of legal claims in court"*.[101] While the exemption applies to and allows for data transfers in connection with all sorts of court proceedings, it is not applicable in administrative and other out-of-court proceedings. Therefore, based on its wording, the provision does not allow for data transfers in connection with investigations by regulatory and law enforcement authorities prior to, or entirely unrelated to, any such court proceedings.[102] Further, pursuant to the Article 29 Working Party, this exemption is only available *"if the rules governing criminal or civil proceedings applicable to this type of international situation have been complied with, notably as they derive from the provisions of the Hague Conventions of 18 March 1970 ("Taking of Evidence" Convention) and of 25 October 1980 ("Access to Justice" Convention)."*[103]

Additional requirements: necessity and balancing of interests. In both cases, data transfers on important public interest grounds and for the establishment, exercise or defense of legal claims in court, the data transfer must be "*necessary*" for the pursuit of the relevant objective.[104] In this respect, as discussed above, a data transfer is only permissible where the information request of the Third Country authority cannot be satisfied by less intrusive means including by formal channels of administrative or legal cooperation (*see* II.B.4. and III.A.1. and B.2. above).

Statutory authorizations as applicable in a domestic context. Finally, in addition to meeting the above-mentioned requirements, data transfers to recipients located in Third Countries not affording an adequate level of data protection must fulfill the criteria applicable in a domestic context.[105] Hence, the purpose for which the data is transferred must correspond to one or more of the purposes explicitly specified in these provisions (including criminal prosecution, averting threats to state or public security, and the protection of the legitimate interests of the company or a third party) and the additional requirements (necessity and balancing of interests) have to be met (*see* II.B. above).

---

[101] Section 4c(1) No. 4 FDPA (German-language version).

[102] Interestingly enough, the authorized English-language versions of both the DPD and the FDPA do not contain the addition "in court". This inconsistency has caused and continues to cause significant uncertainty with respect to the applicability of the relevant provision to administrative or similar out-of-court proceedings.

The addendum "in court" does not appear in Article 49 (1) e) GDPR. Under the GDPR, this exemption may consequently allow for German companies and individuals to transfer personal data for the purpose of the establishment of legal claims or legal defenses, including in administrative and other out-of-court proceedings.

[103] Article 29 Working Party, Working document on a common interpretation of Article 26 (1) of Directive 95/46/EC of 24 October 1995, WP 114, 25 November 2005, p. 15.

[104] Section 4c(1) No. 4 FDPA.

[105] Detlev Gabel, *in* BDSG, Section 4c m.n. 4 (Jürgen Taeger & Detlev Gabel, 2nd ed. 2013); Spiros Simitis, *in* BDSG, Section 4c m.n. 6 (Spiros Simitis, 8th ed. 2014).

5. Specific Permit by Competent Data Protection Authority

Lastly, the FDPA allows for the cross-border transfer of personal data to Third Countries, irrespective of whether or not affording an adequate level of data protection, based on a specific permit by the competent German data protection authority.[106] Accordingly, the competent German data protection authority may authorize individual transfers or certain categories of transfers of personal data to bodies located in Third Countries if the controller guarantees adequate safeguards with respect to the protection of privacy and the exercise of the corresponding rights.[107] This approach obviously requires that the company asks for and is granted adequate safeguards from the requesting Third Country authority, informs the competent German data protection authority of the envisaged data transfer in order to obtain the necessary permit, and is granted the requested permit. This option may oftentimes not be available for the corporate entity concerned, given that a public authority is generally unlikely to contractually assure a certain treatment of the relevant data, in particular in an investigation context.

IV. SUMMARY AND OUTLOOK

Corporate entities based in Germany which face an informal request from a German or foreign regulatory or law enforcement authority for the transfer of personal data will typically be inclined to comply with such an informal request, given the variety of potential adverse consequences of non-cooperation including fines, sanctions, loss of cooperation credit, and negative media coverage. In certain cases, however, compliance of the corporate entity with such an informal request may itself entail a compliance risk, constitute a breach by the corporate entity of the laws applicable to it, and result in criminal prosecution, administrative sanctions, or damage claims and other actions by third party individuals. In this context and in relation to requested transfers of personal data, the data protection laws applicable in Germany, particularly the FDPA, are especially important to be taken into consideration.

The FDPA establishes a complex and strict regime for the transfer of personal data to recipients, including regulatory and law enforcement authorities, both in Germany and abroad. The requirements for data transfers to German regulatory and law enforcement authorities are already rather strict. This is even more true for data transfers to regulatory and law enforcement authorities located in EU or EEA Member States or even in

---

[106] Section 4c(2) FDPA.

[107] Section 4c(2) FDPA. For additional detail, *see* Philipp C. Räther & Nicolai Seitz, *Übermittlung personenbezogener Daten in Drittstaaten – Angemessenheitsklausel, Safe Harbor und die Einwilligung,* MULTIMEDIA UND RECHT, 425 *et seq.* (2002) and Philipp C. Räther & Nicolai Seitz, *Ausnahmen bei Datentransfer in Drittstaaten - Die beiden Ausnahmen nach § 4c Abs. 2 BDSG: Vertragslösung und Code of Conduct*, MULTIMEDIA UND RECHT, 520 *et seq.* (2002).

Third Countries. Particularly strict requirements apply to data transfers to recipients, including regulatory and law enforcement authorities, located in Third Countries which do not afford an adequate level of data protection, especially where the data are transferred for criminal prosecution and similar not strictly business-related purposes.

In the past, companies facing an informal request for the transfer of personal data by a public authority may have considered compliance with German data protection laws a minor priority, especially when approached by authorities from Third Countries. In view of what is stated in the *Yates* Memorandum[108], this may be particularly true in the context of DOJ or SEC investigations. Also, sanctions in Germany, if any, were usually considered soft in comparison to the fear of much more severe sanctions in Third Countries including the U.S. As of the entry into force of the GDPR in May 2018, however, this is likely to change. Based on the GDPR, once applicable, the competent national data protection authorities will be authorized to impose fines in the event of a violation of the GDPR in the amount of up to EUR 20 Million or 4% of the average worldwide annual sales of a company.[109]

[108] DOJ, Office of the Deputy Attorney general, *Yates* Memorandum, September 9, 2015 (www.justice.gov/dag/file/769036/download), p. 3.

[109] Article 83(6) GDPR.

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

PROCEEDINGS OF THE 5TH MUNICH COMPLIANCE TALK

Antonia Orterer & Theresa Albert

AUTHORS

Antonia Orterer is currently working as a scientific associate for Prof. Dr. Hendrik Schneider at the chair for Criminal Law, Criminal Procedure, Criminology, Juvenile Law and Sentencing at the University of Leipzig Faculty of Law, where she is also writing her doctoral thesis. Ms. Orterer passed the first state examination at the University of Munich in 2016.

Theresa Albert studies law at the Johann-Wolfgang Goethe University in Frankfurt/Main. She works as Office & Research assistant for Prof. Dr. Hendrik Schneider. (www.hendrikschneider.eu)

The Munich Compliance Talk entitled "Legal Privilege – What is its use actually about?" took place on April 26th, 2016 at the Literaturhaus Munich. At this event, which has been organized together by the Deutschen AnwaltSpiegel – Gruppe and Recommind, compliance professionals, namely lawyers, employees of in-house legal departments, compliance officers and compliance managers have been present. The conference program included impulsive lectures by the experts Dr. Burkhard Schmitt[1] (Vice President, Head of EMEIA Compliance at Fujitsu, Munich) and Patrick Späth[2], LL.M. (Counsel of WilmerHale in Berlin). Emphasis was – among other things - placed on the legal framework of legal privilege. Moreover the focus was on the company´s point of view, thus the question, how to deal with legal privilege in the company.

The opening was made by the compliance officer of Fujitsu, Dr. Burkhard Schmitt. He spoke about the interests concerned by legal privilege and the aims pursued by means of legal privilege. Furthermore he orated about the legal framework of legal privilege. Thereby he started with two examples from current case law, which deal with the problem of legal seizure of investigation reports in a company, which itself has previously commissioned those reports by extern law firms. In doing so he raised the question whether the seizure has been lawful or not, but in the first instance this question remained unanswered. In order to put explanations regarding the accompanying clashing interests first, one should for instance be aware of the collision of the affected companies´ interests and those interests of the individual or of the state. Moreover the striving for substantive truth on the one hand and procedural guarantees on the other hand would be opposed. Besides internal investigations would pursue different aims than the state´s investigations.

As regards legal privilege, the legal problem would be focused on the guarantee of free communication between the suspect and his defense counsel (§ 148 StPO), as well as on the associated right to refuse to give evidence and correlative confiscation bans (§ 97 StPO in conjunction with § 53 StPO). However, the confiscation of the suspect´s notifications being in the custody of a person who has got the right to refuse to give evidence, i.e. the defense counsel, an attorney or a notary, would be prohibited, but, so said Dr. Schmitt, this would according to the new legal framework not apply – subject to § 53a StPO – for the in-house counsel regarding those information, that was entrusted to him in that capacity. Whereas his work products would, according to the jurisdiction of the *LG Mannheim* be protected by § 148 StPO. Moreover § 148 StPO would as well apply in relations between the company und its attorney. To round off his speech the referee then answered the questions that he asked at the beginning. The investigation report would be covered by § 148 StPO – that is what the *LG Braunschweig* ruled – as far as it has been created for needs of defense.

---

1 Vice President, Head of EMEIA Compliance at Fujitsu: burkhard.schmitt@ts.fujitsu.com.

2 Counsel at Wilmer Hale: patrick.spaeth@wilmerhale.com

The attorney Patrick Späth then took up the company´s point of view. At the beginning of his speech he laid down that companies regularly deal with the question, whether they really "want" legal privilege. In doing so he made reference to the motto of the event "Legal Privilege – What is its use actually about?". As cooperation with the prosecution authorities would be considered positively, the companies should think carefully about their conduct towards the prosecution authorities, even if legal privilege is the companies´ undeniable right. If one pursued legal privilege, the clarification of the intern communication issues in the company would be decisive. It would fundamentally be recommendable to limit the communication to few employees only as well as to limit the written communication if possible. Moreover it might be necessary to acquire specific legal expertise in cases of doubt and there should always be an extern attorney present when it comes to employee interviews.

The subsequent closing discussion broached the issue of whether companies had the obligation to decrypt data that has been encrypted by the company for safety reasons, if required by prosecution authorities. Agreement was reached that there would not be such an obligation in case of an existing confiscation ban, while, conversely, i.e. there is no confiscation ban, decoding would have to be performed. Besides referring to this the difference between duties to tolerate and active obligations to cooperate were discussed. Furthermore the question, whether within the scope of employee interviews, which should only be hold in the presence of an attorney, an intern attorney would be hold sufficient or an extern attorney would be considered to be preferable, came up. The speakers deemed with respect to the still contradicting jurisdiction on such cases hiring an extern attorney as preferable as this would guarantee greater and safer protection.

CEJ
COMPLIANCE
ELLIANCE
JOURNAL

THE LAWWITHOUTWALLS JOURNEY THROUGH COMPLIANCE

Sara M. Klock

AUTHOR

Sara M. Klock is a final year law student at the University of Miami School of Law. She participated in LawWithoutWalls in the Spring of 2016 and her Project of Worth is the backdrop for this piece. Sara currently serves as the Senior Writing Editor and Articles and Comments Editor for the University of Miami Law Review.

TABLE OF CONTENTS

I. INTRODUCTION

Supply chain management—the design, planning, coordination, and monitoring of, supplies, goods, services, and information as they move through the chain from supplier to manufacturer to wholesaler to retailer to consumer—is extremely important yet exceedingly difficult for large global corporations. One of the many intricate and complex challenges of it is ensuring that a supply chain possesses adequate ethics and compliance programs at every tier of the chain. This piece describes the journey of a student on a LawWithoutWalls ("LWOW") team that was charged with helping a large multinational defense firm, Lockheed Martin, solve this problem. This piece is not designed to teach the reader about supply chain management; instead, it will exemplify through a real-life experience how tough it is to teach people who are not compliance experts about the field's complexities and, further, explore the difficulty in developing creative, practicable solutions to compliance problems.

II. BACKDROP

My journey into the world of compliance began with an unconventional approach: instead of a lecture, textbook, or class, I took part in LWOW, a cross-disciplinary, cross-cultural part-virtual experiential learning program designed to change the way lawyers and business professionals collaborate to solve problems. LWOW is offered to lawyers at firms and to law and business school students at more than 30 schools around the world (including the University of Miami, where I am in my final year of JD study). LWOW places 3 students from different schools on a team with two lawyer leaders and 3 mentors (an academic, an entrepreneur, and a business professional). Each multidisciplinary, multicultural team is provided a topic and challenged to explore and source a discreet problem from that topic, and, finally, create a solution to that problem. These topics are issues facing the legal market today. My team's topic focused on compliance. Specifically, our topic was: "Catch 22?: Assessing the Ethics Programs of M&A Targets, Partners, and Suppliers Without Reference to a Specific Country's Laws or Regulations." Lockheed Martin sponsored this topic and provided us with exceptional guidance through one of their employees, who served as our business mentor. LawWithoutWalls' novel approach—combining innovation, teaming, mentorship, and expertise from a multinational facing this compliance hurtle—provided our team with great perspective and drive to discover a solution.

I thought that discovering a solution would be easy. Looking back, I couldn't have been more wrong. Even with a team full of critical thinkers, experienced businesspeople, and compliance experts—all committed to innovating a solution—every step was harder than I imagined. Navigating the world of compliance, understanding the complexities within, and identifying a narrow problem to solve all proved difficult. The biggest difficulty was creating an implementable solution. This difficulty, however, proved to be the

biggest benefit of the entire journey. Through LWOW, I learned that not finding a solution does not equate to failure; rather, through our research, interviews, and countless rounds of going back to the drawing board, we—the students, lawyer leaders, and mentors alike—honed skills critical to twenty-first century professional success: communication, project management, cultural competency, teamwork, leadership, and business acumen. We also gained an understanding of and appreciation for the complexities of supply chain compliance.

III. MY JOURNEY AND PROJECT

A. Meeting My Team and Exploring our Topic

In January 2016, I met my team at IE University in Madrid, Spain at the LWOW KickOff, a two-day event designed to teach innovation, teaming, presentation, and collaboration skills and lay the foundation for the virtual teamwork that would follow. There were three students on my team: an American from MiamiLaw; an Italian at Bucerius Law School in Hamburg, Germany, a French business and law student at École HEAD in Paris; and myself, a law student from the University of Miami. We had the privilege of being led and mentored by five amazing professionals, including: Lauren Schultz, an Ethics Analyst at Lockheed Martin; Mark Snyderman, the Chief Ethics & Compliance Officer and Assistant General Counsel at Laureate Education; Anna Donovan, UCL Law Professor and LWOW alum; Camilla Eliott-Lockhard, a senior associate at Eversheds; Nataia Clements, Legal Counsel at Citibank; and Vasco Bilbao-Bastida, another LWOW alum and Group Director and Digital Strategist at VaynerMedia. Both as a group and individually (given their varying expertise, experience, and interests), our mentors guided our progress, pushed us for answers, encouraged us to think critically, and offered constructive feedback as we devised our solution prototype and financial model.

Quickly, our team realized that, in spite of how cross-disciplinary and cross-cultural we were, the conversation on compliance would be a challenge for all. The differences between laws, policies, and what was considered "the norm" across countries quickly became evident. For example, in the United States, if an employer has an employee tip hotline to report a harassment incident, that report requires anonymous reporting by law. In other words, confidentiality is of the utmost importance, and is required by law. This is not the case in Europe, especially in the United Kingdom, where the thought of anonymous reporting is unheard of. It was within the first few moments and introductory conversations that I began to understand the scope and depth of the challenge ahead.

Our team spent the remainder of the KickOff weekend laying the foundation for the three and a half months to come. Together, we learned from thought leaders engaged in exercises to develop our teaming skills, created and presented an idea in a mini-hackathon, learned how to market ourselves, explored cultural competencies, networked, and more. Once we left Madrid (and returned to Miami, Paris, Hamburg,

London, etc.), the real work began: unpacking the topic, identifying a narrow problem within it, and developing an implementable solution to that problem –virtually.

B. Narrowing the Focus

It quickly became apparent that our project was no small feat, and we needed to narrow our topic down as much as possible. Lockheed Martin had provided us with a very comprehensive understanding of both its philosophy and corporate structure. Lockheed Martin, like many multinationals, is always looking to expand their suppliers, business partners, and targets outside of the United States, as well as develop effective, efficient compliance solutions to accompany a growing supply chain.

With Lockheed Martin's support, we felt it most efficient to focus on the defense industry. We wanted to create something practical that Lockheed Martin (and its competitors) could use. However, after about six weeks of focusing on the defense industry, and a long team meeting, we came to the conclusion that targeting the defense industry was not the best option for us. The defense industry is unique as there are only a few big players; e.g., Boeing Further, concerns over confidentiality proved significant obstacles in investigating the defense industry's supply chain. The starting over was difficult. But, as we learned through the LWOW experience, starting over is a normal part of the innovation and design thinking process. The pathway to innovation, much like the pathway to ensuring compliance within a large, global corporation, is messy, complex, and difficult—a lesson we learned the messy, complex, and difficult way.

When starting over, we returned our focus to the overarching topic: supply chain management as it relates to legal and ethical compliance along the chain from the point of origin to eventual consumer. Our research indicated that (regardless of industry) many compliance measures related to suppliers at the point of origin were in place because of the supplier, manufacturer, or seller's fear of financial loss—that is, these measures are generally reactive, rather than proactive. With that knowledge in mind, we then turned to the parties of the supply chain, and found that due to the global nature of supply chains across several industries, laws and regulations across the globe most commonly and heavily impacted suppliers.

In investigating supply chains, we came across several discoveries. First, chains are often complex and multi-tiered. The end seller is often unaware of who their middle- and bottom-tier suppliers are. These middle- and bottom-tier suppliers are often small- and medium-sized suppliers, such as "mom and pop shops," or suppliers located in a single warehouse, employing 20 people, and making only one specific part. Because these suppliers are not likely known by the entity at the top of the chain, they have little to no relationship with each other, and generally do not have a mandated or standard compliance program that dictates appropriate standards. This is because the relationship between the middle and bottom tier suppliers and the ultimate end-buyer at the other end of the supply chain is attenuated and there are many barriers to developing a compliance program in these small enterprises that may not have an internal need for such a program let alone the internal resources to design, implement, monitor, and enforce it.

The complexity goes beyond supply chain structure. In addition to not having compliance programs in place, suppliers were not held to a common standard across jurisdictions. In an attempt to find some commonality, we compared six international standards, including the Defense Industry Initiative, United Nations Global Compact, Organization for Economics Co-operation and Development, International Code Council: Rules on Combating Corruption, United Kingdom Bribery Act, and the United States Sentencing Guidelines. Our analysis showed that no true global standard—let alone a general list of commonalities across standards—exists. In our discussions with Lockheed Martin, large defense players and contractors are eager to develop a uniform standard that flows across borders, governing treaties, and enterprises of all sizes.

C. Project Development

Although this discovery was daunting, it was our opportunity for innovation. As is part of our charge in LawWithoutWalls and important for any innovation journey, we found a gap – a real need –to be filled. From this moment on, we focused on this gap—the lack of a global standard—and decided to try our hand at designing how a global standard might look, and, further, how small- and medium-sized suppliers could adopt, implement, and enforce these standards when no current ethics and compliance program exists.

1. Research Methodology and Results

We began by attempting to define a global standard. As a foundation, we compared the six global standards noted above. Our comparison showed that, while no global standard existed, six common elements were present among them:

i. Reporting Mechanism, i.e., some tool in place to allow employees to inform management or their boss(es) of any issue they come across.
ii. Communication Plan & Awareness Training, which allows everyone within the company to know what the company's policy is and training on that policy.
iii. Program Assessment & Evaluation, which ensures that the company's policy is current and up-to-date.
iv. Essential Risk Covered, which includes proprietary information and a plan in place if such information is leaked.
v. Leadership Commitment & Core Company Values, which allows company's to focus on the collective where everyone is aware of the company's positions.
vi. Ethics Driven Code of Conduct, which demonstrates that the company is committed to combating corruption, bribery, and fraud.

2. Research Gaps and What Went Wrong

While we identified these six common elements, we thereafter recognized that discrep-

ancies and differences in interpretation of each prevented a concrete conclusion. For example, Leadership Commitment & Core Company Values to one company in one jurisdiction may simply be a statement on a website stating "X Company is Committed to a Compliant Supply Chain," while in another jurisdiction, this statement may not be sufficient enough, and said jurisdiction may require a statement and explanation to appear in a company's Code of Conduct.

Another limitation was manpower. Although research shows that teams that are too large can be ineffective, in this situation, a larger cohort might have been beneficial. If a bigger team were to tackle this research in great—even painstaking—detail, more commonalities and conclusions could be drawn. We were limited from being able to do this but believe that with the right research plan, support, flexibility, and communication, this could be done in the future. And given the need for it, the entire team hopes that it will come to fruition. That said, given the ever-evolving nature of laws, policies, and company goals, this may be difficult. An international standard would need to be readily adaptable to change. Additionally, changes in each country's laws and regulations would need to be constantly monitored. A final challenge lies in measuring the veracity of the information on record: is it accurate, complete, up to date, and truthful? Hopefully, with the help of technology, many of these challenges can be overcome.

IV. WHAT I'VE LEARNED

It is impossible for a newcomer to develop expertise in compliance, let alone a fo-cused area like supply chain management or industry specialization, in four months' time. I did, however, gain an understanding of the complexities and func-tionality of supply chain management, as well as the concurrent interplay of ethics and compliance. I learned about the influence of factors like financials, product quality, and supplier location. Further, I gained great insight into the disconnect between the lack of a global standard and global corporations' expressed desire for one. In our journey, the team began to question: Was this a true desire, or was it merely a well-intended wish? I am still not completely sure but complicating the answer is the reality that: 1) large corporations often value trade secrets and are reluctant to share their information with others; 2) large corporations, for various reasons, do not want to be held to a standard not of their own design or under their own control.

V. CONCLUSION: THE VALUE OF TEAMING TOWARDS PROBLEM SOLVING

When I embarked on my journey into compliance and the LWOW process, I was armed with a blank slate and an eager desire to solve a problem. Yet, in four months, I successfully embraced a steep, rich, and nuanced learning curve. One of the biggest takeaways I've learned is that there is a conflict between the "should" of having a global standard, and the "could" and/or "would" of development and adoption. But the most important takeaway was the value of trying—of working to co-create a solution to one of laws' problems in a multi-disciplinary, multi-cultural team. Although we didn't find the

ultimate solution to the gap we identified, we still created what LWOW so righty coins "a project of *worth*." The LWOW journey was a training experience that most law school students and lawyers never have the opportunity to take part in and it was so worth the effort because, in the end, all of us built skills that will make us better problem solvers and team players in the future.