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INFORMATION TECHNOLOGY MEETS HEALTHCARE: THE PRESENT AND FUTURE OF GERMAN AND EUROPEAN E-HEALTH INITIATIVES

Klaus M. Brisch, LL.M. and Claudia E. Haupt***

INTRODUCTION

A recent Boston Globe Op-Ed aptly summed up the basic concept of e-health, stating that “these technologies let computers do what they do best -- collect and disseminate data -- while letting doctors do the doctoring.”¹ As in the United States, the future of healthcare is a highly important current issue both in Germany and throughout the entire European Union (EU). Information technology is seen as a tool to bring about the improvement of processes and a reduction of costs. Consequently, the EU and Germany are advancing a host of e-health initiatives. On the EU level, the Commission has set its e-health agenda in an action plan it plans to implement by 2010. The initiatives envision better access to care and, simultaneously, a higher quality and lower costs of care. In a largely un-harmonized market due to the principle of subsidiarity,² these initiatives are bound to conflict with national legislation. Nevertheless, the Commission stresses that even though Member States are primarily responsible for healthcare, they have to comply with community law.³

In Germany, structural changes envisioned to strengthen healthcare modernization and, along with it, e-health initiatives found their way into national legislation, most notably the Public Health Insurance Modernization Act (*Gesetz zur Modernisierung der gesetzlichen Krankenversicherung*) of 2003.⁴ In a highly regulated market, however, new initiatives are bound to meet old barriers. The future success of e-health initiatives hinges on several parameters. This article will specifically focus on two spotlight issues, data protection

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¹ Joseph B. Martin, Op-Ed., *Digital Doctoring*, BOSTON GLOBE, March 29, 2007.

² Treaty Establishing the European Community, art. 5, Feb. 7, 1992, O.J. C 325/42. [hereinafter EC Treaty].

³ European Commission, Information Society and Media, *eHealth Topic of the Month: Legal Challenges in eHealth*, June 2007, at 1, available online at http://ec.europa.eu/information_society/newsroom/cf/document.cfm?action=display&doc_id=350 (last visited Oct. 30, 2008) [hereinafter Legal Challenges].

⁴ BUNDESGESETZBLATT TEIL I, NR. 55, S. 2190 (2003).

and issues concerning electronic signatures. As will be shown, both are crucial to the success of many e-health components.

The German struggles with the online pharmacy DocMorris illustrate the interrelationship between national and supranational law in the area of healthcare in an exemplary fashion. The questions raised in connection with DocMorris range from interpretations of domestic law to the application of Community law. In the DocMorris decision of the European Court of Justice (ECJ), the court was faced with the question whether the prohibition of the sale of drugs over the internet conformed to the supranational regulations permitting the free movement of goods.

In the DocMorris case, the German legislature, in anticipation of the ruling of the ECJ, implemented far-reaching reforms to its national legislation. Similarly, EU regulations already apply in the areas of data protection and the electronic signature. Although the EU member states remain nominally in charge of their individual national health policies, they are already significantly influenced by Community law and, as can be seen from the Commission's action plan, the EU intends to further implement its Community e-health initiatives.

Part I of this article provides an overview of the European and German e-health initiatives. As will be shown, the introduction of information technology in the form of the electronic insurance card and the electronic medical record as well as the introduction of information technology-based managed care models are key elements of a current trial phase. Parts II and III will spotlight the key issues in the area of data protection and the use of the electronic signature, especially in connection with the electronic health card. Part IV then turns to the legal problems raised in connection with online pharmacies, which culminated in the DocMorris decision of the European Court of Justice (ECJ).

I. SUPRANATIONAL AND NATIONAL E-HEALTH INITIATIVES

E-health initiatives are currently ongoing both on the EU and the German national level. Both are aimed at improving the efficiency of healthcare while at the same time reducing its costs. The European Union celebrated its 50th birthday in 2007, having been originally

founded in the Rome Treaty in 1957.⁵ Yet, a supranational public health policy is a relatively new phenomenon. It was first introduced into the Maastricht Treaty in 1992 - which contained a provision encouraging the cooperation of Member States and offering support of the Community - and became a stronger presence in the 1997 Amsterdam Treaty.⁶ Article 152(1) of the EC-Treaty contains the mandate to ensure a high level of human health protection in the definition and implementation of all Union policies and activities, with the Community complementing national policies directed at “public health, preventing human illness and diseases, and obviating sources of danger to human health.”⁷ Further, pursuant to Article 152(2), the Union is called upon to encourage cooperation of and lend support to Member States in achieving the policy goals. It should be noted that Article 152(5) itself contains a subsidiarity clause, stating that it does not interfere with the responsibility of the Member States in the area of public health.

A. The European Commission’s “e-Health Action Plan”

As healthcare systems worldwide are faced with major challenges, the Union is engaged in an effort to address the challenges most pertinent in its Member States. The rising demand for health and social services in the EU is largely due to a changing demographic structure of the Union’s population. According to projections, “by 2051 close to 40% of the Union’s population will be over 65 years old.”⁸ At the same time, both patients and health professionals are increasingly mobile within the internal EU market. Moreover, expectations of citizens as to the quality of care are on the rise, and from the perspective of the state actors, a reduction regarding access inequalities is sought. Managing the vast amounts of health information is a challenge; while at the same time, it is intended that the health information be available securely, and quickly accessible when needed in order to be processed efficiently. Complex organizational changes

⁵ Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11.

⁶ Legal Challenges, *supra* note 3, at 1.

⁷ EC Treaty *supra* note 2, art. 152(1).

⁸ COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, *eHealth-making healthcare better for European e-Health Area*, at 5, Brussels, Apr. 30, 2004, COM(2004) 356 [hereinafter: e-Health Action Plan].

are needed in order to match and utilize the potential of the increasing pace of technological advances while ensuring availability of best possible healthcare under budgetary constraints.⁹ On the European level, the focus on e-health is part of a larger effort in the area of community public health. The Commission has proposed further support of the Member States in their individual efforts in reforming national healthcare systems.¹⁰

In 2007, the EU-Commissioner for Information Society and Media, Viviane Reding, stated that the e-health sector is growing faster than many other areas, including the pharmaceutical or drug sectors.¹¹ The European Commission anticipates that by 2010, e-Health spending may comprise up to 5% of the total health budget of the 25 Member States.¹² In 2000, with 15 Member States, the budget amounted to only 1%. European businesses, according to the Commission, have every opportunity to become leading global players in this new industry.¹³ One goal is to support the growing number of national online-services such as the French “Dossier Médical Personnel” or the Danish health portal “Medcom.”¹⁴ Commissioner Reding further emphasized the importance of data security and trust in the system; consequently, data protection remains a key aspect in the Commission’s initiatives. Transnational projects are also at the center of attention. The EU supports a transnational project called “TEN4Health” with health insurance providers and hospitals in Austria, Belgium, the Czech Republic and the Netherlands.¹⁵ EU funding for research in the area of e-health according to Commissioner Reding has been doubled.¹⁶

The European Commission has set an ambitious e-health agenda. The “eEurope 2005” action plan agreed to at the Sevilla European Council in 2002,¹⁷ contained a chapter on e-health.¹⁸

⁹ *Id.* at 4.

¹⁰ *Id.* at 6.

¹¹ “Datensicherheit schafft Vertrauen”, BÄK intern, Juli 2007, at 7, available online at http://www.bundesaerztekammer.de/downloads/BAeK_INTERN_Juli_2007-2.pdf (last visited Oct. 30, 2008) [hereinafter Reding Interview].

¹² e-Health Action Plan, *supra* note 8, at 10

¹³ *Id.*

¹⁴ Reding interview, *supra* note 11. See also e-Health Action Plan, *supra* note 8, at 10 - 12 (for a description of Medcom as well as the British “NHS Direct Online” service).

¹⁵ Reding Interview, *supra* note 11.

¹⁶ *Id.*

¹⁷ COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE ECONOMIC AND SOCIAL COMMITTEES AND THE COMMITTEE OF THE REGIONS, *eEurope 2005: An*

Proposed actions included electronic health cards, health information networks, and online health services.¹⁹ In April 2004, the European Commission adopted an “e-health action plan” entitled “e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area.”²⁰ In this action plan, the Commission outlines a comprehensive program including benchmarks until 2010. Defining e-health as “the application of information and communications technologies across the whole range of functions that affect the health sector,” the Commission states that e-health can improve both access to and quality and effectiveness of health care.²¹ As more than merely internet-based applications, the Commission envisions e-Health tools or solutions to include products, systems and services for both health authorities and professionals as well as personalized health systems for patients and citizens. Examples given by the Commission include “health information networks, electronic health records, telemedicine services, personal wearable and portable communicable systems, health portals, and many other information and communication technology-based tools assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management.”²² The Commission expects better care for less money in citizen-centered care as a result of combining e-health with organizational changes and new skills, thus responding to the challenges faced by the healthcare sector today. In fact, the health sector employs 9% of Europe’s workforce.²³

The Commission views e-Health as a tool for productivity gains and as “tomorrow’s instrument for restructured, citizen-centred health systems and, at the same time, respecting the diversity of Europe’s multi-cultural, multi-lingual health care traditions.”²⁴ Successful

information Society for All, An action plan to be presented in view of the Sevilla European Council at 1, Brussels, May 28, 2002, COM(2002)263 available at http://ec.europa.eu/information_society/eeurope/2002/news_library/documents/eeurope2005/eeurope2005_en.pdf . (last visited Oct. 30, 2008) [hereinafter eEurope 2005]; ULRIKE BECK, MEDICAL CALL CENTER UND MEDIZINISCHE BERATUNG IM INTERNET - HAFTUNGSFRAGEN, 137 (2005).

¹⁸ eEurope 2005, *supra* note 17, at 12.

¹⁹ *Id.* at 13.

²⁰ e-Health Action Plan, *supra* note 8. See also EUROPEAN COMMISSION, EUROPE’S INFORMATION SOCIETY, *The Right Prescription for Europe’s eHealth*, May 5, 2008, http://ec.europa.eu/information_society/activities/health/policy_action_plan/index_en.htm (last visited Oct. 30, 2008) (for an overview of the Commission’s activities).

²¹ e-Health Action Plan, *supra* note 8, at 4.

²² *Id.*

²³ *Id.*, at 8.

²⁴ *Id.*, at 4.

examples of e-Health initiatives cited by the Commission include “health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals.”²⁵ According to the Commission’s account, in 2004 at least four of five European doctors had an internet connection and a quarter of Europeans used the internet for health information.²⁶ The European Community has been supportive of e-health research since the early 1990s.²⁷ Since then, the financial support reached € 500 million, with a total budget about twice that amount.²⁸ Having put much of this research into practice has made Europe a leader in the use of electronic health records in primary care and in the use of electronic health card.²⁹ The Commission attributes the e-health industry, with a turnover of € 11 billion, the potential to become the third largest industry in the health sector, and by 2010, it estimates that the e-health industry may account for 5% of the total health budget although at present, it still mainly consists of small- and medium enterprises in need of a more favourable business environment.³⁰

The Member States, according to the Commission, have sought to combine the best practices and experience from throughout the EU, thus showing their dedication to moving along the e-Health agenda.³¹ The Commission’s plan of creating a “European e-Health Area” would build on a variety of common policies and initiatives and create concerted efforts providing an environment fostering the integration of related policies on the Community level.³² The Commission concludes that a European e-Health Area will provide a useful framework for exchanging best practices and experience, allowing for the development of common approaches. The action plan intends to ensure that by 2010, the EU “will be well placed to measure the impact of e-Health in terms of better access and better, more efficient, services as well as on the overall productivity of the healthcare sector.”³³ It is the Commission’s vision to make e-Health common for health professionals, patients and citizens and to ensure adequate funding.³⁴

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*, at 22.

³⁴ *Id.*, at 23.

In order to realize these objectives, the Commission created a timetable for the implementation of the goals set forth in the action plan.³⁵ The implementation is grouped under three headings: common challenges, pilot actions, and working together and monitoring practices.³⁶ The objectives of the first group include the development of a European Health Insurance Card³⁷ (which was introduced in 2004) as well as, for example, support of e-health services based on fixed and wireless broadband and mobile infrastructures (2004-2008)³⁸, providing a framework for greater certainty of products and services within the existing products liability legislation (until 2009)³⁹. The second group envisions, among others, the creation of a European Union health portal providing access to EU public health information (Health-EU, online at <http://ec.europa.eu/health-eu/>).⁴⁰ By the end of 2008 it expects member states to provide online services such as teleconsults, e-prescription, e-referrer, telemonitoring and telecare.⁴¹ The third group is concerned with facilitating the dissemination and exchange of information, at conferences and through publication of studies.⁴²

B. German e-Health Initiatives and the National Legal Framework

German public (statutory) health insurance law is a part of the German social security laws codified in the ten books of the Social Insurance Code (*Sozialgesetzbuch, SGB*). The fifth volume, SGB V, contains the regulations concerning public health insurance. Health insurance is the oldest of the three classic branches of social insurance - comprised of health insurance, accident insurance, and pension insurance - dating back to the law regarding health insurance of workers of June 15, 1883.⁴³ Although the German Constitution, the

³⁵ *Id.* at 24-26.

³⁶ *Id.* at 24-25.

³⁷ *Id.* See also COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION, *concerning the introduction of a European health insurance card*, Brussels, Feb. 17, 2003, COM (2003) 73.

³⁸ eHealth Action Plan, *supra* note 8, at 25.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*, at 26.

⁴³ Karl Peters, *Vorbemerkungen zum SGB V*, at No. 2 in KASSELER KOMMENTAR SOZIALVERSICHERUNGSRECHT, VOL. 1 (Klaus Niesel, ed., 53rd Update Edition, 2007). See also Rainer Hess, *Das Recht der privaten und gesetzlichen Krankenversicherung incl. Vertragsarztrecht*, 37, 40-47 in: HANDBUCH DES FACHANWALTS MEDIZINRECHT (Frank Wenzel, ed., 2007); Ursula Weide, *A Comparison of American and German*

Basic Law (*Grundgesetz*), does not contain any explicit provisions regarding public health insurance,⁴⁴ Article 20 (1) speaks of the social federal state, codifying the social state principle (*Sozialstaatsprinzip*).⁴⁵ Further, it should be noted that the founders of the Basic Law already knew a more than 60 year old, well-established health insurance system. The Basic Law thus is interpreted as guaranteeing the existence of such an insurance system.⁴⁶

Rather than being an entity of state health care, the statutory health insurance is truly an insurance, and it not only concerns illnesses already incurred but their prevention as well.⁴⁷ It is a compulsory public insurance, largely removed from freedom of contract. Consisting of several individual providers, it does not constitute a uniform insurance.⁴⁸ Unlike tax-based health systems, the German statutory health insurance limits the obligation to enter into the insurance to a statutorily defined income-based limit. When this limit is exceeded, there is no obligation to enter into statutory health insurance (section 6 (1) No. 1 SGB V) but instead a choice between statutory or private health insurance.⁴⁹ There are several significant differences to private health insurances, which only insure a fraction of the German population. The premiums of the private insurances for example are risk-related, and there is no general premium-free insurance of relatives.⁵⁰

The public (statutory) health insurance is the keystone of the German health care system, and it is also employed to perform central control tasks. It further is an important economic factor as numerous healthcare service providers such as hospitals and pharmacies as well as individual physicians and dentists are fundamentally dependent on the public health insurance or, as in the case of the pharmaceuticals

Cost Containment in Health Care: Tort Liability of U.S. Managed Care Organizations vs. German Health Care Reform Legislation, 13 TUL. EUR. & CIV. L.F. 47, 58-60 (1998) (for historical overviews of the German public health care system).

⁴⁴ Peters, *supra* note 43, at No. 16.

⁴⁵ See Translation: AXEL TSCHENTSCHER, THE BASIC LAW, available online at http://www.servat.unibe.ch/jurisprudentialit/the_basic_law.pdf (last visited Oct. 30, 2008) (Article 20 states "The Federal Republic of Germany is a democratic and social federal state.").

⁴⁶ Peters, *supra* note 43, at No. 16.

⁴⁷ *Id.* at No. 24. See also Weide, *supra* note 43, at 61 (for an overview of insurance benefits available under German statutory health insurance).

⁴⁸ Peters, *supra* note 43, at No. 24.

⁴⁹ Hess, *supra* note 43, at 48.

⁵⁰ Peters, *supra* note 43, at 25. See also Hess, *supra* note 43, at 47 (for a systematic comparison of statutory and private health insurance).

industry, have an important market in the state health insurance. Finally, the significance of public health insurance in the overall economy is illustrated by the fact that the general rates for public health insurance are a key factor in determining ancillary labor costs.⁵¹

1. Social Insurance Law and Healthcare Modernization

Currently, the German healthcare system is described as largely split into sectors, with little interaction between the individual parts, such as physicians in private practice, hospitals, and rehabilitation facilities.⁵² A special feature of the German health system is the strict separation between ambulant and hospital care. This division has been identified as burdening the quality of care as improvements are only made within the respective sectors, but the interfaces between the sectors are neglected and therefore, trans-sector processes are uncoordinated. This can result in long waiting periods, repeated examinations, lack of consistency in treatment, and communication problems.⁵³ The Associations of Statutory Health Insurance Providers (*Kassenärztliche Vereinigungen, KV*) are mandated to ensure medical care for members of the public (statutory) health insurance as stated in sections 72 (1), 75 (1) SGB V. To provide for medical care, the KVs use physicians licensed to provide statutory healthcare services (*Vertragsärzte*).⁵⁴ Every individual physician has a claim to access to this system, *i.e.*, to be licensed to provide statutory healthcare services, unless license restrictions are in place in areas in which the number of licensed physicians is deemed too high. Access to this market entitles each physician licensed in the statutory system to treat all insured individuals of the public health insurances.⁵⁵ The Associations of Statutory Health Insurance Providers and the public health insurance

⁵¹ Peters, *supra* note 43, at 26. *See also* Till-Christian Hiddemann & Stefan Muckel, *Das Gesetz zur Modernisierung der gesetzlichen Krankenversicherung*, 57 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 7 (2004)(stating that the employer contributions to social insurance are seen as a key obstacle to employment growth.)

⁵² Joachim Kartte, *Qualitätsoptimierung durch Vernetzung im Gesundheitswesen* 47, in *EHEALTH 2003* (Gesellschaft für Versicherungswissenschaft und -gestaltung e.V., eds., 2004).

⁵³ Matthias von Schwanenflügel, *Moderne Versorgungsformen im Gesundheitswesen -- Förderung der Qualität und Effizienz*, 15 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 285 (2006).

⁵⁴ Hiddemann & Muckel, *supra* note 51, at 7; Hess, *supra* note 43, at 73-74.

⁵⁵ Hiddemann & Muckel, *supra* note 51, at 7. *See also* Hess, *supra* note 43, at 109-116 (for details of the licensing process).

providers close contracts governing the specifics of public health care, thus engaging in a type of de facto rule-making. All physicians licensed to provide statutory healthcare services are obliged to enter into these contracts negotiated and closed by the KV and the insurance providers.⁵⁶ This type of collective contract system has been subject to criticism. First, the legitimacy of de facto rule-making by collectively entering into contracts has been questioned as a general matter. Second, the lack of competition and the inability to close individual contracts has been criticized.⁵⁷ Several new concepts are envisioned to cut costs and improve the efficiency of health care at the same time. A primary goal is overcoming the scattering of individual actors and replacing it with a network of health care providers.⁵⁸ In the area of healthcare modernization, as will be shown, the federal government and the legislature envisioned the introduction of information technology to be a central building block of a new healthcare infrastructure. Before addressing the role of information technology, however, this section will first provide an overview of the envisioned new concepts.

There is a growing demand, especially of public health insurance providers, to develop and implement some type of managed care systems. The health care costs in Germany are among the highest in Europe and they are continuously on the rise.⁵⁹ In fact, it has been asserted that the very concept of the social state has entered a critical phase and the currently high level of social welfare benefits cannot be financed in the long term.⁶⁰ Managed care models frequently referred to as having been successfully implemented are, for example, approaches taken in the United States and in Switzerland.⁶¹ In the wake of healthcare modernization, healthcare service providers were given new opportunities for trans-sector cooperation and interdisciplinary services. The goal was to increase competition among the service providers. The formerly more or less strict boundary between ambulant and hospital

⁵⁶ Hiddemann & Muckel, *supra* note 51, at 7. *See also* Hess, *supra* note 43, at 75-84 (for details on the contractual relationship).

⁵⁷ Hiddemann & Muckel, *supra* note 51, at 7.

⁵⁸ Kartte, *supra* note 52, at 48.

⁵⁹ Peter Bach & Stephan Hütt, *Rechtsfragen des Gesundheitsmanagements*, No. 85 in PRIVATE KRANKENVERSICHERUNG (PETER BACH AND HANS MOSER, EDS, 3rd Ed. 2002).

⁶⁰ Hiddemann & Muckel, *supra* note 51, at 7.

⁶¹ *Id.*; Michael Quaas, *Krankenhausrecht*, 1113, 1165 in HANDBUCH DES FACHANWALTS MEDIZINRECHT, *supra* note 32. *See also* BECK, *supra* note 17, at 43-47 (discussing call centers and web portals in Switzerland).

care was further eroded.⁶² New concepts envisioned by the legislature were, for example, integrated care concepts, comprehensive medical care centers (*Medizinische Versorgungszentren, MVZ*) and disease management programs (*DMP*).

Integrated care concepts had been envisioned prior to the latest health insurance reform and were already codified in the 2000 reform of the SGB V.⁶³ The goal of integrated medical care is to overcome the strict separation between hospital care and ambulant care currently in place in Germany, and to offer a more individualized healthcare approach.⁶⁴ Individual healthcare service providers can directly enter into contractual agreements with each other under sections 140a et seq. SGB V with the goal of providing comprehensive integrated care of insured individuals.⁶⁵ After the reform, individual physicians can enter into contracts with health insurance providers just as the holding companies, which themselves of course do not offer medical care. The body then must offer the contracted services by medical care providers, such as contracted physicians or hospitals. The advantage of such a solution would be that the company performs the necessary management tasks while the service providers focus exclusively on medical care.⁶⁶ The Associations of Statutory Health Insurance Providers no longer set the framework for treatment in integrated care.⁶⁷ Oftentimes, the topic of MVZs is seen in connection with integrated care concepts, although there is no necessary connection between the two. The MVZ can be a contractual partner in the framework of integrated care concepts, and it structurally lends itself to involvement in integrated care.⁶⁸ The topic of disease management programs (*DMP*) is also discussed in this context.⁶⁹

⁶² Joachim Kasper § 17, No. 1 in MÜNCHENER ANWALTS HANDBUCH SOZIALRECHT (Hermann Plagemann, ed, 2nd Edition,); Rainer Hess Vor § 140a No. 1 SGB V in KASSELER KOMMENTAR, *supra* note 43; Hess, *supra* note 43, at 167.

⁶³ Kasper, *supra* note 62, at § 17, No. 4; Hiddemann & Muckel, *supra* note 51, at 8; von Schwanenflügel, *supra* note 53, at 287. *See also generally* Hess, *supra* note 43, at 167-170

⁶⁴ Kasper, *supra* note 62, at § 17, Rn. 4; Hess, *supra* note 43; Hiddemann & Muckel, *supra* note 51, at 8; von Schwanenflügel, *supra* note 53, at 287.

⁶⁵ Kasper, *supra* note 62, at § 17, No. 4; Hess, *supra* note, 43; Hiddemann & Muckel, *supra* note 51, at 8.

⁶⁶ Hiddemann & Muckel, *supra* note 51, at 8; von Schwanenflügel, *supra* note 53, at 287.

⁶⁷ Von Schwanenflügel, *supra* note 53, at 287-288.

⁶⁸ Kasper, *supra* note 62, at § 17, Rn. 6; Hiddemann & Muckel, *supra* note 51, at 8.

⁶⁹ Von Schwanenflügel, *supra* note 53, at 287 (explaining that integrated care can include DMPs).

The idea of the MVZ has been traced to the concept of *Polikliniken* in the former German Democratic Republic.⁷⁰ The goal of the creation of MVZs is providing patients with one-stop-healthcare. Physicians of different specializations, but also pharmacists and physical therapists, would be enabled to work in the same space, thus creating a variety of advantages for patients, such as improved care management and are more structured exchange of information between the medical care providers. The repetition of examinations, for example, would be eliminated. Further, care is to be better coordinated and waiting times are to be reduced.⁷¹ According to the definition contained in section 95(1) SGB V, MVZs are interdisciplinary entities under the direction of physicians in which licensed physicians work either as employees or as physicians licensed to provide public health insurance services.⁷² The novelty of the concept lies in the assumption that care by physicians contracted under statutory health insurance is no longer solely provided by self-employed physicians licensed to provide statutory healthcare services in private practice and in the collective contract system described above.⁷³ Instead, MVZs themselves are licensed and now act as competitors, which was the legislature's stated intention.⁷⁴ It has been pointed out that, in practice, not only physicians but also hospitals and pharmacies are increasingly interested in participating in MVZs as a way to utilize synergy effects and access the ambulant care market.⁷⁵ MVZs can be founded and run by hospitals, and set up in immediate proximity. It is legally permissible to employ hospital physicians part-time at the MVZ and thus to ensure a close relationship between the MVZ providing ambulant care and the hospital. In addition to the medical advantages of a closer coordination between ambulant care and hospital care, management tasks can be performed by the hospital.⁷⁶ This creates another advantage in freeing

⁷⁰ Kasper, *supra* note 62, at § 17, Rn. 5; Hiddemann & Muckel, *supra* note 51, at 9; von Schwanenflügel, *supra* note 53, at 289.

⁷¹ Von Schwanenflügel, *supra* note 53, at 290.

⁷² Kasper, *supra* note 62, at § 17, Rn. 5. *See also* André Fiedler and Tilmann Weber, *Medizinische Versorgungszentren*, 13 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 358 (2004)(providing a detailed analysis of the legal definition and its problem areas).

⁷³ Kasper, *supra* note 62, at § 17, Rn. 5; Friedrich E. Schnapp, *Konkurrenzschutz für niedergelassene Ärzte gegen medizinische Versorgungszentren*, 13 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 449, 449 (2004).

⁷⁴ Schnapp, *supra* note 73 at 449; Hiddemann & Muckel, *supra* note 51, at 9-10; Quaas, *supra* note 51, at 1166-1167.

⁷⁵ Kasper, *supra* note 62, at § 17, Rn. 5.

⁷⁶ Hiddemann & Muckel, *supra* note 51, at 10.

physicians from their administrative tasks which, in private practice, have been found to account for one fifth of the work time of physicians.⁷⁷ The question has been raised, however, whether the law was designed to give MVZs a competitive advantage over private practice physicians and whether legislatively awarding this advantage is, in fact, constitutional.⁷⁸ While the question has therefore been raised whether and, if so, how physicians can challenge the creation of MVZs,⁷⁹ others point out that especially for young physicians MVZs provide an attractive way to enter the job market.⁸⁰

It is claimed that the quality and efficiency of a health care system can be judged by its treatment of chronically sick individuals.⁸¹ Disease Management Programs (DMPs) offer a form of disease-centered management of care problems. They contain interdisciplinary care tasks and demand the continuous evaluation of service scope and contents. Economic evaluations are thus a central aspect of DMPs, and the ultimate goal is the standardization of care, constituting a form of quality management.⁸² The legal ramifications were instituted in 2002, allowing for programs in the areas of diabetes, coronary heart disease, breast cancer and pulmonary disease.⁸³ The primary goal of DMPs is to address the risk of insuring chronically sick individuals by treating chronic illnesses more efficiently and more economically.⁸⁴ One of the key problems regarding chronic illnesses is to find a reasonable level of

⁷⁷ Von Schwanenflügel, *supra* note 53, at 290.

⁷⁸ Schnapp, *supra* note 73, at 450 (expressing doubt that the competitive advantage for MVZs is constitutional and pointing out difficulties in constitutionally challenging the provisions allowing MVZs).

⁷⁹ *Id.* at 450-452.

⁸⁰ Kasper, *supra* note 62, at § 17, Rn. 5; von Schwanenflügel, *supra* note 53, at 290; Udo Degener-Hencke, *Integration von ambulanter und stationärer Versorgung - Öffnung der Krankenhäuser für die ambulante Versorgung - Rahmenbedingungen nach dem GKV-Modernisierungsgesetz (GMG)*, 12 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 629, 630 (2003).

⁸¹ Von Schwanenflügel, *supra* note 53, at 287.

⁸² Jens Ricke, *Informationsmanagement in Disease Management Programmen*, 105, 105, in *EHEALTH: INNOVATIONS- UND WACHSTUMSMOTOR FÜR EUROPA* (Jörg Eberspächer, Arnold Picot, Günter Braun, eds., 2006); Hess, *supra* note 32, at 165-166. *But see, e.g.*, Gernot Rüter, *Auf der Strecke bleibt die ärztliche Ethik*, 98 DEUTSCHES ÄRZTEBLATT A3016 (2001)(criticizing DMPs because they result in a loss of the patient's control regarding treatment).

⁸³ Ricke, *supra* note 82, at 107; Thomas Vollmöller, *Rechtsfragen bei der Umsetzung von Disease-Management-Programmen*, 13 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 63 (2004); Hess, *supra* note 32, at 166.

⁸⁴ Ricke, *supra* note 82, at 106-107; Vollmöller, *supra* note 83, at 63.

care as chronic illnesses tend to be over-treated or under-treated.⁸⁵ DMPs provide two key functions: first, an integration of ambulant and hospital care, and second, a guiding function in which patients can be guided in treatment- and care processes.⁸⁶ The health insurance providers themselves are responsible for developing the programs, which are only broadly permitted by law, without specific detail regulations.⁸⁷ Generally, all types of contractual relations of the SGB V are permissible in the framework of DMPs.⁸⁸ However, because of the nature of public health insurance, procurement, competition, and antitrust regulations have to be followed.⁸⁹ For purposes of this discussion, one key DMP program type is the institution of Medical Call Centers and Web Portals, especially in the area of health coaching programs. The parameters to be monitored are set by the physician and the implementation of the program and the monitoring is performed by the patient and the call center.⁹⁰ These programs are especially sought-after by health insurances seeking to influence the relationship between the insured individual and the health care professional before medical treatment becomes necessary. Exercising influence can take two main avenues: On the one hand, health insurances are seeking to directly address the insured individual and thus try to indirectly influence the relationship with the health care professional. One example would be medical call centers for medical advice or medical advice information material. Further, new insurance premium structures are intended to reward the insured individual if he seeks advice from a general care provider, such as a family doctor, before consulting a specialist. On the other hand, there are tendencies to implement new legal relationships between insurance providers and health care professionals. Examples would be contracts between insurance providers and individual hospitals. Quality standards are subject to those agreements. Further examples would be the support of physician networks or financial participation in hospitals.⁹¹ Thus, DMP relates back to the integrated care and MVZ models already described.

⁸⁵ Ricke, *supra* note 82, at 113.

⁸⁶ Vollmöller, *supra* note 83, at 64.

⁸⁷ *Id.*; Beck, *supra* note 17, at 31.

⁸⁸ Vollmöller, *supra* note 83, at 64.

⁸⁹ *Id.* at 65-66.

⁹⁰ Beck, *supra* note 17, at 31.

⁹¹ Bach & Hütt, *supra* note 59, at No. 85.

2. Introducing Information Technology

Provisions concerning the development of healthcare are contained in sections 63 et seq. SGB V. These provisions are the basis for pilot projects of the state health insurances. By introducing modern information technology into the healthcare system, the goals are to improve care and the flow of information, to cut costs, to advance research and to influence the insured individuals, promoting a healthy lifestyle.⁹² The legislature envisioned a significant improvement with respect to the innovation capabilities of the healthcare system and the public health insurance system.⁹³ The primary target area of the pilot projects are information technology and organizational improvements of the use of data.⁹⁴ This includes granting wider competences regarding the gathering, processing and use of personal data.⁹⁵ As an example, the electronic health card (patient chip card) is mentioned in the legislative materials.⁹⁶ Electronic health cards are found to be important for three different reasons: (1) they constitute important storage devices for patients' personal health data, (2) they constitute a test case in which to evaluate the possibilities of interconnection between different providers, and (3) the electronic health card is regarded as a prerequisite for testing newly developed systems such as electronic prescriptions.⁹⁷

The introduction of electronic communication methods is one key aspect in the envisioned e-health design. Section 67 (1) SGB V states the goal to significantly improve both the quality and the economics of healthcare by employing electronic communication.⁹⁸ Electronic communication is viewed to be indispensable especially for integrated care concepts and disease management programs.⁹⁹ Therefore, paper-based communication among the health service providers - including clinical findings, diagnoses, therapy recommendations and therapy reports - is intended to be eliminated and

⁹² Gerrit Hornung, DIE DIGITALE IDENTITÄT - RECHTSPROBLEME VON CHIPKARTENAUSWEISEN: DIGITALER PERSONAL AUSWEIS, ELEKTRONISCHE GESUNDHEITSKARTE, JOBCARD-VERFAHREN 43 (2005); Korbinian Höfler, SGB V, § 63, No. 2-3 in KASSELER KOMMENTAR SOZIALVERSICHERUNGSRECHT, *supra* note 32.

⁹³ Höfler, *supra* note 92.

⁹⁴ *Id.* at No. 5.

⁹⁵ *Id.*

⁹⁶ *Id.* at No. 3 and 6.

⁹⁷ *Id.* at No. 6.

⁹⁸ *Id.* at § 67 at No. 2.

⁹⁹ *Id.*

replaced with electronic communication as soon and as comprehensively as possible.¹⁰⁰ The provision is to be seen in connection with section 291a SGB V, regulating the further development of the already introduced insurance card into an electronic health card. The electronic health card is envisioned to be an essential component in the future electronic data transfer among service providers.¹⁰¹ Section 67 (2) contains the mandate for health insurance providers to financially support the shift from paper-based to electronic communication.¹⁰² The new electronic health card will be mandatory for those covered by statutory health insurance.¹⁰³

Electronic insurance cards have been in use since 1995. They enable statutory health insurances to electronically transfer the basic patient data into physicians' data processing systems which previously had been entered by hand.¹⁰⁴ The current electronic insurance card is a simple storage card without a processing device. There are no safety features such as personal identification numbers and the cards are not write-protected.¹⁰⁵ These existing insurance cards are to be developed into electronic health cards, containing data regarding the insured person, emergency treatment, patient medical history, medication documentation, and medical services rendered as well as their costs.¹⁰⁶ Further, the cards must be suited to be used for the transmission of prescriptions and proof of entitlement to receive health services within the EU.¹⁰⁷ Section 291a SGB V regulates the content of the electronic health card, data access, and the financing of an accompanying organizational structure that creates a new agency, the *Gesellschaft für Telematik*.¹⁰⁸ On the basis of calculations in 2004, the electronic prescription was to be the primary use area of the electronic health card as it was deemed the most likely to recover the costs for introduction of the card. Once 500 to 600 million prescriptions were to be transmitted

¹⁰⁰ *Id.* at No. 3.

¹⁰¹ *Id.* at No. 4; Hornung, *supra* note 92, at 43.

¹⁰² Höfler, *supra* note 92, at No. 5.

¹⁰³ Hornung, *supra* note 92, at 60.

¹⁰⁴ *Id.* at 42.

¹⁰⁵ *Id.*

¹⁰⁶ Höfler, *supra* note 92, at No. 4; Hornung, *supra* note 92, at 42. *See also* Wolfgang Kilian, *Rechtliche Aspekte bei Verwendung von Patientenchipkarten*, 45 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 2313 (1992).

¹⁰⁷ Höfler, *supra* note 92, at No. 4; Hornung, *supra* note 92, at 44.

¹⁰⁸ Karl Peters, SGB V, § 291a, No. 2, in KASSELER KOMMENTAR SOZIALVERSICHERUNGSRECHT, *supra* note 43. *See also* Hornung, *supra* note 92, at 45 (for more on the gematik Gesellschaft für Telematikanwendungen der Gesundheitskarte GmbH); *Id.* at 372-374 (for an analysis of organization aspects).

electronically, the estimated investment of 1.3 billion Euros was to be recovered within about three years.¹⁰⁹ Possibly the e-prescription is the only application with short-term economic benefits.¹¹⁰

Asserted benefits for the patient include a better ability to determine the use of data. Saving data on or with a chip card can give the insured individual the ability to independently decide on the use of his or her data, depending, of course, on the technical design of the data access. Patients could thus receive more information on treatment and costs. For the service providers, the asserted key benefit is the improvement of the level of care by faster and more reliable data access. Further, there are new possibilities regarding e-consults and cooperation among hospitals. Moreover, reducing administrative tasks leads to a reduction in costs.¹¹¹ The system of the electronic health card also encompasses the introduction of the health professional card which in most cases will be necessary to access the data. The health professional card will enable the creation of qualified electronic signatures. Although this is not necessary for the electronic health card, they, too, can be used for qualified electronic signatures.¹¹² The contents of the electronic health card are divided into a mandatory and a voluntary part. The mandatory part includes three parts: the storage of basic patient data, the transmission of the e-prescription and the storage of the EU proof of entitlement.¹¹³ The voluntary part, which under section 291a (3)(3) SGB V will only be stored on the card with the insured individual's prior consent, are medical emergency data, the electronic discharge letter, the electronic medical record, the data regarding pharmaceutical product safety, data provided by the patient regarding previous medical services and their preliminary costs (patient receipt).¹¹⁴

Although there has been intense work toward the introduction of the electronic health card, it is still in the trial phase.¹¹⁵ One reason the introduction of a widely used electronic health card requires

¹⁰⁹ Doris Pfeiffer, *Stand und Perspektiven der Gesundheitstelematik aus Sicht der gesetzlichen Krankenversicherung* 35-36 in *eEurope 2005*, *supra* note 17. Hornung, *supra* note 92, at 43 cites a recovery of costs of 1.2 to 1.5 billion Euros within only 1 to 2 years. See also Hornung, *supra*, note 92, at 374-375 (for an overview of the costs involved).

¹¹⁰ Hornung, *supra* note 92, at 209.

¹¹¹ *Id.* at 44.

¹¹² *Id.* at 46.

¹¹³ *Id.* at 61.

¹¹⁴ *Id.* at 207.

¹¹⁵ *Id.* at 44-45.

significant efforts is the vast amount of data. Around 70 million individuals are members of the public health insurances (amounting to roughly 90% of the German population) and the public health insurance itself is divided into numerous subsections.¹¹⁶ The provision of section 291a, however, has been subject to criticism, mainly because of what is asserted to be a general problem of modern legislation: section 291aSGB V appears to be obsessed with detail regulations.¹¹⁷ The data protection-inspired regulations regarding the information of the insured individuals and their consent are well-intended; however, it has been pointed out that the execution of such detailed rules in mass-transactions such as the introduction of an electronic health card may be neither practical nor verifiable.¹¹⁸ Further, since a new agency is established, it has been argued that the stated objective to decrease bureaucracy has not been achieved.¹¹⁹

The new provisions concerning the electronic insurance card were challenged in a constitutional complaint (*Verfassungsbeschwerde*) before the Federal Constitutional Court.¹²⁰ The petitioner alleged the violation of his constitutional right to informational self-determination under Article 2(1) in connection with Article 1(1) of the Basic Law. In addition, he claimed violations of the general equality clause, Article 3(1). Although the Court did not address the merits for lack of standing, it did state that the petitioner had raised significant constitutional questions. The petitioner, however, did not have standing because he had not exhausted all remedies before filing his complaint.¹²¹ As an extraordinary remedy, constitutional complaints can only be filed after a final judgment of a court has been rendered.¹²² It does not appear inconceivable, however, that the issue may return to the courts in the future. The significant data protection issues as well as the electronic signature issues raised in connection with the electronic health card will be outlined and analyzed in further detail below.¹²³

¹¹⁶ Peters, *supra* note 43, at No. 4; Kilian, *supra* note 106, at 2314.

¹¹⁷ Peters, *supra* note 43, at No. 4.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Bundesverfassungsgericht [BVerfG][Federal Constitutional Court], Feb 13, 2006, docket no. 1 BvR 1184/04.

¹²¹ *Id.*

¹²² Alfred Rincken, *The Federal Constitutional Court and the German Political System, in CONSTITUTIONAL COURTS IN COMPARISON: THE U.S. SUPREME COURT AND THE GERMAN FEDERAL CONSTITUTIONAL COURT* 55, 67 (Ralf Rogowski and Thomas Gawron eds., 2002).

¹²³ *Infra* Parts II and III.

Ideally, electronic medical records enable “any doctor anywhere to access the full profile of any patient anywhere.”¹²⁴ The EU Commissioner for Information Society & Media pointed out that the Czech Republic already has implemented a personal electronic medical record.¹²⁵ In Germany, section 68 SGB V contains a provision allowing for the financial support of electronic medical records by the health insurance companies records intended to improve the quality and economics of medical care especially in the framework of the public health insurance.¹²⁶ According to section 68 SGB V, electronic health records contain patient related health data of the insured individuals, for example relevant medical information regarding previous diagnoses.¹²⁷ The electronic medical record is specifically designed to support the goals of integrated care and the improvement of communication between individual physicians involved in patient care.¹²⁸ The use of the electronic medical record is said to have advantages for both the patient and the healthcare provider. It eliminates administrative tasks on the part of the physician and leads to a higher transparency as both the patient and the physicians have access to the same information.¹²⁹

3. Challenges and Restrictions

Managed care and medical call centers providing advice to insured persons by the insurance companies face various legal restrictions. As a general matter, section 3 of the Unfair Competition Act (*Gesetz gegen den unlauteren Wettbewerb, UWG*) has to be observed. Information regarding medical products and service providers has to be objective and factually substantiated and cannot contain one-sided advertisings.¹³⁰ Aside from such general laws, medical health professionals are subject to further professional regulations.

Recommending physicians is subject to the regulations of the prohibition of advertising contained in section 27 of the Model Code of Professional Conduct for Physicians (*Musterberufsordnung für Ärzte*)

¹²⁴ Martin, *supra* note 1.

¹²⁵ Reding Interview, *supra* note 11.

¹²⁶ Höfler, *supra* note 92, at § 68, Rn. 2

¹²⁷ *Id* at No. 3

¹²⁸ *Id* at No. 4

¹²⁹ Pfeiffer, *supra* note 109, at 38.

¹³⁰ Bach & Hütt, *supra* note 59, at No. 85.

which, though sections 3 and 4 No. 11 of the Unfair Competition Act (formerly section 1 UWG) also applies to the insurances. As a general matter, recommending individual physicians is impermissible.¹³¹ However, listing medical specialists without a qualitative ranking is permissible as patients have an interest in learning of methods designed to treat a specific illness and of the health care providers who offer them.¹³² Antitrust regulations create restrictions on recommendations made by the health insurance if they are (indirectly) addressed at the healthcare provider. The Act against Restraints on Competition (*Gesetz gegen Wettbewerbsbeschränkungen, GWB*) in section 21 prohibits boycotts. If, for example, the insurance recommends specific dental labs and the insured passes on this recommendation to the dentist, who is a businessperson in the sense of the GWB, this might be regarded as an indirect request of the insurance, addressed at the dentist, to prefer certain dental labs. A boycott in the sense of section 21 GWB encompasses any attempt to influence another businessman to refrain from entering into or keeping up certain supply relationships. If dentists commission a specific dental lab in order to avoid billing problems for patients, this already constitutes such interference.¹³³ If this is not the case, however, tips on cheap services of certain providers are permissible.¹³⁴ General information regarding appropriate prices of dental lab services is permissible. While providers of statutory health insurance are expressly permitted under section 88 (2)(3) SGB V to inform their members as well as dentists of economical service opportunities, a complementary provision does not exist for private insurances.¹³⁵

Medical advice offered by medical call centers via the telephone is subject to professional regulations for physicians. Important professional conduct provisions concern the diligent exercise of professional duties (section 2 (2) of the Model Code of Professional Conduct) and the tenet of personal rendering of services (section 7 (3) of the Model Code of Professional Conduct, stating that the physician may not perform individual treatment and consulting exclusively via

¹³¹ See Federal Court of Justice [Bundesgerichtshof][BGH] 16 MEDIZINRECHT [MEDR] 131 (1998); Regional Court of Appeals of Munich [OLG München] 17 Medizinrecht [MedR] 76 (1999).

¹³² See District Court Kiel [LG Kiel] 17 Medizinrecht [MedR] 279 (1999).

¹³³ Federal Court of Justice [Bundesgerichtshof][BGH] 49 WIRTSCHAFT UND WETTBEWERB [WuW] 725, 727 (1999).

¹³⁴ Federal Court of Justice [Bundesgerichtshof][BGH] decision of March 14, 2000, docket no. KZR 15/98.

¹³⁵ Bach & Hütt, *supra* note 59, at No. 87.

telecommunication media.) This means that individual medical advice may only be disseminated after personal contact. Diagnoses may not be made over the phone and no concrete therapy suggestions may be made. Health advice over the phone may only be concerned with general health questions which may also be found in literature, including generally which groups of diseases might be considered in a given case and what the general criteria of these diseases might be.¹³⁶ Considering possible liability risks, it is considered advisable that the insurance refrain from further consulting as well.¹³⁷

Restrictions also apply in the area of pharmaceutical products. In connection with medications, the provisions of the Law on the Advertising of Medicinal Products (*Heilmittelwerbegesetz, HWG*) have to be observed. Advertising prescription drugs to consumers is prohibited. Further, no advertising is allowed regarding medications for specific illnesses and ailments.¹³⁸ Outside of online order pharmacies, as was the subject of the DocMorris decision of the ECJ,¹³⁹ there are specific questions regarding online advertising for drugs.¹⁴⁰ Posting the package inserts for prescription drugs online has been the subject of several lawsuits. While posting the package inserts was not deemed unlawful online advertising by the Munich district court and regional court of appeals, the district court of Hamburg took the opposite stance.¹⁴¹ Beyond questions of advertising, pharmaceuticals are highly regulated in Germany. As in most European states, the prices of drugs are not set solely by the market but instead are subject to state regulation. The authorization for regulating the prices of drugs originates in section 78 of the Law on Medicinal Products (*Arzneimittelgesetz, AMG*).¹⁴² Based on the authorization, the Regulation on Prices of Medicines (*Arzneimittelpreisverordnung, APO*) regulates the prices at which prescription drugs are sold to consumers.

¹³⁶ Regional District Court Heidelberg [LG Heidelberg] 17 MEDIZINRECHT [MEDR] 420 (1999).

¹³⁷ Bach & Hütt, *supra* note 59, at no. 88.

¹³⁸ *Id.* at no. 85.

¹³⁹ *Infra* Part IV.

¹⁴⁰ Ralph Alexander Lorz, *Internetwerbung für verschreibungspflichtige Arzneimittel aus gemeinschaftsrechtlicher Perspektive*, 54 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT INTERNATIONALER TEIL [GRUR INT] 894 (2005).

¹⁴¹ LG München, decision of November 6, 2003, docket no. 17 HKO 7494/03; OLG München, decision of May 6, 2004, docket no. 6 U 5565/03.

¹⁴² Elmar Mand, *Internationaler Versandhandel mit Arzneimitteln - Das Ende der einheitlichen Apothekenverkaufspreise gemäß AMPPreisV?*, 54 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT INTERNATIONALER TEIL [GRUR INT] 637, 638 (2005).

While manufacturers may freely set prices for their drugs, the APO imposes fixed prices and maximum prices for prescription drugs to be sold in pharmacies, thus eliminating competition of pharmacies in the area of prescription drugs.¹⁴³ The goal of the regulation is to keep the prices of prescription drugs low in the interest of a well-functioning and affordable health care system.¹⁴⁴ Further areas of conflict between e-health initiatives and the highly regulated pharmaceuticals market will be illustrated in the context of online pharmacies.¹⁴⁵

II. E-HEALTH AND DATA PROTECTION

This section will illustrate a few key issues of crucial importance for the future success of e-health initiatives in Germany and Europe. Data protection and data security have been identified as critical factors in the success of e-health as they directly relate to the trust of the patient and the reliability of electronic processes.¹⁴⁶ The European Commission identifies data protection and data security as major challenges for the wider implementation of e-health concepts.¹⁴⁷ A variety of rules govern data protection on the European and German national level. A rough overview of these regimes will be given in this section, starting with the general laws on data protection and then turning to the area-specific data protection provisions in the area of healthcare including transnational health data processing. Finally, the key concerns regarding data access and protection in connection with the electronic health card will be illustrated.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Infra* Part IV.

¹⁴⁶ Heinz Thielmann, *Datenschutz und Datensicherheit - Kritische Erfolgsfaktoren für eHealth* 195, 195 in EHEALTH, *supra* note 82.

¹⁴⁷ e-Health Action Plan, *supra* note 8, at 14.

A. General Data Protection Regime

In Germany, the first data protection efforts started in the 1970s on the state (*Länder*) level.¹⁴⁸ The very first general data protection law worldwide, in fact, was implemented in the state of Hesse in 1970.¹⁴⁹ In 1977, the first national data protection act was implemented which in its entirety entered into force in 1979.¹⁵⁰ A milestone in the area of German data protection was a 1983 decision of the Federal Constitutional Court. In its census decision (*Volkszählungsurteil*), the Court held that there is an unwritten fundamental right to informational self-determination based on Articles 1 and 2 of the German Constitution, the Basic Law (*Grundgesetz*).¹⁵¹ This fundamental right guarantees that the individual maintains control over the disclosure and use of personal data, including the right to decide when and within which limits personal information is revealed. In addition, the individual must know who knows what at a given point in time.¹⁵² Although the Court acknowledged that there are limits to this right, it developed strict requirements for such limits. They are only permissible on the basis of a law codifying an overwhelming common interest. The conditions of the limits on freedom of informational self-determination have to be unambiguous. Further, the requirement of proportionality must be observed. The collection and processing of personal data is subject to a further strict requirement, the specified purpose. Personal data may only be collected for a specified purpose and can neither take place for any other than the originally stated purpose nor in advance for an unspecified purpose. Finally, the amount of data has to be kept to the absolutely necessary minimum.¹⁵³

¹⁴⁸ Wolfgang Durner, *Zur Einführung: Datenschutzrecht*, 46 JURISTISCHE SCHULUNG [JUS] 213 (2006); Spiros Simitis, *Einleitung - Geschichte, Ziele, Prinzipien*, No. 1 in: BUNDESDATENSCHUTZGESETZ (Spiros Simitis, ed., 6th Edition, 2006).

¹⁴⁹ Peter Gola & Rudolf Schomerus, BDSG BUNDESDATENSCHUTZGESETZ KOMMENTAR, Einleitung, No. 1 (7th Edition 2002).

¹⁵⁰ Durner, *supra* note 148, at 213; GOLA AND SCHOMERUS, *supra* note 149, at Einleitung, No. 1.

¹⁵¹ Bundesverfassungsgericht [BVerfG][Federal Constitutional Court], Dec 15, 1983, 65 ENTSCHEIDUNGEN DES BUNDESVERFASSUNGSGERICHTS [BVERFGGE] 1 (F.R.G.) [hereinafter: Census decision].

¹⁵² Durner, *supra* note 148, at 213.

¹⁵³ *Id* at 214.

The fundamental right to informational self-determination is primarily protected by the Federal Data Protection Act¹⁵⁴ (*Bundesdatenschutzgesetz, BDSG*) and the data protection acts of the states, all of which underwent major changes following the European Data Protection Directive.¹⁵⁵ In addition to this general data protection legislation, special legislation exists in a wide variety of area-specific laws. Data protection hence is identified as a typical cross-section of legal regulations that is not subject to a uniform legislative competence.¹⁵⁶ The reason for the multitude of legislative competences is the absence of a competence title regarding data protection in the Basic Law.¹⁵⁷ The general data protection laws, such as the Federal Data Protection Act in section 1(4), contain subsidiarity clauses so that in any given instance, the area-specific data protection regulations take precedence.¹⁵⁸

Especially interesting in the data protection context are questions of utilizing third parties for data processing services. Oftentimes, automated data processing is not performed by the responsible entity, the principal, itself. The BDSG in section 11 provides the privileged instrument of commissioned data processing (*Auftragsdatenverarbeitung*). The provision is intended to ensure that the data protection and data security standards imposed by the BDSG do not limit the possibility of outside data processing. The commissioned data processing provider legally is seen as forming a single entity with the principal.¹⁵⁹ In other words, those who engage in commissioned data processing are not considered “third parties.”¹⁶⁰ If personal data is gathered or employed, *i.e.*, processed or used under section 3(5) BDSG) by way of commissioned data processing, the special provisions of section 11 (1)(1) BDSG apply. The provider of

¹⁵⁴

http://www.bfdi.bund.de/cIn_029/nn_946430/EN/DataProtectionActs/Artikel/Bundesdatenschutzgesetz-

FederalDataProtectionAct,templateId=raw,property=publicationFile.pdf/Bundesdatenschutzgesetz-FederalDataProtectionAct.pdf (for an English translation) (last visited Oct. 30, 2008).

¹⁵⁵ 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. *See* Simitis, *supra* note 148, at No. 89 - 102 (providing a detailed account of the legislative process incorporating the changes).

¹⁵⁶ Durner, *supra* note 148, at 214; Simitis, *supra* note 148, at No. 48.

¹⁵⁷ Durner, *supra* note 148, at 214.

¹⁵⁸ *Id.*

¹⁵⁹ Stefan Walz, § 11 No. 1 in BUNDESDATENSCHUTZGESETZ, *supra* note 148.

¹⁶⁰ Gola & Schomerus, *supra* note 149, at § 11 No. 3.

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commissioned data processing only has to ensure that the technical and organizational measures are in place to provide for data availability, integrity and privacy. Beyond that, all responsibility regarding the compliance with data protection provisions remains with the principal entity that remains the “responsible entity” in the sense of section 3(7) BDSG. Thus, only the principal entity is liable in relation to third parties.¹⁶¹ Notably, the individual whose data is transferred by way of commissioned data processing is not required to consent to the transfer.¹⁶²

The problem, however, is to identify the privileged instances of commissioned data processing. The BDSG does not provide clear identification guidelines.¹⁶³ Commissioned data processing is to be distinguished from “functional assignments” (*Funktionsübertragung*). A functional assignment involves not only the transfer of parts of automated data processing but rather the entire task for which the data processing takes place.¹⁶⁴ Several criteria have been suggested to identify commissioned data processing. Most importantly, the service provider does not have any competences regarding the data and depends entirely on the demands of the principal, especially regarding the type and scope of data it gathers and/or uses and only exercises a supporting or auxiliary role.¹⁶⁵ Moreover, the focus of the service provided in commissioned data processing generally is the purely technical performance of data processing.¹⁶⁶ On the other hand, a functional assignment can be assumed if the underlying business processes are entirely or partially handed over or if the external data processor fulfills his own business objectives, especially if he performs material contractual services with the data provided. Then, the service provider is no longer merely a contractor but (insofar) becomes the responsible entity.¹⁶⁷ Criteria suggested to identify a functional assignment are, first, the service provider has independent decision competences regarding the manner of data processing and the selection of the data. The tasks are independently carried out and the principal

¹⁶¹ Philipp Kramer & Michael Herrmann, *Auftragsdatenverarbeitung*, 19 COMPUTER UND RECHT [CR] 938 (2003).

¹⁶² Mark Hoenike & Lutz Hülsdunk, *Outsourcing im Versicherungs- und Gesundheitswesen ohne Einwilligung?* 7 MULTIMEDIA UND RECHT [MMR] 788 (2004).

¹⁶³ Kramer & Herrmann, *supra* note 161, at 938.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*; Walz, *supra* note 159, at No. 1.

¹⁶⁶ Kramer & Herrmann, *supra* note 161, at 938.

¹⁶⁷ Simitis, *supra* note 148, at § 11 No. 17.

generally has little or no influence over the data processing itself. Sometimes, a further indication is that a service is provided that goes beyond the mere technical assignment of data processing and, even further, the service provider may have the right to use the data for own purposes and has an own interest in the use of the data.¹⁶⁸ If the data processing occurs in part for own purposes and in part because of a commissioning, the commissioning provisions only apply to the commissioned part. The quantitative volume of each part is irrelevant. Such a split legal situation particularly occurs with data processing centers that in addition to the data supplied for commission purposes also process for themselves data of their employees and clients.¹⁶⁹

B. Healthcare-Specific Data Protection

“Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.”¹⁷⁰ This passage of the Hippocratic Oath has been referred to as one of the oldest data protection laws.¹⁷¹ The protection of medical data is subject of the physicians’ professional code of conduct as well criminal prohibitions¹⁷² and data protection regulations. Data protection in the health care area is especially sensitive due to the special relationship based on mutual trust between the patient and the physician. The protection of medical data thus is indispensable. The scope of the confidentiality requirement is wide, concerning not only the diagnoses but even the fact of the doctors’ visit as such. Everyone who does not take part in the treatment procedure itself is excluded from access to the protected information, including other physicians not involved in the treatment. Passing on medical information is only permissible with express consent of the patient.¹⁷³ Members of statutory health insurance, however, are subject to the assumption that

¹⁶⁸ Kramer & Herrmann, *supra* note 161, at 939.

¹⁶⁹ Simitis, *supra* note 148, at § 11No. 19.

¹⁷⁰ Hippocratic Oath, Translation, *available at* National Institutes of Health http://www.nlm.nih.gov/hmd/greek/greek_oath.html (last visited Nov. 12, 2008).

¹⁷¹ Helge Sodan, *Verfassungs- und europarechtliche Grundlagen des Medizinrechts*, 18, in *HANDBUCH DES FACHANWALTS MEDIZINRECHT*, *supra* note 43.

¹⁷² See Hoenike & Hülndunk, *supra* note 162 (for an in-depth discussion of the criminal law implications of outsourcing in the area of insurance and healthcare).

¹⁷³ Sodan, *supra* note 160, at 18; Frank Wenzel, *Das Recht der medizinischen Behandlung*, 221, 307-308, in *HANDBUCH DES FACHANWALTS MEDIZINRECHT*, *supra* note 43.

they at least implicitly agree with the transmission of all relevant data, including the diagnosis, to assess the obligation of the insurance to cover the costs incurred (section 60 SGB I), but disclosure of these facts has to be contained to the amount of information necessary.¹⁷⁴ When considering the connection between the confidentiality requirement, the documentation requirement, and data protection provisions, there has to be a distinction among the different uses. Collecting data is part of the treatment contract since treatment without the health information is impossible. At the same time, it allows only for the gathering of data immediately necessary for the treatment itself.¹⁷⁵

As already mentioned, the area-specific data protection legislation takes precedence over the general data protection legislation. In the area of healthcare, such area-specific data protection legislation is contained primarily in the 10th book of the Social Insurance Code, SGB X. Medical data protection not only protects the patient-physician relationship but also the patients' fundamental right to informational self-determination.¹⁷⁶ The area-specific legislation of the SGB X, too, was subject to changes based on the EU data protection directive.¹⁷⁷ It has been argued, however, that prior to the implementation of the EU data protection directive the provisions of the SGB X largely conformed to the directive. On the other hand, generally applicable changes, such as definitions as well as information rights, data transfer abroad and to trans- and international entities, had to be incorporated in to the social insurance code, especially into the SGB X, because this data protection regime is area-specific and insofar precedes the BDSG.¹⁷⁸

One of the key questions is when and how personal data becomes social data, of which health data is a subset. Section 67 (1)(1) SGB X states that personal data becomes social data when it is gathered, processed or used by an entity enumerated in section 35 SGB I (usually a social insurance provider) in the framework of activities under the social insurance code.¹⁷⁹ Of course, not every activity of a social insurance provider is an activity under the social insurance code.

¹⁷⁴ Sodan, *supra* note 171, at 18. See also Hoenike & Hülsdunk, *supra* note 162.

¹⁷⁵ Hornung, *supra* note 92, at 60.

¹⁷⁶ Sodan, *supra* note 171, at 18.

¹⁷⁷ See, e.g., Robert Steinbach, *Die Umsetzung der EG-Richtlinie Datenschutz im Sozialgesetzbuch*, 11 NEUE ZEITSCHRIFT FÜR SOZIALRECHT [NZS] 15 (2002)(providing an overview of the changes).

¹⁷⁸ *Id.* at 16.

¹⁷⁹ *Id.*; Sodan, *supra* note 171, at 18.

For example, there might be personal data related to employees of the social insurance provider which may be gathered, processed or used there, but do not constitute social data, as employment with a social insurance provider is not subject to the social insurance code.¹⁸⁰

In the area of health data processing, too, questions of third party involvement are of special interest. As already stated, before employing the general provisions of the BDSG, possible area-specific rules have to be considered.¹⁸¹ Thus, before turning to section 11 BDSG in the area of health data processing, the provisions of the SGB have to be examined. Social insurance providers fall under the regime of section 80 SGB X as far as commissioned data processing is concerned. Commissioned data processing in the sense of section 80 SGB X is given if the entity at which the data is stored uses a service contractor to perform the processing of social data but who, regarding the manner and extent of data processing, entirely depends on the requests of the storing entity.¹⁸² It is, in other words, the same mechanism as in section 11 BDSG. This, however, only applies in the area of social insurance. A special feature of the SGB, however, is that social data includes not only personal data but also trade and business secrets. If, as in the example above, data processed outside is for purposes of employment with the insurance provider and therefore does not constitute social data, section 11 BDSG applies.¹⁸³

Transnational health data processing poses a number of questions. Section 77 SGB X regulates the transmission of social data abroad or to a supranational or international entity. The provision was changed to take into account the harmonization of the data protection level among EU Member States under the EU data protection directive. Data transmissions within the EU and in countries with an adequate level of data protection are to be treated differently than data transmissions to third countries without an adequate level of data protection.¹⁸⁴ The provision primarily concerns transmissions to service providers (for example insurance providers or hospitals, etc) who exercise the same functions as German social insurance providers under section 35 SGB I. While a complete identity is not necessary, a

¹⁸⁰ Steinbach, *supra* note 177, at 16.

¹⁸¹ Walz, *supra* note 159, at No. 7.

¹⁸² Dirk Bieresborn, § 80 No. 3 in SGB X SOZIALVERWALTUNGSVERFAHREN UND SOZIALDATENSCHUTZ KOMMENTAR (Matthias von Wulffen, ed., 5th Ed., 2005).

¹⁸³ Walz, *supra* note 159, at No. 9.

¹⁸⁴ Bieresborn, *supra* note 182, at § 77 No. 2; Steinbach, *supra* note 177, at 21.

functional equivalence must exist.¹⁸⁵ Section 77 (2) makes the provision applicable to non-EU Member States if they have an adequate level of data protection. The entities determining whether an adequate level of data protection exists are the Federal Insurance Agency (*Bundesversicherungsamt*) along with the German Foreign Office (*Auswärtiges Amt*) and the Federal Ministry of the Interior (*Bundesministerium des Innern*) in close cooperation with the European Commission.¹⁸⁶ Further, section 77(3) declares the transfer of data abroad to be permissible if the data subject has declared his consent (No. 1), or the transmission is based on a treaty in the area of social security (No. 2), or the data transmission is necessary for a criminal trial or other court procedure (No. 3). In the cases of section 77 (3) No. 3 SGB X, however, an appropriate level of data protection has to be present. An additional limit on the transmission under section 77(3) is that the individual has no legitimate interest in preventing the transmission.¹⁸⁷ Legitimate interests in this context include the possibility that the transmitted data can lead to racial, religious or political discrimination of the individual or if they can be used to draw conclusions regarding possible violations of the laws of other states by the individual.¹⁸⁸

A question that might arise in the area of transnational health data processing is whether a managed care service provider operating in another EU Member State can access data stored on the server of a statutory health insurance provider in Germany to evaluate the data for health coaching programs in the area of chronic illnesses. Under the standards outlined above, data transmission and access within the EU is generally permissible.

C. Data Access, Data Protection, and the Electronic Health Card

Specific data protection related issues have been raised in connection with the introduction of the electronic health card (patient chip card). The key question concerns the control over the card itself and the stored data. With regard to the electronic health card, the provisions regarding storage, transmission and use of personal data are especially important.¹⁸⁹ The most recent health modernization

¹⁸⁵ Bieresborn, *supra* note 182, at § 77 No. 5; Steinbach, *supra* note 177, at 21-22.

¹⁸⁶ Bieresborn, *supra* note 182, at § 77 No. 8; Steinbach, *supra* note 177, at 23.

¹⁸⁷ Bieresborn, *supra* note 182, at § 77 No. 9; Steinbach, *supra* note 177, at 23.

¹⁸⁸ Bieresborn, *supra* note 182, at § 77 No. 9.

¹⁸⁹ Kilian, *supra* note 106, at 2316.

legislation concerns the use of data that in the past have been gathered, processed and used. The provisions governing this data are also applicable to the electronic health card.¹⁹⁰ A central problem, however, is the large number of interfaces that would have to be programmed in a manner to ensure that indeed only the authorized individuals have access to the data.¹⁹¹ In connection with the electronic health card, large quantities of personal data are processed which contain information regarding the individual's health. As already mentioned, health data is to be interpreted widely, an approach that is also shared by the European Court of Justice.¹⁹² While the majority of voluntary applications of the electronic health card would fall under data section 3(9) BDSG¹⁹³ (*i.e.*, data regarding the racial or ethnic origin, political opinions, religious or philosophical beliefs, union membership, health, or sex life) only the e-prescription is a mandatory application falling in this category as it contains information pertaining to health. No such data can be taken from the EU proof of entitlement or the basic data.¹⁹⁴ If, however, the card contains a photo of the individual this is to be interpreted as data regarding the racial or ethnic origin.¹⁹⁵

In principle, the electronic health card is regulated by a comprehensive legal framework. However, the law does not provide any detailed technical requirements for implementation.¹⁹⁶ Section 291a SGB V states explicitly that data has to be stored on the card in electronic form, which means that it has to be a chip card. Moreover, it has to enable authorization by the insured individual. There is no provision governing the place of storage, though. Possibilities include storage of the data on the card itself or on decentralized or centralized servers.¹⁹⁷

The Federal Court of Justice has held that the patient generally has the right to determine the fate of the patient data rather than the physician.¹⁹⁸ However, it has been pointed out that complete control of the patient may not sufficiently serve the interests of all parties

¹⁹⁰ Hornung, *supra* note 92, at 58.

¹⁹¹ Sodan, *supra* note 171, at 19; Hornung, *supra* note 92, at 363.

¹⁹² Hornung, *supra* note 92, at 278.

¹⁹³ *Id.*

¹⁹⁴ *Id.* at 279.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* at 58.

¹⁹⁷ *Id.* at 211-212. *See also Id.* at 213-218 (discussing the various storage possibilities).

¹⁹⁸ *See, e.g.*, Federal Court of Justice [Bundesgerichtshof][BGH] 45 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 763 (1992). *See also* Kilian, *supra* note 106, at 2316.

involved since the physician has various obligations in connection with the data as well. For example, the physician is obliged to maintain proper documentation. Exclusive control of the data by the patient would prevent the physician from fulfilling her duty.¹⁹⁹ The issue of data access on the electronic health card has to be seen in connection with the central demands of data protection which include the requirement to only collect data for a specified purpose and to avoid the uncontrolled confluence of data collected for different purposes. To ensure these demands of data protection, it has been suggested that all individual applications of the electronic health card have to be stored and processed separately.²⁰⁰ Patients, it is rightly pointed out, are in a conflicting position. On the one hand, only the disclosure of health data enables the physician to effectively offer treatment. On the other hand, the disclosed data is processed and used in ways that are outside the control of the patient.²⁰¹ Further, the autonomy of the patient encompasses the right to freely choose a physician, the right to refuse treatment, and the right to freely decide which information to disclose to the health service provider. The patient must have the opportunity to get an independent second opinion. This, however, is made virtually impossible by disclosing the entire medical history to each physician.²⁰² On the other hand, the physician may not receive all information necessary regarding medical history because the patient may not consider it relevant or withholds the information for whatever reason.²⁰³ Some applications only make sense if they are complete and current. This requires that the card be used for documentation of every treatment and medication.²⁰⁴

III. ELECTRONIC SIGNATURE

Generally, the use of electronic signatures is intended to eliminate the risks of using digital methods of communication that can arise on the side of the sender as well as on the side of the recipient.²⁰⁵

¹⁹⁹ Hornung, *supra* note 92, at 215.

²⁰⁰ *Id.* at 218.

²⁰¹ *Id.*

²⁰² *Id.* at 209-210.

²⁰³ *Id.* at 210.

²⁰⁴ *Id.*

²⁰⁵ Frank Bitzer & Klaus Brisch, DIGITALE SIGNATUR: GRUNDLAGEN, FUNKTION UND EINSATZ (1999), 127.

These risks include the uncertainty of origin of a message and the possibility of tampering with or intercepting messages during the transmission process. The use of electronic signatures has the goal to provide solutions for technical and legal security in transmitting messages online. The electronic signature is to be used in several ways in the e-health context. According to the German federal government's "e-Card Strategy" of 2005, the electronic health card - which should have been introduced at the beginning of 2006 but currently is in trial phases in eight regions throughout Germany - is intended to be equipped with the capacity to generate qualified electronic signatures.²⁰⁶ Consequently, section 291 (2a) SGB V states that the electronic health card must enable the patient to authenticate, encode, and generate electronic signatures.²⁰⁷ Further, electronic health records are outfitted with electronic signatures to ensure procedural evidence quality.²⁰⁸

A. The German Signature Act

The use of electronic signatures is governed by the German Signature Act (*Signaturgesetz, SigG*) of 1997, the first national law worldwide governing the basic technical and organizational requirements concerning the safety infrastructure of electronic signatures.²⁰⁹ The original 1997 version was reformed in 2001 on the basis of the EU Directive on Electronic Signatures (Directive 1999/93/EC of the European Parliament and the Council of December 13, 1999). The key to understanding German electronic signature law presents itself as follows. The Civil Code (*Bürgerliches Gesetzbuch, BGB*) of January 1, 1900, defines the written form as necessarily containing a manual signature.²¹⁰ As this fundamental one hundred year

²⁰⁶ Hornung, *supra* note 92, at 313; Alexander Roßnagel, *Die Ausgabe sicherer Signaturerstellungseinheiten*, 9 MULTIMEDIA UND RECHT [MMR] 441, 442 (2006).

²⁰⁷ Hornung, *supra* note 92, at 313.

²⁰⁸ RALF BRANDNER, DIGITALE SIGNATUR VON DOKUMENTEN IM KRANKENHAUS 9 (2002).

²⁰⁹ Alexander Roßnagel, *Signaturgesetz*, No. 1 in RECHT DER MULTIMEDIA-DIENSTE KOMMENTAR (Alexander Roßnagel, ed., 6th Update, 2005).

²¹⁰ Section 126 Written form

(1) If written form is prescribed by statute, the document must be signed by the issuer with his name in his own hand, or by his notarially certified initials.

(2) In the case of a contract, the signature of the parties must be made on the same document. If more than one counterpart of the contract is drawn up, it suffices if each party signs the document intended for the other party.

old concept remains unchanged, section 126a²¹¹ was enacted to codify the variation of section 126 (3) which allows the electronic form. Under section 126a, only qualified electronic signatures under the Signature Act fulfill the requirements of the written form pursuant to section 126 of the Civil Code and can thus replace the manual signature.

The electronic signature under the Signature Act provides security in two areas: first, the identity of the communication partner and, second, the integrity of the data communicated. To achieve this goal, messages are outfitted with an electronic signature using a mathematical transformation. From the information to be signed, consisting of a number of bits, a value is generated whose length according to the permitted procedure under the Signature Act is 160 bit. This value is akin to a finger print, the so-called hash value.²¹² The verification of the value makes it possible for the recipient to ascertain that the signed message indeed originated from the sender claiming to have sent the message. This is commonly referred to as the authenticity of data origin. Moreover, upon verification of the signature, the recipient can tell whether the data has been manipulated or whether the data is still intact. Only if there are no changes to the original message a positive result indicates that the transmitted data is intact.²¹³

The law generally distinguishes between simple (section 2 No. 1 Signature Act), advanced (section 2 No. 2 Signature Act), qualified (section 2 No. 3 Signature Act) and accredited qualified (section 2 No. 3, section 15 (1)(4) Signature Act) electronic signatures. The first two do not meet the legal requirements of section 126a of the

(3) Written form may be replaced by electronic form, unless the statute leads to a different conclusion.

(4) Notarial recording replaces the written form.

Translation: Federal Ministry of Justice/Juris GmbH:
http://bundesrecht.juris.de/englisch_bgb/index.html (last visited: Oct. 30, 2008).

²¹¹ Section 126a Electronic form

(1) If electronic form is to replace the written form prescribed by law, the issuer of the declaration must add his name to it and provide the electronic document with a qualified electronic signature in accordance with the Electronic Signature Act [Signaturgesetz].

(2) In the case of a contract, the parties must each provide a counterpart with an electronic signature as described in subsection (1).

Translation: Federal Ministry of Justice/Juris GmbH, *supra* note 210.

²¹² Britta E. Brisch & Klaus M. Brisch, *Elektronische Signatur und Signaturgesetz*, No. 1-3 in HANDBUCH MULTIMEDIARECHT (Thomas Hoeren and Ulrich Sieber, eds., 17th Update, 2007).

²¹³ *Id.* at No. 7-10.

Civil Code and thus cannot be equated with a manual signature.²¹⁴ Only qualified electronic signatures and accredited qualified electronic signatures fulfill the requirements set by the Signature Act.²¹⁵ Qualified electronic signatures under section 2 No. 3 Signature Act at the time of their creation are based on a valid qualified certificate and are generated with a secure signature creation unit. This is the key difference between qualified electronic signatures and simple or advanced electronic signatures. The qualified electronic signature implies that the signature key is saved to a non-readable hardware unit. Because of the high technological standard, the law equates the qualified electronic signature with the manual signature. Thus, all natural persons are entitled to submit a request for a qualified electronic signature, unlike corporations or public administration entities. Under section 7 (1) No. 1 Signature Act, a qualified certificate must contain the name of the owner of the key, the assigned signature key, the algorithms, the serial number of the certificate and the beginning and end of the validity of the certificate. The information of section 7 (1) No. 7 Signature Act is of special interest, as the certificate can also contain information regarding the limit of use of the signature key.

Under section 15 (1) Signature Act, there is a “proven” security associated with accredited qualified electronic signatures. All products, components, and the entire procedure of electronic signatures are tested and affirmed by an independent entity pursuant to section 18 Signature Act (e.g., TÜV Informationstechnik GmbH). The inspection and authentication is not only verified by the cachet designating the accredited certification center. Rather, the cachet provides proof of the comprehensively inspected technical and administrative safety.²¹⁶ Only the certification services for accredited electronic signatures have so-called root certificates issued by the Federal Network Agency (*Bundesnetzagentur*) (section 16 Signature Act). Through these certificates, not only the membership certificates of users but also the certificate of the certification service can be verified. Only such verification leads to certainty that the certificate service provider who issued the user certificate indeed exists. Thus, the difference between a qualified electronic signature and an accredited qualified electronic

²¹⁴ *Id.* at No. 85.

²¹⁵ *Id.* at No. 86.

²¹⁶ *Id.* at No. 97-98; Ivo Geis, *Die elektronische Signatur: Eine internationale Architektur der Identifizierung von E-Commerce*, 3 MULTIMEDIA UND RECHT [MMR], 667, 670 (2000).

signature (with cachet) lies in the technical safety check.²¹⁷ The certificate service providers offering qualified electronic signatures compile a security concept outlining in detail the maintenance of the safety requirements. The decisive factor, however, is that the technologies employed are not tested and approved by an independent expert entity. An exception exists for the chip card as a secure signature generating unit and carrier of the secret signature key. It must be approved with regard to its safety by a testing and approval entity. For all other products, a declaration of the manufacturer is sufficient (section 17 (4) Signature Act in connection with section 15(5)SigV-E). In the declaration, issuer and product have to be specifically designated and specific statements have to be made as to the provisions of the Signature Act and the Signature Regulation that are fulfilled; thus, one speaks of “asserted security.” The certification service provider has to keep the certificates for the duration of their validity plus five years. The qualified electronic signatures are only verifiable for this period of time. Should the certification provider become bankrupt in the meantime, the time span may be even shorter. When signatures are no longer verifiable, they become worthless as evidence.²¹⁸

B. Electronic Documents as Evidence

Using electronically signed documents raises the question of their evidence quality. Electronic documents can be submitted as evidence pursuant to section 371(2) of the Federal Code of Civil Procedure (*Zivilprozessordnung, ZPO*). The value of the submitted evidence is governed by the concept of the judge’s free consideration of evidence (*freie Beweiswürdigung*) under section 286 of the Federal Code of Civil Procedure. Central aspects to be considered are the integrity of the contents and the authenticity of the producer of an electronic document. However, since electronic documents can be easily manipulated, integrity and authenticity may be hard to prove. In civil proceedings, producing a deed as evidence has exceptional importance as the court is bound to the content of the deed pursuant to section 416 of the Federal Code of Civil Procedure. Documents only have deed quality if they contain an individual’s thought in written form and are signed by the issuer. Electronic documents can take

²¹⁷ Brisch & Brisch, *supra* note 212, at No. 92.

²¹⁸ Alexander Roßnagel, *Das neue Signaturgesetz - Grundlage des elektronischen Rechtsverkehrs*, 4 MULTIMEDIA UND RECHT [MMR] 201, 202 (2001); Brisch & Brisch, *supra* note 212, at No. 96.

several forms: they can be saved to a storage device, they can be visualized on a monitor, or a printout can be presented. The problem is, however, that neither form of the electronic document contains a signature conforming to section 126 of the Civil Code so that they are not of deed quality. If the electronic document in all its forms does not have the quality of a deed, the court is not bound to the contents of the document pursuant to section 416 of the Federal Code of Civil Procedure.²¹⁹

The evidence quality of electronically signed documents depends on the quality of the electronic signature. Only the qualified electronic signature of an accredited certificate provider reaches the highest evidence quality. The Judicial Communication Act (*Justizkommunikationsgesetz*) of 2004²²⁰ documents the intention to support the use of electronic signatures. It grants qualified electronic signatures the highest evidence quality. The deed provisions are to be applied pursuant to section 371a (1) of the Federal Code of Civil Procedure to private electronic documents. Moreover, they are awarded the appearance of authenticity under section 371a. Thus, the private electronic document is equal in quality to the public electronic document with qualified electronic signature, which also enjoys the presumption of authenticity, section 371a (2)(2) and section 437 of the Federal Code of Civil Procedure. The deficit of electronic documents with qualified electronic signatures in the area of evidence as opposed to deeds has been eliminated.

C. Electronic Signatures and E-Health

In the area of electronic signatures, e-health programs pose specific challenges. In the U.S. context, the need for a federal standard for electronic signatures in e-health was raised as a key concern.²²¹ The e-prescription, for example, is intended to be included in the German

²¹⁹ Ivo Geis, *Beweisqualität elektronischer Dokumente*, passim, in HANDBUCH MULTIMEDIARECHT, *supra* note 212; Klaus Oertel, *Elektronische Form und notarielle Aufgaben im elektronischen Rechtsverkehr*, 4 MULTIMEDIA UND RECHT [MMR] 419 (2001); Michael Schmidl, *Die elektronische Signatur. Funktionsweise, rechtliche Implikationen, Auswirkungen der EG-Richtlinie*, 18 COMPUTER UND RECHT [CR] 508, 517 (2002).

²²⁰ Gesetz über die Verwendung elektronischer Kommunikationsformen in der Justiz (Law on the use of electronic communication forms in the judiciary) of October 28, 2004, BT-Drucksache 15/4067.

²²¹ Ashoke S. Talukdar, *Electronic Signatures in E-Healthcare: The Need for a Federal Standard*, 18 J.L. & HEALTH 95, 103-04 (2003/2004).

pilot projects and is based on the electronic signature. In this context, the procedure of attaching an electronic signature has been criticized as too complicated, since first, the electronic health card of the insured patient is inserted into the card reader, followed by the electronic health professional ID card of the physician. Then, the physician has to enter the six-digit PIN.²²² It has been asserted that this procedure takes twelve times longer than manually signing the prescription: according to one study it took a physician only two seconds to manually sign a prescription while entering a six digit PIN took about 24 seconds.²²³ Of course, this is not the most serious problem concerning digital signatures in the area of health care. It does, however, illustrate an example of the importance of acceptance of the new initiatives in the realm of the key players. Here, a parallel to data security and protection issues - subjective acceptance of the new technology as a prerequisite for its successful implementation - can be drawn.

The use of the electronic signature further becomes relevant in the context of electronic storage of medical documentation. Medical documentation is primarily necessary for patient care, but also for administrative tasks, research and teaching, and quality management.²²⁴ While one objective of medical documentation is making available medical knowledge in order to prevent, diagnose, and efficiently treat diseases, the primary goal is the support of the medical treatment of patients. In order to ensure that the relevant information is available at the right time, in the right place, and in the right form, documentation systems have to meet high standards.²²⁵

1. Electronic Health Card and E-Prescription

The electronic signature and encoding are especially relevant in connection with the electronic health card. The Card is a central component of the future structure of German health care. Data safety issues are especially relevant because of multiple interactions with peripheral systems, in contrast to the electronic ID card, for example. The sensitive data should therefore not be transmitted via the internet but rather via virtual private networks (VPNs). Encoding the data stored on servers can avoid or at least hinder others from accessing the

²²² Klaus Schmidt, *Bürokratie- und Kostenschub in der Praxis*, 32 NOTFALL & HAUSARZTMEDIZIN 567 (2006).

²²³ *Id.*

²²⁴ Brandner, *supra* note 208, at 9.

²²⁵ *Id.* at 15.

data.²²⁶ As already mentioned, the electronic prescription (e-prescription) is intended to be a key application of the health card. The physician creates a prescription, signs and encodes it, and transmits it to a pharmacy. The pharmacy then transmits the data to a central entity which in turn transmits it to the health insurance.²²⁷ The e-prescription is stored independent of the intent of the insured individual. The legislature has not decided whether storage will take place on a server or on the card. Thus, there is no legislative basis for allowing a data transfer to external service providers. If storage takes place on the card itself, there is no data transfer to external third parties. However, if data is transmitted on a server, end-to-end encoding should be employed. In this case, the prescription would be outfitted with the public key of the health card. Thus, data transmission by third parties can be conducted safely.²²⁸

2. Long-Term Storage of Medical Records

Another important application of the electronic signature in the area of e-Health concerns medical records. In fact, long term storage of electronically signed documents has been identified as one of the key challenges in the e-health area.²²⁹ Different laws and regulations demand that medical records and documentation be kept for differently long periods of time.²³⁰ One of these regulations is the Model Professional Code of Conduct for Physicians (*Musterberufsordnung für Ärzte, MBO-Ä*). Under section 10 of the MBO-Ä, physicians are obliged to keep records of their professional activities that are not only considered an aid to their own memory, but also serve the interest of the patients.²³¹ Proper medical documentation in fact is a secondary obligation following directly from the contract regarding medical treatment.²³² Thus, the Federal Court of Justice (*Bundesgerichtshof, BGH*) decided that maintaining proper documentation regarding the

²²⁶ Hornung, *supra* note 81, at 363.

²²⁷ Volker Leienbach, *Das elektronische Rezept aus Sicht der Privaten Krankenversicherung*, in *EHEALTH*, *supra* note 82, at 41, 43.

²²⁸ Hornung, *supra* note 92, at 290-291.

²²⁹ *Id.* at 366.

²³⁰ Brandner, *supra* note 208, at 9. *See also* PAUL SCHMÜCKER, ARCHIVIERUNG UND PRÄSENTATION VON HETEROGENEN KLINISCHEN OBJEKTEN IN ELEKTRONISCHEN PATIENTENAKTEN 68 (1998) (for an overview of medical documentation and medical record storage requirements).

²³¹ Brandner, *supra* note 208, at 16.

²³² *Id.* at 16; Kilian, *supra* note 106, at 2316; Hornung, *supra* note 92, at 59.

patient is an obligation of the physician.²³³ Further documentation obligations follow from other statutes. Under Article 1 of the Health Structure Act (*Gesundheitsstrukturgesetz*) of 1992, physicians and medical care providers are obliged to transmit diagnoses and a description of the services rendered to the health insurances. Hospitals also have to provide the day and time of admission and the identification number of the referring physician. Other provisions demanding documentation are, for example, section 43 Radiation Protection Regulation (*Strahlenschutzverordnung*), section 29 X-Ray Regulation (*Röntgenverordnung*), section 19 of the Regulation on hazardous industrial materials (*Arbeitsstoffverordnung*), section 37 of the Youth Employment Protection Act (*Jugendarbeitsschutzgesetz*).²³⁴ The Model Code of Professional Conduct states that medical documentation must be kept for at least ten years while other provisions contain a thirty year requirement, such as section 28 No. 4 (1) X-Ray Regulation, section 42 (3) Radiation Protection Regulation, section 14 (3) Transfusion Act (*Transfusionsgesetz*), section 15 (2) Transplantation Act (*Transplantationsgesetz, TPG*). In relation to data protection, it may be worth pointing out that these documentation provisions demand continued storage of data without the patient's consent as to specific data or without the patient's ability to have certain data deleted, as otherwise the rule in data protection law. The documentation, however, is to be limited to the data the insured individual has disclosed voluntarily.²³⁵

Hospital archives, however, are reaching their capacities due to the volume of paper-based patient records and the long time periods for which they have to be kept. Further problems with traditional archives include long searches, limited hours of operation, incomplete or lost records, and the general problem of diverging organization criteria.²³⁶ Thus, while electronic archives as a general matter appear to be a favorable solution to the problem of hospital documentation requirements, they, too, contain specific potential hazards. This particularly concerns the long-term safety of electronically signed archives which in the e-Health context not only include hospital archives but also archives of health insurances. Especially in the case of

²³³ Federal Court of Justice [Bundesgerichtshof][BGH] June 27, 1978, 31 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 2337, 2338-2339 (1978).

²³⁴ Brandner, *supra* note 208, at 17.

²³⁵ Hornung, *supra* note 92, at 60.

²³⁶ Brandner, *supra* note 208, at 19.

archives with great volumes of data, solutions regarding potentially decreasing security have to be found.²³⁷

The algorithm used for creating the electronic signature can lose its security due to new scientific insights or technical advances. Electronically signed documents, in turn, lose certain properties with the decline of the signature security. Most importantly, they can lose their evidence quality.²³⁸ Thus, the Federal Network Agency is discontinuing the validity of certificate key lengths of 1024 bit by the end of 2007 and changing instead to a bit length of 2048 bit. For many documents, a qualified electronic signature is a prerequisite for their validity, as expressed in section 126a of the Civil Code. If, after long periods of time, it is disputed that the original signature was a qualified electronic signature, it has to be proven that the signature did in fact have this quality. This problem specifically concerns the security of the public key. It may become possible over time, with advances in cryptanalysis and increased computer capacities to calculate a secret key.²³⁹

This results in the necessity to renew the electronic signatures used in digital archives. The statutory basis is found in section 6 Signature Act and section 17 of the Signature Regulation (*Signaturverordnung, SigV*). Under section 6 of the Signature Act, the certification center has to inform the applicant that data with electronic signatures have to be signed again if necessary, before the security of the existing signature decreases. This, however, does not lead to an obligation of the applicant to follow the recommendations of the certification center. Rather, it is the sole responsibility of the applicant to take the necessary steps ensuring data safety. The necessary security measures are to be qualified as obligations.²⁴⁰ The omission to take necessary safety measures does not have any consequences for the attribution of the digital signature.²⁴¹ This is confirmed by the evidence rules regarding electronic documents. Under section 371a (1)(2) of the

²³⁷ Alexander Roßnagel, Stefanie Fischer-Dieskau, Ulrich Pordesch & Ralf Brandner, *Erneuerung elektronischer Signaturen*, 19 COMPUTER UND RECHT [CR] 301 (2003).

²³⁸ Brandner, *supra* note 208, at 79. See also legislative materials (Begründung zum Entwurf einer Verordnung zur elektronischen Signatur in der Fassung des Kabinettsbeschluss vom 24.10.2001, zu § 17, S. 34).

²³⁹ Willi Geiselmann, Jörn Müller-Quade, Rainer Steinwanddt, *Über Quantencomputer und Quantenkryptographie*, 26 DATENSCHUTZ UND DATENSICHERHEIT [DUD] 453 (2002).

²⁴⁰ Legislative materials § 5 Abs. 2 S. 2 des Art. 2 des 1. Referentenentwurfs zum IuKDG of June 28, 1996

²⁴¹ Roßnagel, *supra* note 209, at § 6 No. 38.

Federal Code of Civil Procedure, the appearance of authenticity of a declaration in electronic form can only be destroyed if there are serious doubts that the declaration was given by the owner of the signature key. If the key owner asserts that the renewed signature was forgotten, however, no serious doubts arise that the original electronically signed document originated from the key owner. The content of the document is assigned to the key owner. It is important to note, however, that neglecting to perform the necessary safety measures does lead to the loss of the appearance of security.²⁴² In order to preserve the original evidence quality of electronic archives and document management systems, a new signature has to be created. The existing signatures are encompassed by the new signatures and thus conserved. It is irrelevant who produces the new signature so that it can be produced by an archivist.²⁴³ This is possible because no individual will is expressed in attaching the new signature; rather it expresses that the intended security function be fulfilled.²⁴⁴ Section 17 Signature Regulation determines the procedure for long-term data security by use of re-signing the documents with qualified electronic signatures if they are needed for longer periods of time. Prior to the expiration of the security of the algorithms or the respective parameters, the documents are to be outfitted with a new qualified electronic signature. This has to be done with new algorithms or parameters and include prior signatures. Moreover, the re-signature has to include a qualified time stamp. Thus, by conserving the original signature, its original form can be proven.²⁴⁵

IV. ONLINE PHARMACIES

While both European and German initiatives are intended to further the advancement of e-health, some elements are bound to clash with existing laws. Although the use of information technology is generally supported, some areas are still regulated by concepts predating the intended large-scale introduction of information technology in healthcare. One such example is provided in the following section which outlines and examines the German legal struggles involving the online pharmacy DocMorris, culminating in

²⁴² *Id.* at No.39

²⁴³ Roßnagel et al, *supra* note 237, at 302 (citing BR-Drucksache 966/96, 29).

²⁴⁴ *Id.* at No. 303.

²⁴⁵ Alexander Roßnagel & Ulrich Pordesch, *Signaturverordnung, § 17 No. 5 in RECHTE DER MULTIMEDIA-DIENSTE, supra* note 209.

decision of the European Court of Justice (ECJ) in December 2003.²⁴⁶ Another question, concerning the online distribution of drugs subject to licensing in Germany but not subject to licensing elsewhere in the EU, was answered by the German Federal Court of Justice (BGH) in 2006.²⁴⁷ Even after these decisions, there continue to be legal uncertainties regarding the status of online pharmacies. Especially DocMorris has a continued presence in the legal discussions.

A. The DocMorris Decision of the ECJ

0800 DocMorris NV is a limited company established in the Netherlands. In addition to its physical pharmacy presence in Landgraaf, Netherlands, it conducts an online business. Both the pharmacy and the website are covered by a Dutch license.²⁴⁸ Also named as a defendant in the original lawsuit was Mr. Waterval, an authorized pharmacist who until May 30, 2001, was a director of DocMorris.²⁴⁹ Since 2000, DocMorris had been offering prescription and non-prescription drugs on its website in different languages, including German, targeting end consumers in Germany. Only authorized drugs were sold, some of which were authorized in Germany and others in the Netherlands.²⁵⁰

On the DocMorris website, the individual drugs were divided into product groups. Following a brief introduction, the drugs were then listed in alphabetical order under their product name with a description of the content and the price in Euro. Further information about the product could be obtained by clicking on the product name.²⁵¹ Prescription requirements were noted next to the product description. A given drug was classified as a prescription only drug either if it was available on prescription in the Netherlands or in the customer's country of residence. If the prescription status differed in the Netherlands and the country of residence, the stricter rule applied. Prescription drugs were only supplied upon submission of the original prescription.²⁵² By clicking on the appropriate icon, the customer could

²⁴⁶ ECJ Case C-322/01, available online at www.curia.europa.eu [hereinafter: DocMorris decision]

²⁴⁷ Federal Court of Justice [Bundesgerichtshof][BGH] decision of Mar 30, 2006, docket no. I ZR 24/03, 9 MULTIMEDIA UND RECHT [MMR] 461 (2006).

²⁴⁸ DocMorris decision, *supra* note 246, at para. 35.

²⁴⁹ *Id.*

²⁵⁰ *Id.* at ¶ 36.

²⁵¹ *Id.* at ¶ 37.

²⁵² *Id.* at ¶ 38.

also look for a particular product from the range offered and consult a group of experts on health issues. DocMorris could be contacted by consumers either via the internet or on a toll-free phone number or by mail.²⁵³ Pickup of the order could take place either in person at the physical presence of the pharmacy at Landgraaf, a town close to the German-Dutch border, or the order could be delivered by courier, either by a service of the defendant's choice at no additional cost or by service of the customers' choice, at their own expense.²⁵⁴

Several lawsuits against DocMorris were filed in Germany.²⁵⁵ The lawsuit leading to the ECJ judgment was brought before the Regional Court of Frankfurt (*Landgericht Frankfurt am Main*).²⁵⁶ Plaintiff was an association representing the interests of German pharmacies whose members are the federations and associations of pharmacists at the state (*Länder*) level.²⁵⁷ The plaintiff argued that the provisions of the Law on Medicinal Products (*AMG*) and the Law on Advertising of Medicinal Products (*HWG*) do not permit the defendants to engage in such a business, and the prohibition imposed by those two laws cannot be challenged as violating supranational law on the basis of Article 28 EC and 30 EC.²⁵⁸ The Frankfurt court expressed doubt whether the prohibitions of section 43(1) and 73(1) of the Law on Medicinal Products violated the free movement of goods. Assuming an infringement on Article 28 EC, the court then asked whether the German legislation is necessary to effectively protect the health and life of humans for purposes of Article 30 EC or whether in light of the increasing harmonization of procedures for authorizing medicinal products, human health and life may be protected as effectively by less restrictive measures. Finally, it asked whether advertising bans such as those imposed by the Law on Advertising of Medicinal Products are compatible with the principles of the free movement of goods and the free movement of information society services within the meaning of Article 1(1) and (2) of the directive on electronic commerce.²⁵⁹ Due to these questions concerning Community law, the Frankfurt court stayed

²⁵³ *Id.* at ¶ 39.

²⁵⁴ *Id.* at ¶ 40.

²⁵⁵ *E.g.*, LG Frankfurt a.M. and OLG Frankfurt a.M., 1 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT RECHTSPRECHUNGS-REPORT [GRUR-RR] 244 (2001).

²⁵⁶ DocMorris decision, *supra* note 246, at ¶ 41.

²⁵⁷ *Id.* at ¶ 34.

²⁵⁸ *Id.* at ¶ 41.

²⁵⁹ *Id.* at ¶ 43.

its proceedings and referred three questions to the ECJ for a preliminary ruling.²⁶⁰

Indicating its exceptional importance, the case was referred to the full court pursuant to Article 16(5) of the ECJ Statute.²⁶¹ Important new developments were expected in the area of the free movement of goods. In fact, it was asserted that *DocMorris* promised to join the group of landmark cases in the area of the free movement of goods, such as the *Dassonville*,²⁶² *Cassis de Dijon*,²⁶³ and *Keck*²⁶⁴ decisions.²⁶⁵ The decision in fact did elaborate on the content and scope of the *Keck* formula, and the ECJ - albeit silently - diverged from its prior jurisprudence.²⁶⁶

The questions presented to the ECJ concerned the interpretation of Article 28 and Article 30 EC on the advertising of medical products for human use, in conjunction with Directive 200/31/EC of the European Parliament and of the Council of June 8, 2000, on certain legal aspects of information society services, in particular electronic commerce, in the internal market (the Directive on electronic commerce).²⁶⁷ A preliminary judgment of the ECJ was sought concerning three questions.²⁶⁸ The Court answered the first question regarding the free movement of goods, and the second question of advertising. The third question, which concerned a follow-up question on advertising, namely whether despite an infringement on advertising regulations the cross-border trade was lawful,²⁶⁹ was not answered by the Court in light of its answer to the second question.²⁷⁰

²⁶⁰ *Id.* at ¶ 44.

²⁶¹ Christofer Lenz, *Warenverkehrsfreiheit nach der DocMorris-Entscheidung zum Versand von Arzneimitteln*, 57 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 332 (2004).

²⁶² Case, 8-74, *Procureur du Roi v. Benoît*, 1974 E.C.R. 837

²⁶³ Case 120-78, *Rewe-Zentral v. Bundesmonopolverwaltung für Branntwein*, 1979 E.C.R.

²⁶⁴ Cases C-267/91 and C-268/91, *Criminal Proceedings against Bernard Keck and Daniel Mithouard*, 1993 E.C.R. 6097.

²⁶⁵ Lenz, *supra* note 261.

²⁶⁶ Benjamin Koch, *Eine erste Bewertung der Entscheidung "DocMorris" des EuGH*, 15 EUROPÄISCHE ZEITSCHRIFT FÜR WIRTSCHAFTSRECHT [EuZW] 50 (2004).

²⁶⁷ *DocMorris* decision, *supra* note 246, at ¶ 1.

²⁶⁸ *Id.* at ¶ 44.

²⁶⁹ *Id.*

²⁷⁰ *Id.* at ¶ 150.

1. Free Movement of Goods

The first question raised the issue of the free movement of goods under Articles 28 EC and 30 EC. It asked whether national legislation restricting the sale of drugs to pharmacies in the Member State and prohibiting the commercial import via mail order in response to individual orders placed by consumers over the internet through pharmacies approved in other Member States violates the free movement of goods.²⁷¹ The ECJ first examined drugs not authorized in Germany, then drugs authorized in Germany. Regarding authorized drugs, the Court distinguished between prescription drugs and non-prescription drugs.²⁷²

Regarding drugs not authorized in Germany, section 73(1) Law on Medicinal Products generally prohibits the import. The prohibition is based on the lack of authorization or registration for the German market. Thus, their import is not permitted irrespective of the mode of sale.²⁷³ The Court found that section 73(1) Law on Medicinal Products complies with community law. In fact, the prohibition corresponds to a prohibition at the Community level, formerly Article 3 of Directive 65/65, now replaced by Article 6(1) of the Community Code.²⁷⁴ If pharmaceuticals are to be placed on the market in a Member State, they have to be authorized by the competent authority of that state or under community rules, even if they are already authorized in another Member State.²⁷⁵ This finding certainly was the least surprising aspect of the decision.²⁷⁶

Turning to drugs authorized for sale in pharmacies Germany, the Court presents the question as whether the prohibition on the mail-order sale of drugs which in the Member State are only sold in pharmacies violates the free movement of goods.²⁷⁷ It breaks the question down into three parts, namely first, whether the national prohibition on mail-order sales is a measure of equivalent effect,²⁷⁸ second, whether the prohibition can be justified (here, the Court

²⁷¹ *Id.* at ¶ 45.

²⁷² *Id.* at ¶ 46.

²⁷³ *Id.* at ¶ 47.

²⁷⁴ *Id.* at ¶ 52.

²⁷⁵ *Id.*

²⁷⁶ Elmar Mand, *Anmerkung*, 7 MULTIMEDIA UND RECHT [MMR] 155 (2004).

²⁷⁷ DocMorris decision, *supra* note 235, at ¶ 55.

²⁷⁸ *Id.* at ¶ 55 et seq.

distinguishes between prescription and non-prescription drugs),²⁷⁹ and third, the question of reimport of drugs.²⁸⁰

Under *Dassonville*, all measures capable of hindering intra-Community trade directly or indirectly, actually or potentially, are regarded as measures having equivalent effect to quantitative restrictions. As such, they are prohibited under Article 28 EC.²⁸¹ If a measure is not intended to regulate trade between Member States, the determining factor is its actual effect. Thus, obstacles to the free movement stemming from the imposition of requirements on goods coming from other Member States where they are lawfully manufactured and marketed constitute measures of equivalent effect even if the rules apply to all products alike. Such restrictions are prohibited by Article 28 EC. However, as the Court held in *Cassis de Dijon* and *Keck*, such restrictions are permissible if they can be justified by a public interest objective that outweighs the requirement of the free movement of goods.²⁸² Under *Keck*, even if commercial rules do not relate to the actual characteristics of the products but only govern sale arrangements, they may constitute measures of equivalent effect under Article 28 EC. In order to pass Article 28 EC muster, the rules must meet two conditions: (1) The rules must apply to all relevant traders operating in national territory and, (2) they must, in law and in fact, affect the marketing of domestic products and those from other Member States in the same manner.²⁸³

The Court finds that section 43(1) of the Law on Medicinal Products applies equally to all traders so that the first requirement of the *Keck* standard is met. Section 43(1) Law on Medicinal Products, however, fails to meet the second *Keck* requirement. The prohibition contains a requirement that certain medicines be sold only in pharmacies as well as a prohibition on drug mail-order sales. The latter may be regarded as a mere consequence of the former. However, in the Court's view, the emergence of the internet as a method of cross-border sales requires a broad-scale look at the scope and the effect of the prohibition.²⁸⁴ Section 43(1) Law on Medicinal Products poses a greater obstacle to pharmacies outside of Germany than to those in Germany. Even though pharmacies in Germany may not use mail-order

²⁷⁹ *Id.* at ¶ 77 et seq.

²⁸⁰ *Id.* at ¶ 125 et seq.

²⁸¹ *Id.* at ¶ 66.

²⁸² *Id.* at ¶ 67.

²⁸³ *Id.* at ¶ 68.

²⁸⁴ *Id.* at ¶ 73.

sales as an additional or alternative method of gaining access to the German market, they are still able to sell the products at their physical locations. For pharmacies not established in Germany, on the other hand, the internet provides a more significant way to gain direct access to the German market. Thus, the impact of the provision is greater on pharmacies outside of Germany as their market access is hindered more significantly than German pharmacies' market access.²⁸⁵ As a result, the Court finds that the prohibition on mail-order pursuant to section 43(1) of the Law on Medicinal Products is a measure having an effect equivalent to a quantitative restriction under Article 28 EC.²⁸⁶

Turning to the justification of section 43(1), the Court looks at Article 30 EC. The Court points out that Article 30 continues to apply to the manufacture and marketing of drugs absent full harmonization of national rules. With regard to the sale of drugs to consumers, the Court states that there is no full Community harmonization.²⁸⁷ Health and life of humans are the foremost interests protected by Article 30 and, within the limits of the Treaty, Member States can decide on the level of protection.²⁸⁸ As national rules will have a restrictive effect, however, only such national rules are permissible that are necessary for the effective protection of health and life of humans. National rules do meet the standard "if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade."²⁸⁹ Before analyzing the rules under the standard, the Court points out that the virtual pharmacy is subject to supervision by the Dutch authorities.²⁹⁰ Further, it points out the arguments that may justify the prohibition of mail order: the need to provide individual advice to the customer, the ability to check if prescriptions are genuine, and guaranteeing the wide availability of drugs.²⁹¹

The Court proceeds by distinguishing between non-prescription and prescription drugs. It finds that regarding the former, there are no reasons justifying the prohibition.²⁹² Prescription drugs, however, need to be more strictly controlled.²⁹³ Therefore, it finds that "the need to be able to check effectively and responsibly the authenticity of doctors'

²⁸⁵ *Id.* at ¶ 74.

²⁸⁶ *Id.* at ¶ 76.

²⁸⁷ *Id.* at ¶ 102.

²⁸⁸ *Id.* at ¶ 103.

²⁸⁹ *Id.* at ¶ 104.

²⁹⁰ *Id.* at ¶ 105.

²⁹¹ *Id.* at ¶ 106.

²⁹² *Id.* at ¶ 112-116.

²⁹³ *Id.* at ¶ 117.

prescriptions and to ensure that the medicine is handed over either to the customer himself, or to a person whom its collection has been entrusted by the customer, is such as to justify a prohibition on mail-order sales.”²⁹⁴ The Court then turns to the issue of drug prices which, in its view, would support the prohibition, but which was not submitted.²⁹⁵ Overall, the Court thus finds that while a prohibition on mail order cannot be justified under Article 30 for non-prescription drugs, the prohibition on prescription drugs is justified.²⁹⁶ The question of reimport of prescription drugs does not change the Court’s prior assessment.²⁹⁷

Overall, thus, the ECJ asserted a relatively comprehensive ability of the Member States to restrict drug mail order businesses in the interest of consumer protection. Only general national prohibitions for the mail order of non-prescription drugs were found to be incompatible with community law. However, regulatory provisions for consumer protection still remain possible in this area as well.²⁹⁸

2. Advertising

The Court identifies three prohibitions on advertising. First, under section 3 Law on Advertising of Medicinal Products, a prohibition on advertising of drugs subject to authorization for which authorization has not been obtained. As this prohibition corresponds to a provision in community law, the Court does not further examine the national regulation.²⁹⁹ Second, section 10(1) Law on Advertising of Medicinal Products prohibits generally advertising for prescription drugs. Since this provision implements a harmonization measure of the Community, this provision, too, requires no further consideration.³⁰⁰ Third, section 8(1) Law on Advertising of Medicinal Products prohibits advertising mail order sales of drugs which may only be sold in

²⁹⁴ *Id.* at ¶ 119.

²⁹⁵ *Id.* at ¶ 122-123. Here the Court states that “a national market for prescription medicines could be characterized by non-commercial factors, with the result that national legislation fixing the prices at which certain medicinal products are sold should, in so far as it forms an integral part of the national health system, be maintained.” *Id.* at ¶ 122.

²⁹⁶ *Id.* at ¶ 124.

²⁹⁷ *Id.* at ¶ 134.

²⁹⁸ Mand, *supra* note 276, at 158.

²⁹⁹ DocMorris decision, *supra* note 246, at ¶ 138.

³⁰⁰ *Id.* at ¶ 139.

pharmacies.³⁰¹ There is no corresponding provision in Community law, the Court states.³⁰² Again, the Court distinguishes between prescription and non-prescription drugs, holding that while “Community law does not preclude a prohibition on mail-order selling of prescription medicines”³⁰³ it does preclude a national prohibition on advertising the mail order sale of drugs only sold in pharmacies in the Member State if the drugs can be bought without a prescription.³⁰⁴

3. Assessment and Legislative Changes

Unsurprisingly, assessments of the decision varied. On the one hand, it was pointed out that the impact of the decision would be relatively small, mainly because profoundly divergent rules regarding prescription requirements exist in the Member States. These differences pose a significant obstacle to transnational commerce with prescription drugs. It was pointed out though that perhaps the decision would be a stepping stone for a further harmonization of the rules regarding prescription requirements for drugs and for the operation of pharmacies.³⁰⁵ On the other hand, however, it was asserted that the decision is highly important beyond the scope of the pharmaceuticals sector as it contained a modification to the *Keck* rule, imposing more burdens on the Member States.³⁰⁶ Moreover, the ECJ itself engaged in an examination of the neutrality principle and imposed the burden of proof regarding the neutrality of the effect on the Member States. As far as the justification level is concerned, it has been observed that the ECJ is moving further away from a German-style proportionality analysis and instead seeks the solution in the ever-growing area of secondary Community legislation. From secondary legislation, the ECJ distills value judgments that in turn influence its decisions regarding necessity and adequacy in its justification analysis. Claims have been made that this practice makes decisions of the ECJ in the area of the free movement of goods even harder to predict.³⁰⁷

The effect of the decision was limited in Germany. In 2004, the ban on all mail order sales of medicines, including prescription drugs,

³⁰¹ *Id.* at ¶ 140.

³⁰² *Id.* at ¶ 141.

³⁰³ *Id.* at ¶ 147.

³⁰⁴ *Id.* at ¶ 148.

³⁰⁵ Mand, *supra* note 276, at 158.

³⁰⁶ Lenz, *supra* note 261, at 334.

³⁰⁷ *Id.*

was lifted in the Statutory Healthcare Modernization Act. The permissibility is contingent on obtaining a mail-order license. However, the extent of the new regulation undermines the arguments made before the ECJ concerning prescription drugs.³⁰⁸ The resulting legislative change thus goes beyond what the ECJ required.³⁰⁹ The ongoing DocMorris proceedings before the ECJ may have been helpful in finding a consensus among Germany's government and opposition parties regarding a change in the law permitting drug mail orders. As a result, Germany proceeded to widely liberalize the mail order of drugs.³¹⁰

B. Continued Legal Battles

Following the ECJ decision, legal disputes over issues connected with online pharmacies continued. The Federal Court of Justice decided in March 2006 that a prohibition on the sale of drugs subject to licensing in Germany but not in other EU Member States is permissible.³¹¹ The important decision extends far beyond the immediate area of drug mail order. It has, in fact, been called a milestone in the law of online marketing.³¹² A Dutch company offered on its website various products for medicinal purposes (*e.g.*, garlic and St. John's wort capsules). The website contained a disclaimer stating "German speaking Europeans, but not to German addresses".³¹³ A key aspect of the decision concerned conflict of laws issues. The Federal Court of Justice found that a website is subject to German competition law if the content has an intended effect in Germany.³¹⁴ Disclaimers may be used to exclude these effects, but they have to be genuine. In this case, the disclaimer was held to be not genuine as deliveries to Germany were in fact made.³¹⁵ The country of origin principle, which requires compliance only with the laws of the country of origin, does not apply since national regulations regarding the protection of health

³⁰⁸ Rudolf Streinz, *Freier Warenverkehr - Grenzüberschreitende Tätigkeit von Apotheken - DocMorris*, 44 JURISTISCHE SCHULUNG [JUS] 518, 521 (2004); Koch, *supra* note 266, at 51.

³⁰⁹ Streinz, *supra* note 308, at 521.

³¹⁰ Mand, *supra* note 276, at 158.

³¹¹ Federal Court of Justice, *supra* note 247, at 461.

³¹² Thomas Hoeren, *Anmerkung*, 9 MULTIMEDIA UND RECHT [MMR] 464 (2006).

³¹³ Federal Court of Justice, *supra* note 247, at 461-462.

³¹⁴ *Id.* at 463.

³¹⁵ *Id.*

can be imposed by national law.³¹⁶ In the case of medicinal products not authorized domestically, the Court referred to the Community laws expressly permitting prohibitions for advertising of non-authorized drugs.³¹⁷

On a different front, DocMorris is currently involved in litigation concerning the permissibility of pharmacy ownership by a capital corporation (in this case, a Dutch stock corporation). Although this aspect is not directly related to DocMorris's e-commerce activities, it illustrates the difficulties of harmonizing the EU health market in exemplary fashion. The facts are simple yet perhaps - knowing drug store giants such as CVS or Rite Aid with integrated pharmacies - somewhat perplexing from an outside perspective. DocMorris bought a pharmacy in the German state of Saarland and employed as the responsible pharmacist the former owner, a licensed pharmacist.³¹⁸ Even after the most recent legislative changes, the individual pharmacist in his own pharmacy, as described in the famous Pharmacy decision (*Apothekenurteil*) of the Federal Constitutional Court,³¹⁹ is still the guiding legislative principle in Germany while in other Member States of the EU corporations may own pharmacies.³²⁰ Capital corporations (such as a GmbH or AG) cannot obtain licenses for pharmacies (section 8 of the Pharmacy Act, *Apothekengesetz*).

Although the district court (*Landgericht*) of Saarbrücken in August 2006 rejected the challenge of another pharmacist on unfair competition grounds,³²¹ the Saarlouis Administrative Court in September 2006 ruled that a store operated by DocMorris had to close.³²² On appeal, the State Administrative Court reversed.³²³ The prohibition of outside ownership constitutes a limit on the freedom of

³¹⁶ *Id.*

³¹⁷ *Id.* at 463-464.

³¹⁸ See, e.g., Wolfgang Semmroth, *DocMorris als Einfalltor für Normenverwerfungskompetenz der Verwaltung?* 25 NEUE ZEITSCHRIFT FÜR VERWALTUNGSRECHT [NVWZ] 1378 (2006).

³¹⁹ Federal Constitutional Court [Bundesverfassungsgericht][BVerfG] decision of June 11, 1958, 17 ENTSCHIEDUNGEN DES BUNDESVERFASSUNGSGERICHTS [BVerfGE] 232 (240). The decision is famous because the Court articulated its Three Step Theory (*Dreistufentheorie*) as the doctrinal basis for Article 12 freedom of occupation.

³²⁰ Koch, *supra* note 266, at 51.

³²¹ District Court [Landgericht] Saarbrücken, Aug. 9, 2006, docket no. 7 IO 06. See also Semmroth, *supra* note 318, at 1379 (discussing the case).

³²² Administrative Court [Verwaltungsgericht] Saarlouis, decision of Sept. 13, 2006, docket nos. 3 F 38/06 and 3 F 39/06.

³²³ State Administrative Court, decision of January 22, 2007, docket nos. 3 W 14/06 and 3 W 15/06.

establishment pursuant to Articles 43, 48 EC. As such, it needs justification. In order to be justified, it must be appropriate and necessary to further the intended goal.³²⁴ At the center of attention is the question whether the case is analogous to a case decided by the ECJ involving opticians in Greece.³²⁵ In this decision, the Court held:

In this case, it is sufficient to note that the objective of protecting public health upon which the Hellenic Republic relies may be achieved by measures which are less restrictive of the freedom of establishment both for natural and legal persons, for example by requiring the presence of qualified, salaried opticians or associates in each optician's shop, rules concerning civil liability for the actions of others, and rules requiring professional indemnity insurance.³²⁶

The state administrative court held that the same must apply to pharmacies under the condition that there is no higher health risk involved that would generally require a higher responsibility. Even if higher health risks may exist, however, a licensed pharmacist has the necessary qualification to avoid such potential risks.³²⁷ The matter will eventually be resolved by the ECJ as the Commission in 2006 initiated proceedings against Austria, Italy and Spain because of similar restrictions on pharmacy ownership.³²⁸ Meanwhile, DocMorris has become engaged in franchising operations. Several pharmacies now operate under the DocMorris franchise while being owned by individual pharmacists. DocMorris teamed up with a pharmacist in order to sell non-prescription merchandise.³²⁹

³²⁴ See, e.g., Case C-140/03, Comm'n of the European Cmty's v. Hellenic Republic, 2005 E.C.R. ¶ 4 [hereinafter Greek opticians case]. See also, Tobias Kruis, *Das Leitbild des Apothekers in der (nicht notwendig eigenen) Apotheke*, 18 EUROPÄISCHE ZEITSCHRIFT FÜR WIRTSCHAFTSRECHT [EUZW] 175, 177 (2007).

³²⁵ Greek opticians case, *supra* note 324.

³²⁶ *Id.* at ¶ 34.

³²⁷ Kruis, *supra* note 324, at 177.

³²⁸ Eberhard Eichenhofer, *Auswirkungen europäischen Rechts auf das deutsche Gesundheitswesen*, 25 MEDIZINRECHT [MEDR] 329, 329-330 (2007).

³²⁹ *Id.* at 329.

V. THE FUTURE OF E-HEALTH

Healthcare reform remains at the top of the agenda, not only in Germany but throughout Europe. The underlying factors in many of the current disputes, such as in the DocMorris cases, are fundamental questions of health policy. The potential of information technology seemingly lends itself to offering new solutions and has been discovered by lawmakers in the Member States as well as on the supranational level. The EU is attempting to foster development of a unified health market while the Member States assert their ultimate competence in the area of national health policy. To a large extent, though, they appear to be following the same goals as the supranational initiatives. However, in both instances, appropriate regulation in the healthcare area increasingly clashes with the ever accelerating speed of technological advances.³³⁰ Underlying the reform process, too, is a change in the role of the state. Rather than “providing”, it has been suggested that the state should focus on “enabling”.³³¹ When information technology meets healthcare, the legal ramifications have to accommodate a rapidly changing and a highly regulated environment. Striking a feasible balance, between regulation and innovation as well as between national and supranational public health policy, is the core challenge to the legal framework of e-health.

³³⁰ Marie-Theres Tinnefeld, *Die Novellierung des BDSG im Zeichen des Gemeinschaftsrechts*, 54 NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 3078, 3078-3079 (2001).

³³¹ *Id.*

